

Advances in Patient Safety: New Directions and Alternative Approaches

Volume 1. Assessment

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Preface

It has been nearly 10 years since the Institute of Medicine (IOM) published its 1999 landmark report, *To Err Is Human: Building a Safer Health System*. Although we have made improvements in the safety of the health care system since that time, there is much more work to be done.

In February 2005, the Agency for Healthcare Research and Quality (AHRQ) and the Department of Defense (DoD)-Health Affairs collaborated to publish *Advances in Patient Safety: From Research to Implementation* to help the health care system by providing state-of-science information on preventing medical errors and the harm they can cause. The publication included work by AHRQ-funded patient safety researchers as well as the patient safety initiatives of other components of the Federal Government.

This new publication, *Advances in Patient Safety: New Directions and Alternative Approaches* builds on and expands the growing body of evidence for reducing medical errors and improving patient safety. It also provides a forum for the airing of new ideas and approaches that are likely to be successful in the future.

The 115 papers distributed across four volumes—Assessment, Culture and Redesign, Performance and Tools, and Technology and Medication Safety—cover a considerable breadth of content dealing with reporting systems, taxonomies and measurement, risk assessment, safety culture and organizational issues, process improvement, system redesign, patient involvement, teamwork, simulation, human factors, tools and practices, health information technology and medication safety.

Advances in Patient Safety: New Directions and Alternative Approaches presents contributions from a wide variety of disciplines and clinical settings—a very promising sign that the development and spread of patient safety initiatives continues to grow.

It is important to note that some of the same issues and areas of research interest as appeared in the 2005 *Advances of Patient Safety: From Research to Implementation* appear in this *Advances* as well. Although no one takes pleasure in recognizing that some threats to patient safety are quite resistant to change, these four volumes give testimony to the perseverance and technical skills of our best researchers. They continue to seek answers to the most challenging patient safety questions.

Excellent progress is being made, and many of the papers describe patient safety success stories in a variety of health care settings. Other papers focus on what we still need to accomplish. This is as it should be.

The bottom line is that improving patient safety and reducing medical errors must continue to be an important priority for the Nation and for our health care system. To achieve a safe, high quality health care system, we need dedication, leadership, and the best information available. AHRQ is very pleased to bring you *Advances in Patient Safety: New Directions and Alternative Approaches* for you to use as a vital tool in meeting that challenge.

Carolyn Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Acknowledgments

The present *Advances in Patient Safety: New Directions and Alternative Approaches*, like its predecessor, *Advances in Patient Safety: From Research to Implementation*, contains well over a hundred patient safety papers distributed across four volumes. In undertaking a project of this scope and completing it in a timely fashion, the editors depend upon the good will, collaborative efforts, and commitment of many people, both internal and external to the Agency for Healthcare Research and Quality (AHRQ). Foremost among this group are the patient safety researchers and their teams, whose work will be found in the pages that follow. We are indebted to them for their scholarship, research skills, and willingness to share with us their conceptual schemes, empirical findings, and lessons learned in addressing significant patient safety issues. Given the breadth of content, readers are sure to find much of interest to their own work. At the same time, a large number of peer reviewers willingly gave of their time in commenting constructively on the submitted manuscripts to ensure their quality and appropriateness. A list of the peer reviewers can be found in the back of each volume.

Also in evidence throughout the entire effort were the organizing skills of Ms. Alene Kennedy, Ms. Felicia Cerbone, and their colleagues at the National Opinion Research Center (NORC) at the University of Chicago. Their assistance in keeping track of submitted manuscripts, maintaining communication with authors and reviewers, and engaging the editing skills of Dr. Lane Lenard of BioMedical Communications, Inc., is very much appreciated.

We also would like to acknowledge the support and encouragement from AHRQ's Office of the Director, the Center for Quality Improvement and Patient Safety (CQuIPS), and the Office of Communications and Knowledge Transfer (OCKT). Within OCKT, a hearty thank you is extended to Ms. Randie Siegel and other helping hands in her Print and Electronic Publishing group. Of special note are the desktop design skills of Ms. Frances Eisel and Mr. Joel Boches. Editorial assistance was provided by Ms. Stephanie Grant of EEI Communications, Inc.

Kerm Henriksen
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Editors

Contents

Volume 1. Assessment

Prologue: Laying the Foundation

Kerm Henriksen

Looking Forward, Benefiting from the Past

Envisioning Patient Safety in the Year 2025: Eight Perspectives

Kerm Henriksen, Caitlin Oppenheimer, Lucian Leape, et al.

What Exactly Is Patient Safety?

Linda Emanuel, Don Berwick, James Conway, et al.

Reporting Systems

Improving the Value of Patient Safety Reporting Systems

Peter J. Pronovost, Laura L. Morlock, J. Bryan Sexton, et al.

The Association Between Pharmacist Support and Voluntary Reporting of Medication Errors: An Analysis of MEDMARX[®] Data

Katherine J. Jones, Gary L. Cochran, Liyan Xu, et al.

Proactive Postmarketing Surveillance: Overview and Lessons Learned from Medication Safety Research in the Veterans Health Administration

Robert R. Campbell, Andrea M. Spehar, Dustin D. French.

Medical Product Safety Network (MedSun) Collaborates with Medical Product Users to Create Specialty Subnetworks

Donna Engleman, Suzanne Rich, Tina Powell, et al.

Physician-Reported Adverse Events and Medical Errors in Obstetrics and Gynecology

Martin November, Lucy Chie, Saul N. Weingart.

26,000 Close Call Reports: Lessons from the University of Texas Close Call Reporting System

Debora Simmons, JoAnn Mick, Krisanne Graves, et al.

Using an Anonymous Web-Based Incident Reporting Tool to Embed the Principles of a High-Reliability Organization

Paul Conlon, Rebecca Havlisch, Narendra Kini, et al.

Voluntary Adverse Event Reporting in Rural Hospitals

Charles P. Schade, Patricia Ruddick, David R. Lomely, et al.

Improving Error Reporting in Ambulatory Pediatrics with a Team Approach

Daniel R. Neuspiel, Margo Guzman, Cari Harewood.

Relationship Between Patient Harm and Reported Medical Errors in Primary Care: A Report from the ASIPS Collaborative

David R. West, Wilson D. Pace, L. Miriam Dickinson, et al.

Structure and Features of a Care Enhancement Model Implementing the Patient Safety and Quality Improvement Act

William Riley, Bryan A. Liang, William Rutherford, et al.

Taxonomies and Measurement

Development of a Comprehensive Medical Error Ontology

Pallavi Mokkarala, Julie Brixey, Todd R. Johnson, et al.

Mapping a Large Patient Safety Database to the 2005 Patient Safety Event Taxonomy

John R. Clarke, Janet Johnston, Monica Davis, et al.

A System to Describe and Reduce Medical Errors in Primary Care

Victoria Kaprielian, Truls Østbye, Samuel Warburton, et al.

Beyond Nursing Quality Management: The Nation's First Regional Nursing Virtual Dashboard

Carolyn Aydin, Linda Burnes Bolton, Nancy Donaldson, et al.

Using ICD-9-CM Codes in Hospital Claims Data to Detect Adverse Events in Patient Safety Surveillance

Paul Hougland, Jonathan Nebeker, Steve Pickard, et al.

Adaption of AHRQ Patient Safety Indicators for Use in ICD-10 Administrative Data by an International Consortium

Hude Quan, Saskia Drösler, Vijaya Sundararajan, et al.

Racial Disparities in Patient Safety Indicator (PSI) Rates in the Veterans Health Administration

Stephenie L. Shimada, Maria E. Montez-Rath, Susan A. Loveland, et al.

Challenges and Lessons Learned

Patient Safety Learning Pilot: Narratives from the Frontlines

Shirley E. Kellie, James B. Battles, Nancy M. Dixon, et al.

A Visual Computer Interface Concept for Making Error Reporting Useful at the Point of Care

Ranjit Singh, Wilson Pace, Ashok Singh, et al.

Christiana Care Health System: Safety Mentor Program

Michele Campbell, Christine Carrico, Carol Kerrigan Moore, et al.

News Media and Health Care Providers at the Crossroads of Medical Adverse Events

Pamela Whitten, Mohan J. Dutta, Serena Carpenter, et al.

Risk Assessment

Risk-Based Patient Safety Metrics

Matthew C. Scanlon, Ben-Tzion Karsh, Kelly A. Saran.

Leveraging Existing Assessments of Risk Now (LEARN) Safety Analysis: A Method for Extending Patient Safety Learning

Donna M. Woods, Jane L. Holl, Jon Young, et al.

A Model of Care Delivery to Reduce Falls in a Major Cancer Center

Nancy E. Kline, Bridgette Thom, Wayne Quashie, et al.

Using a Computerized Fall Risk Assessment Process to Tailor Interventions in Acute Care

Mary L. Hook, Elizabeth C. Devine, Norma M. Lang.

Home Health Care Patients and Safety Hazards in the Home: Preliminary Findings
Robyn R.M. Gershon, Monika Pogorzelska, Kristine A. Qureshi, et al.

Cause Analysis

The New York Model: Root Cause Analysis Driving Patient Safety Initiative to Ensure Correct Surgical and Invasive Procedures
Lawrence L. Faltz, John N. Morley, Ellen Flink, et al.

Department of Veterans Affairs Emergency Airway Management Initiative
Erik J. Stalhandske, Michael J. Bishop, James P. Bagian.

Using Root Cause Analysis to Reduce Falls in Rural Health Care Facilities
Patricia Ruddick, Karen Hannah, Charles P. Schade, et al.

Common Cause Analysis: Focus on Institutional Change
Anne Marie Browne, Robert Mullen, Jeanette Teets, et al.

Peer Reviewers

Additional Articles in this Publication

Volume 2. Culture and Redesign

Prologue: Culture and Redesign for Improved Patient Safety
James B. Battles

Safety Culture and Organizational Issues

The AHRQ Hospital Survey on Patient Safety Culture: A Tool to Plan and Evaluate Patient Safety Programs
Katherine J. Jones, Anne Skinner, Liyan Xu, et al.

Hospital Administrative Staff vs. Nursing Staff Responses to the AHRQ Hospital Survey on Patient Safety Culture
Karen L. Hannah, Charles P. Schade, David R. Lomely

Using the AHRQ Hospital Survey on Patient Safety Culture as an Intervention Tool for Regional Clinical Improvement Collaboratives
Inga Adams-Pizarro, ZeAmmia Walker, Janet Robinson, et al.

Measuring Safety Climate in Primary Care Offices
Gurdev Singh, Ranjit Singh, Eric J. Thomas, et al.

The PeaceHealth Ambulatory Medication Safety Culture Survey
Ronald Stock, Eldon R. Mahoney

Views of Emergency Medicine Trainees on Adverse Events and Negligence: Survey Results from an Emergency Medicine Training Program in a Regional Health Care System Following the National Standard of Care
Hardeek H. Shah, Annie Gjelsvik, Leo Kobayashi, et al.

Is There an Association Between Patient Safety Indicators and Hospital Teaching Status?
Peter E. Rivard, Cindy L. Christiansen, Shibei Zhao, et al.

Organizational Behavior Management in Health Care: Applications for Large-Scale Improvements in Patient Safety
Thomas R. Cunningham, E. Scott Geller

Confidential Performance Feedback and Organizational Capacity Building to Improve Hospital Patient Safety: Results of a Randomized Trial
Peter M. Layde, Linda N. Meurer, Clare E. Guse, et al.

Clinical Process Improvement

Resident Sign-Out: A Precarious Exchange of Critical Information in a Fast-Paced World
Stephen M. Borowitz, Linda A. Waggoner-Fountain, Ellen J. Bass, et al.

Documentation of Mandated Discharge Summary Components in Transitions from Acute to Subacute Care
Amy J.H. Kind, Maureen A. Smith

Challenges to Real-Time Decision Support in Health Care
Mark Fitzgerald, Nathan Farrow, Pamela Scicluna, et al.

Risk Reduction and Systematic Error Management: Standardization of the Pediatric Chemotherapy Process

Beverly Ann David, Ana Rodriguez, Stanley W. Marks

Analysis of Patient Safety: Converting Complex Pediatric Chemotherapy Ordering Processes from Paper to Electronic Systems

Donald K. Baker, James M. Hoffman, Gregory A. Hale, et al.

Promoting Best Practice and Safety Through Preprinted Physician Orders

George Ehringer, Barbara Duffy

The Impact of Standardized Order Sets on Quality and Financial Outcomes

David J. Ballard, Gerald Ogola, Neil S. Fleming, et al.

Clinical Impact of an Anticoagulation Screening Service at a Pediatric Tertiary Care Facility

Kathy M. Harney, Patricia A. Branowicki, Margaret McCabe, et al.

Creating Safety in the Testing Process in Primary Care Offices

Nancy C. Elder, Timothy R. McEwen, John M. Flach, et al.

Role of External Coach in Advancing Research Translation in Hospital-Based Performance Improvement

Nancy Donaldson, Dana Rutledge, Kristin Geiser

Strategies for Improving Patient Safety in Small Rural Hospitals

Judith Tupper, Andrew Coburn, Stephanie Loux, et al.

Systems Redesign

Systems-Based Practice: Improving the Safety and Quality of Patient Care by Recognizing and Improving the System in Which We Work

Julie K. Johnson, Stephen H. Miller, Sheldon D. Horowitz

Designing the Built Environment for a Culture and System of Patient Safety – A Conceptual, New Design Process

Kenneth N. Dickerman, Paul Barach

Implementation of Systems Redesign: Approaches to Spread and Sustain Adoption

Heather Woodward Hagg, Jamie Workman-Germann, Mindy Flanagan, et al.

Transforming the Morbidity and Mortality Conference into an Instrument for Systemwide Improvement

Jamie N. Deis, Keegan M. Smith, Michael D. Warren, et al.

Collaboratives and Patient Involvement

The Patient Safety Education Project: An International Collaboration

Linda Emanuel, Merrilyn Walton, Martin Hatlie, et al.

Harnessing the Potential of Health Care Collaboratives: Lessons from the Keystone ICU Project

Christine A. Goeschel, Peter J. Pronovost

VHA's National Falls Collaborative and Prevention Programs

Erik Stalhandske, Peter Mills, Pat Quigley, et al.

Hospital Language Services: Quality Improvement and Performance Measures

Marsha Regenstein, Jennifer Huang, Catherine West, et al.

Using Patient Complaints to Promote Patient Safety

James W. Pichert, Gerald Hickson, Ilene Moore

From Public Testimony to Vehicle for Statewide Action: Experience of the Michigan State Commission on Patient Safety

Diane Valade, Ruth Mohr, Vicky Debold, et al.

The Rural Physician Peer Review Model[®]: A Virtual Solution

Josie R. Williams, Kathy K. Mechler, John R. Holcomb, et al.

Volume 3. Performance and Tools

Prologue: The Shift toward Performance and Tools

Margaret A. Keyes

Teamwork and Communication

TeamSTEPPS[™]: Team Strategies and Tools to Enhance Performance and Patient Safety

Heidi B. King, James Battles, David P. Baker, et al.

Understanding Quality and Safety Problems in the Ambulatory Environment:
Seeking Improvement with Promising Teamwork Tools and Strategies
John S. Webster, Heidi B. King, Lauren M. Toomey, et al.

Building Self-Empowered Teams for Improving Safety in Postoperative Pain
Management
Ranjit Singh, Bruce Naughton, Diana Anderson, et al.

Beyond Rapid Response Teams: Instituting a “Rover Team” Improves the
Management of At-Risk Patients, Facilitates Proactive Interventions, and Improves
Outcomes
Rémi M. Heuckel, Jennifer L. Turi, Ira M. Cheifetz, et al.

Improving Referral Communication Using a Referral Tool Within an Electronic
Medical Record
Tejal K. Gandhi, Nancy L. Keating, Matthew Ditmore, et al.

Improving Patient Safety Through Provider Communication Strategy
Enhancements
Catherine Dingley, Kay Daugherty, Mary K. Derieg, et al.

Improving Clinical Communication and Patient Safety: Clinician-Recommended
Solutions
Donna M. Woods, Jane L. Holl, Denise Angst, et al.

Simulation

In Situ Simulation: Challenges and Results
Mary D. Patterson, George T. Blike, Vinay M. Nadkarni

The Nature, Characteristics and Patterns of Perinatal Critical Events Teams
William Riley, Helen Hansen, Ayse P. Gürses, et al.

Failure Modes and Effects Analysis Based on *in Situ* Simulations: A Methodology
to Improve Understanding of Risks and Failures
Stanley Davis, William Riley, Ayse P. Gürses, et al.

The Mobile Mock Operating Room: Bringing Team Training to the Point of Care
John T. Paige, Valeriy Kozmenko, Tong Yang, et al.

Examining the Effectiveness of Debriefing at the Point of Care in Simulation-Based Operating Room Team Training

Ramnarayan Paragi Gururaja, Tong Yang, John T. Paige, et al.

Effect of Recent Refresher Training on *in Situ* Simulated Pediatric Tracheal Intubation Psychomotor Skill Performance

Akira Nishisaki, Louis Scrattish, John Boulet, et al.

Simulation-Based Education Improves Patient Safety in Ambulatory Care

Beth A. LaVelle, Joanne J. McLaughlin

Human Factors

Pillars of a Smart, Safe Operating Room

F. Jacob Seagull, Gerald R. Moses, Adrian E. Park

High-Hanging Fruit: Improving Transitions in Health Care

Shawn J. Perry, Robert L. Wears, Emily S. Patterson

Minding the Gaps: Creating Resilience in Health Care

Christopher Nemeth, Robert Wears, David Woods, et al.

Error Producing Conditions in the Intensive Care Unit

Frank A. Drews, Adrian Musters, Matthew H. Samore

Patient Monitors in Critical Care: Lessons for Improvement

Frank A. Drews

Tools and Practices

Developing the Tools to Administer a Comprehensive Hospital Discharge

Program: The ReEngineered Discharge (RED) Program

Brian Jack, Jeffrey Greenwald, Shaula Forsythe, et al.

Creating an Accurate Medication List in the Outpatient Setting Through a Patient-Centered Approach

Kathryn Kraft Leonhardt, Patti Pagel, Deborah Bonin, et al.

The Use of Modest Incentives to Boost Adoption of Safety Practices and Systems

Gregg S. Meyer, David F. Torchiana, Deborah Colton, et al.

Using Data Mining to Predict Errors in Chronic Disease Care
Ryan M. McCabe, Gediminas Adomavicius, Paul E. Johnson, et al.

Venous Thromboembolism Safety Toolkit: A Systems Approach to Patient Safety
Brenda K. Zierler, Ann Wittkowsky, Gene Peterson, et al.

Using Process Measures to Improve Patient Safety Practices to Prevent Pulmonary Embolism
Ellen Flink, Harold Kilburn, Jr., Tong Wang, et al.

A Tool to Assess Compliance in Anticoagulation Management
Carla S. Huber, James M. Levett, Joan M. Atkinson

Using Lean Six Sigma® Tools to Compare INR Measurements from Different Laboratories Within a Community
Brion Hurley, James M. Levett, Carla Huber, et al.

Using Six Sigma® Methodology to Improve Handoff Communication in High-Risk Patients
Kshitij P. Mistry, James Jagers, Andrew J. Lodge, et al.

10-Year Experience Integrating Strategic Performance Improvement Initiatives: Can the Balanced Scorecard, Six Sigma®, and Team Training All Thrive in a Single Hospital?
Jon N. Meliones, Michael Alton, Jane Mericle, et al.

Impact of Staff-Led Safety Walk Rounds
Vicki L. Montgomery

Development of a Web-Based Patient Safety Resource: AHRQ Patient Safety Network (PSNet)
Niraj L. Sehgal, Sumant R. Ranji, Kaveh G. Shojania, et al.

Volume 4. Technology and Medication Safety

Prologue: Technology and Medication Safety

Mary L. Grady

Health Information Technology

“Safeware”: Safety-Critical Computing and Health Care Information Technology

Robert L. Wears, Nancy G. Leveson

Improving Perioperative Patient Safety Through the Use of Information Technology

Paul J. St. Jacques, Michael N. Minear

The Impact of Health Information Technology on Work Process and Patient Care in Labor and Delivery

Emily M. Campbell, Hong Li, Tomi Mori, et al.

Consolidated Imaging: Implementing a Regional Health Information Exchange System for Radiology in Southern Maine

Stephanie Loux, Robert Coleman, Matthew Ralston, et al.

Personal Health Records to Improve Health Information Exchange and Patient Safety

James R. Fricton, Diane Davies

Improving Patient Safety Using ATHENA-Decision Support System Technology: The Opioid Therapy for Chronic Pain Experience

Martha Michel, Jodie Trafton, Susana Martins, et al.

Implementing an Ambulatory e-Prescribing System: Strategies Employed and Lessons Learned to Minimize Unintended Consequences

Emily B. Devine, Jennifer L. Wilson-Norton, Nathan M. Lawless, et al.

Measuring IT Sophistication in Nursing Homes

Gregory L. Alexander, Dick Madsen, Stephanie Herrick, et al.

The Potential of Hand-Held Assistive Technology to Improve Safety for Elder Adults Aging in Place

Shirley Ann Becker, Frank M. Webbe

Efficiency Gains with Computerized Provider Order Entry

Andrew M. Steele, Mical DeBrow

Medication Safety

Clinical Pharmacists in Emergency Medicine

Rollin J. Fairbanks, Erik A. Rueckmann, Karen E. Kolstee, et al.

Intravenous Infusion Safety Initiative: Collaboration, Evidence-Based Best Practices and “Smart” Technology Help Avert High-Risk Adverse Drug Events and Improve Patient Outcomes

Ray R. Maddox, Sherry Danello, Carolyn K. Williams, et al.

Continuous Respiratory Monitoring and a “Smart” Infusion System Improve Safety of Patient-Controlled Analgesia in the Postoperative Period

Ray R. Maddox, Harold Oglesby, Carolyn K. Williams, et al.

Evaluation of a Medication Therapy Management Program in Medicare Beneficiaries at High Risk of Adverse Drug Events: Study Methods

Andrew L. Masica, Daniel R. Touchette, Rowena J. Dolor, et al.

Medication Management Transactions and Errors in Family Medicine Offices: A Pilot Study

John Lynch, Jonathan Rosen, Andrew Selinger, et al.

Evaluation of Medications Removed from Automated Dispensing Machines Using the Override Function Leading to Multiple System Changes

Karla Miller, Manisha Shah, Laura Hitchcock, et al.

Imbedding Research in Practice to Improve Medication Safety

Marsha A. Raebel, Elizabeth A. Chester, David W. Brand, et al.

Risk of Concurrent Use of Prescription Drugs with Herbal and Dietary Supplements in Ambulatory Care

Robert E. Graham, Tejal K. Gandhi, Joshua Borus, et al.

Using Home Visits to Understand Medication Errors in Children
Kathleen E. Walsh, Christopher J. Stille, Kathleen M. Mazor, et al.

Developing a Community-Wide Electronic Shared Medication List
Ron Stock, Eldon R. Mahoney, Dawn Gauthier, et al.

Prologue

Laying the Foundation

Kerm Henriksen, PhD

The volume starts with papers that look to the future and examine the past with respect to patient safety; however, its overarching theme is assessment. An underlying premise to any volume that focuses on assessment is that the time spent in trying to understand the nature of the problem is well worth the effort. A good understanding of the problem space provides the foundation upon which all subsequent efforts are based. Without adequate assessment, the likelihood that subsequent steps and initiatives will be wide of the mark increases substantially.

In our efforts to understand the nature and prevalence of departures from patient safety, it comes as no surprise that reporting systems and surveillance activities and efforts to improve them continue to generate considerable research interest. The present volume provides ample evidence of this with papers on reporting systems and surveillance efforts that focus on the intensive care unit, rural and critical access hospitals, ambulatory pediatric care, primary care, and a teaching hospital obstetrics/gynecology service. Also spanning the surveillance landscape are papers on a national medication error reporting system, proactive medication studies, a system that embeds the principles of high-reliability organizations, another that targets high-risk device-use areas, a close call-good catch system, and a care enhancement model relevant to the Patient Safety and Quality Improvement Act of 2005.

Of course, we would like to believe that everybody buys into the use of reporting systems, that under-reporting is not a problem, that doubts about discoverability and confidentiality do not exist, that reporting systems are not burdensome to use, that reported events do not disappear into data graveyards, and that useful information for system improvement is faithfully reported back to the relevant local unit, but few of us live in a fantasy world. The papers' authors do not shy away from the traditional challenges associated with reporting systems; in their breadth of interest, considerable intellectual vigor is demonstrated.

Challenges of reporting quickly give rise to challenges of encoding and organizing the adverse event data into a meaningful classification structure. To date, the lack of a standard set of patient safety terms, data elements, and taxonomic structure has hampered the transfer and sharing of information across different datasets and systems. Attempting to map from one system to another is not a task for the light-hearted. Papers that address these issues can be found in the taxonomies and measurement section of the volume, as can papers on a nursing virtual dashboard, a system for describing and classifying errors in primary care, the use of ICD-9-CM codes in hospital claims data, adaptation of AHRQ Patient Safety Indicators (PSI) for use in ICD-10 administrative data, and racial disparities in PSI rates at the Veterans Health Administration.

Strategies and efforts aimed at adverse event surveillance, creating useable taxonomies, and addressing measurement issues represent just part of the picture. While much of the focus is on

the development of reporting tools and indicator sets, other papers remind us that the perceptions and sensemaking that occur among the frontline personnel that are expected to use these systems need to be taken into account. Sharing this sentiment are papers that report on narratives from the frontlines, how a visual interface can help create a common vision of system vulnerabilities, and how a mentor program can help staff navigate a reporting system while alleviating fears. Another paper examines the perceptions of health care leaders and news media professionals related to adverse event reporting.

Yet another assessment approach in our pursuit of patient safety is to focus on risk. Risk is treated by safety scientists as the likelihood that exposure to a hazard will lead to adverse consequences. In other high-stakes industries, risk assessment generally involves identifying underlying hazards and assessing risk—that is, the probability that exposure to a hazard will lead to an adverse consequence. While one finds various uses of safety science terminology in health care, there is a growing interest in the risk assessment methods. Here the reader finds papers that deal with risk-based patient safety metrics, a "risk-binning" methodology applied across institutions, a case-control study to determine risk factors for falls in a cancer center, use of a computerized fall risk assessment process that tailors interventions in acute care, and an assessment of patient and safety hazards found in home health care.

Eventually, well conceived and executed assessment efforts lead to actionable recommendations and targeted interventions. The final set of papers describes initiatives that have as their point of departure root cause analysis (RCA). Root cause analysis driven initiatives include an extended protocol to ensure correct surgical and invasive procedures in New York State, a highly focused effort by the Department of Veterans Affairs to reduce emergency airway management difficulties, a statewide effort to encourage falls prevention programs in rural health care facilities in West Virginia, and a common cause analysis effort that organizes RCA action items into themes for consideration as part of the organization's yearly operating plan.

In our pursuit of safe patient care, we hope this volume on assessment provides a solid foundation and serves as a useful point of departure for readers to benefit from the diverse range of patient safety issues and approaches found in the other three volumes.

Looking Forward, Benefitting from the Past

Envisioning Patient Safety in the Year 2025: Eight Perspectives

Kerm Henriksen, PhD; Caitlin Oppenheimer, MPH; Lucian L. Leape, MD; Kirk Hamilton, FAIA, FACHA, MS; David W. Bates, MD, MSc; Susan Sheridan, MBA; Mark E. Bruley, CCE; David M. Gaba, MD; Robert L. Wears, MD, MS; Paul M. Schyve, MD

Abstract

Envisioning the future of patient safety is more than an academic exercise. Appealing visions can help channel human energies, set new directions, and open the doors to alternative approaches. Eight thought leaders participated in an exercise of envisioning patient safety in the year 2025. Two tasks were assigned for preparing a brief response. The first task simply called for the invited thought leaders to envision patient safety in the year 2025 as they would like it to be from the vantage point of their particular area of expertise. The areas of expertise included health care system change, design of the physical environment, health information technology, patient-centeredness, device safety, simulation, transitions of care, and complex systems. For the second task, they were asked to describe what changes need to “fall into place” between now and then in order for their visions to be realized. Concluding observations are provided.

Introduction

Much of the change that happens in health care occurs in a reactive, piecemeal mode with the crises of the moment serving as the prime drivers. Rarely is the time taken to reflect upon and envision the safety and quality of care that patients, providers, and health care professionals would like to have. One way of responding to the changes occurring in health care is to get out in front of them and consider them an opportunity to shape the future as we would like it to be. Visions help to do this. Clear and compelling visions start us along a path of generating a future we deserve to have – a journey that very much needs to be taken in health care. They have the power to dislodge the status quo, alter comfortable patterns of behavior and infuse the uncertainties of tomorrow with a new sense of opportunity and purpose.

Toward these ends, and in keeping with the subtitle of this publication, *New Directions and Alternative Approaches*, the first two authors in the byline identified eight different areas of patient safety expertise and asked the remaining authors (a deliberate sample based on their particular area of expertise) if they would be willing to envision patient safety in the year 2025. All the invited thought leaders accepted the invitation. Eight domains of patient safety expertise are represented: health care system change, the design of the physical environment, health information technology, patient-centered care, device safety, simulation, transitions of care, and complex systems.

The thought leaders were presented with two tasks: first, envision patient safety as you would like it to be in the year 2025 and beyond from the perspective of your own area of expertise; and second, describe what changes need to “fall into place” between now and then in order for your visions to be realized. Given a practical limitation regarding the length of manuscripts that could be submitted to *Advances*, the thought leaders were asked to prepare their individual perspectives within a relatively tight 600-word limit. Also, as an inducement to focus on the future and resist the magnetic pull of the present, they were encouraged to forego the need for references. Their perspectives appear next and flow from a broad, macro-level of analysis to a more micro-level and then onto an analysis of technical work and complexity issues.

Health Care System Change

Lucian L. Leape. In 2025, the health care system has been transformed at all levels: national, regional, local, and institutional. At the institutional level—hospital, group, ambulatory care center, nursing home—we have achieved a culture of safety. Safety is truly the first priority for the board, the leadership, and the staff, and every individual feels personally responsible for ensuring safe care. The environment is nonpunitive for errors, which are seen as opportunities for learning, but intolerant of deliberate unsafe acts. Caregivers are open and transparent with patients. Patients are truly partners in their own care. We treat each other with respect and work well together in teams.

An outside observer is struck by three characteristics that are very different from the culture of the early 21st century: a deep sense of individual and institutional accountability for safety, an emphasis on fairness and transparency, and pervasive collaboration and teamwork based on mutual respect.

Our processes have been redesigned, resulting in elimination of 90 percent of current adverse events, including virtually all infections, postoperative complications, and medication errors. Managers no longer talk about the “business case” for safety. When errors do occur, our pride leads us to respond with surprise (*This should never happen here!*), curiosity (*How could this have happened?*), and commitment (*This will never happen again.*) Patients are fully compensated for all costs of injuries; we provide emotional support for patients and caregivers after adverse events.

At the macro level, all institutions and caregivers are members of integrated care networks (true managed care organizations), which are held accountable by the national government to submit quality and safety data to verify that they are meeting national standards of care. Federal agencies, such as the Food and Drug Administration (FDA), ensure that all drugs, devices, products, and procedures are safe, effective, and ergonomically sound. Whatever the financing system, there are no barriers for anyone to receiving appropriate health care.

A transformation of this magnitude requires that we address the underlying cause of our current—i.e., 2008—system failures: fee-for-service, for-profit reimbursement that rewards poor care, penalizes good care, and promotes overuse. Episode-oriented, it provides disincentives for efficient coordinated multidisciplinary care. Insurance-based, it lacks fairness through exclusions, disallowals, skimming, and high costs. Profit-driven, it rewards production over quality and safety. The experience of the past 20 years provides abundant evidence that this

commercial for-profit system is incapable of providing universal coverage, controlling costs, or assuring quality and safety.

Changing this system is the ultimate political challenge. Because of powerful vested interests, change will not occur without substantial increases in public indignation over insurance failures, lack of access, and poor quality. Four major changes are required:

- First, we must provide universal coverage, whether by tax-based, single-payer, or mandatory regulated insurance. A single (lean) standard benefits package of essential care must be provided for all, without exclusions, restrictions or copayments.
- Second, government or private payers will not reimburse individuals but only pay not-for-profit integrated networks on a capitated basis. These entities represent a new type of managed care organization that will be responsible for defined populations; they will provide evidence-based, appropriate, preventive, episodic, and comprehensive continuing care by multidisciplinary teams in all settings. Global budgets will provide strong incentives to eliminate unsafe, ineffective, and inefficient care.
- Third, the entire system requires oversight at the national level by the Federal Government, through regional organizations that assure sufficient facilities (e.g., emergency rooms, cardiac centers, transplantation centers) and monitor quality of care by plans, not by individuals. Government regulates insurance companies, sets standards (like the National Quality Forum), and requires health care organizations to compensate patients for costs of treatment-related injuries.
- Finally, we must require our professional schools to provide training in basic safety science (e.g., error theory, ergonomics, system analysis), leadership skills, respect for coworkers, teamwork, communication skills, and emotional support of patients and colleagues.

Design of the Physical Environment

Kirk Hamilton. An ideal, well-designed environment for health care in 2025 will be safe, efficient, and designed to enhance the calm, healing aspects of the setting, where advanced technologies will support clinical care delivery. The physical environment of the future will play a role in improved safety by contributing to increased compliance with hand-hygiene guidelines, reduced patient falls, improved medication administration, and reduced numbers of transfers. The environment will be constructed without the use of toxic materials and solvents, and surfaces will be far more effective in reducing the danger from infectious organisms. Surfaces will have antimicrobial characteristics, improved “cleanability,” and be made from materials designed not to harbor moisture that could support organisms. Each of these important outcomes associated with design has already been demonstrated.

One important aspect of safety in the future is the issue of isolation for patients with contagious and drug-resistant conditions. We also need to be prepared for large numbers of serious cases in the event of a pandemic. The ability to switch rooms and units to outside air that is highly filtered and not recirculated will allow many more spaces to be available for isolation cases.

Among the simplest of design interventions is the ability to reduce stress for patients, families, staff, and physicians. Stress exacerbates all known clinical conditions, increases staff fatigue, and contributes to errors. The potential impact of design to improve the quality of the patient experience and the quality of the staff experience is enormous. Noise reduction, natural light, a view to the outdoors with a glimpse of nature, and calming elements in occupied spaces are all important contributors to stress reduction.

The health care facilities of 2025 will need to be far more efficient than today's buildings. Efficiency will be required in energy consumption, as well as in the work performance of the building's occupants. Technology, including robotics, will continue to be utilized for its "best practice" standardization and labor-saving advantages. Process redesign, paired with quality improvement, will be employed to reduce waste, redundancy, and nonproductive time of highly skilled staff. Configuration of systems, departments, units, and individual work settings will lead to measurable performance improvement.

Communication is vitally important in the health care arena, and design can affect the quality of interaction among caregivers and patients, as well as among the health care professionals collaborating in teams. Improved communication will be a major factor in improved safety.

The most effective health care environments of the future will be characterized by the ambulatory-dominant campus as part of a regionally distributed health care model. The shift to a preventive care model, with a single national risk pool and full coverage for all citizens, will reduce the overall cost and workload of the health care system at a time when the need to operate with fewer trained professionals is compelling. The new ambulatory-dominant management and facility model will be paired with a regionally centralized system of critical and trauma services supported by telemedicine, which will include the remnants of today's hospital-dominant model.

The single most important contribution to the development of these new safe and efficient health care environments will be the widespread adoption of evidence-based design and an accompanying full investment in relevant research. At the same time, there is a need to revise standard accounting procedures, whose requirement of separating operating and capital expenses, makes it difficult for decisionmakers to adopt plans that optimize the life-cycle cost of a building and equipment. If trustees, executives, and the government align themselves to achieve the best of what has already been successfully demonstrated in piecemeal, the future is bright for far better, safer, and more productive health care environments.

Health Information Technology

David W. Bates. By 2025, it should be possible to make care dramatically safer than it is today, and information technology will be a central tool in this safety transformation. Inside hospitals, patients and providers will be tracked from the time they enter the hospital until they leave, using radiofrequency identification devices, thus improving efficiency. All monitoring data will be captured electronically, and processing will be done in the background to identify patients who appear likely to decompensate before decompensation occurs. Handoffs between providers will occur electronically. Notifications about laboratory abnormalities will be communicated directly to the responsible provider using the information system.

Medications will be ordered using computerized systems that will check orders for issues and suggest appropriate dosages, tailored to the patient's age, sex, and in some instances, genetic makeup. Drugs will be dispensed using robots for solid forms of medications and, in specialized instances, for liquids like chemotherapy. Intravenous medications will be administered using "smart" pumps, which "know" the type of medication ordered and appropriate dosage. The solid form of administered medications will be tracked using barcoding and electronic medication administration records. Patients' response to medications will be tracked by nurses using handheld devices and by patients themselves on their personal health records, available via the Web in every hospital room. All these technologies will be electronically linked, lowering the probability of error substantially.

At the same time, much more care will be delivered outside the hospital than is the case today. Outside the hospital, providers will use electronic health records as they interact with patients. All prescribing will be electronic; and prescriptions will be transmitted directly to pharmacies, most of which will be through the mail. The medication error rate will be a tiny fraction of what it is today because initial prescribing will be improved, and dispensing will be safer. Tracking to ensure that abnormal laboratory tests receive appropriate followup will be routine. Background processing will help ensure that providers do not miss important diagnoses.

Home monitoring of patients with serious medical conditions, such as severe congestive heart failure, will be ubiquitous, substantially improving both quality and safety outcomes for these conditions. Much of the monitoring will be done using "smart" devices, such as scales that are wirelessly linked to the patient's personal health record. The actual monitoring will be done largely using electronic tools that can sift through the data and notify team members when important signals, such as a significant increase in the patient's weight, are identified. Personal health records will prove to be especially valuable for patients when they need to report medication and other problems.

Transitions between care settings will be managed far more effectively. Because of seamless interoperability, critical health information will be more accessible, regardless of patient setting—hospital, nursing home, assisted living, or the home.

To realize the 2025 vision, the payment structure needs to be reformed. Payment must be higher for safer care. To pay providers for safer care, better tools and indicators for measuring safety will need to be developed. With the advent of widespread use of electronic health records, it will be possible to detect adverse events on a wide-scale basis. The computerized adverse event monitoring capability makes it possible to assess safety objectively, on an ongoing basis. Furthermore, patients will contribute a great deal of key information themselves through their personal health records. However, if computerized monitoring is to achieve a significant impact, research support to develop it effectively will be essential.

New information technology and safety interventions need to be fully tested, and continued Federal support—much more than is available today—will be needed for their development and testing. With payment reform in place, the effectiveness of new technology carefully validated, and robust indicators of safety developed and embedded in the care process itself, health care organizations will find it in their economic interests to make the delivery of care considerably safer than it is today.

Patient-Centered Care

Susan Sheridan. In 2025, the definition of patient-centered care, within the patient safety domain, will have evolved to a broader and more provocative significance, beyond simply delivering what patients say they “want.”

The health care system will have completed the shift from a model of physician self-governance, autonomy, and paternalism to a model of co-creation and partnership with patients, based on mutual respect and trust, transparency, shared decisionmaking, shared learning, and accountability. In essence, patient-centered care will transcend from being considered the redesign of health care *for* patients and families to the redesign of health care *with* patients and families.

Patient perspectives, experiences, wisdom, behavior, and participation will be considered priceless and essential resources for the design and evaluation of the health care system. They will drive funding, solutions, guidelines, patient and provider education, ethics, research, policymaking, and consumer choice of providers and health care institutions to assure that the system is safe, compassionate, and just.

In 2025, patient safety materials, available to the public in a variety of mediums, will be significantly retooled to integrate the triggers and human dimensions that motivate patients and families to become engaged in their own safety. They will be research-based, tested by patients, action-oriented, and “medically honest” in that they will communicate all risks no matter how small.

Patient safety education will encourage and support patient and family participation to ask questions about risk, guidelines, processes, treatments, medications, and patient rights, as well as providers’ and hospitals’ safety indicators and performance measurements. Patients will be encouraged to collect and understand personal medical records, test results, and medication orders and, in general, to seize opportunities to contribute to their own safety.

However, the ultimate litmus test for authentic patient-centeredness will be when harm occurs. In 2025, patient-centered care will be viewed as a comprehensive continuum and will not cease when a medical error occurs or because of the perceived threat of liability; it will honor and respect the needs of the patients and their families who have been harmed.

Disclosure, no longer optional in 2025, will be understood as simply the “right thing to do” and as the cornerstone of patient-centeredness, not just a strategic maneuver. Disclosure and apology will be validated by compensation when appropriate and/or the implementation of sincere changes in policy and practice to prevent similar events in the future. Patients and families will be considered a valued source of input to policy and practice changes by being integrated into root cause analyses, accrediting surveys, and other investigations.

Also, in the event of medical error, patients and family members will be able to report errors to a responsive, authoritative entity via a national consumer reporting system that assures accountability and systemic learning and improvement.

To realize this vision of “patient-centeredness” within patient safety in 2025, the necessary changes that need to occur include:

- Legislative action for the creation of an authoritative national commission or board at the “helm,” made up of health care professionals and consumers who will be accountable to health care consumers for their safety and who will respond to reports of medical errors and harm with urgency to assure safety to future patients. (Similar to the National Consumer Product Safety Commission.)
- Creation and implementation of alternatives to the tort system that are honorable, fair, reliable, equitable, fast, and that directly influence safety in health care.
- Mechanisms to incubate and support consumer groups to assure authenticity, to accelerate progress in patient safety through public pressure, and to collect, package, and communicate patient wisdom and expectations regarding patient safety to all stakeholders in health care.
- The repositioning of patient safety research so that patient priorities, research agendas, and science are aligned, integrated, and complementary. Some topics include:
 - Significant investment in learning about the human dimensions of the patient population and how to transform passive patients to active participants.
 - Exploration of the depths of the human toll and total economic impact to society from medical errors.
 - Research on the dynamics of communication of risk and the impact on patient engagement.
 - Identification of the effects and contributions to patient safety of a patient reporting system of medical errors.
- The reengineering of patient safety solutions and “best practices,” identifying opportunities for patient involvement as part of the processes of care to contribute to safety.
- Leadership that is courageous, passionate, innovative, and willing to offer tools and training to providers and staff to transition to patient-centered care
- Creation of a consumer reporting system that directly influences standards of care, protocols, and guidelines and is responsive to patients.

Device Safety

Mark Bruley. From the viewpoint of 2025, improvements in medical device safety are quite evident. Improvements over the past 20 years have resulted from advances in information technology, enhanced regulatory oversight, and increased concentration on human factors in device design.

Advances in radio frequency identification (RFID) technology have made medical devices readily identifiable and traceable in the hospital, home, supply chain, and inside the patient. Virtually all devices, regardless of size—including implants, surgical instruments, and consumables (needles, staples, sponges)—now have embedded RFID tags. This has vastly enhanced device identification for adverse event and problem reporting and for tracking recalled, contaminated, reprocessed, reconditioned, or obsolete devices. At the regulatory level, RFIDs

have enhanced surveillance to identify counterfeit devices. The unification by regulatory authorities of RFID information protocols and device nomenclatures has enhanced this oversight, streamlined problem reporting databases, and facilitated data mining and analysis of adverse events.

RFIDs in medical devices have helped to virtually eliminate two of the three most notorious surgical errors—wrong site/wrong side/wrong patient surgery and retained instruments. Linking patients' identification and health care information in the hospital wrist band RFID tag to the electronic medical record (EMR) and to therapeutic and life support devices (e.g., infusion pumps, enteral feeding pumps, ventilators, anesthesia machines, linear accelerators) has helped eliminate delivery of inappropriate procedures, medications, and therapies.

Medical errors, such as retained surgical instruments and sponges, are now virtually unheard of due to RFID tags and the advent of routine patient RFID scanning at the completion of surgery using RFID readers in the operating table or those now present in all wearable computers, vidcom cell phones, and PDAs.

Surgical fires, the third notorious error involving devices, continue to pose technologic challenges because of the complex physics of ignition and flame spread. No advances have been made in fire-retardant surgical devices and materials for safe use in the oxygen-enriched atmospheres (OEAs) that continue to be present during surgery. Attempts to interconnect anesthesia machines with electrosurgical units and lasers to prevent them from activating when a surgical site OEA is automatically detected have resulted in adverse patient outcomes from hypoxia, delayed therapy, or exsanguinations and have been abandoned. Surgical fire prevention continues to require surgical team vigilance and perioperative communication.

Device interconnectivity has helped to ensure proper patient monitoring during laparoscopy (e.g., prevention of laparoscopic CO₂ insufflation if heart rate and blood pressure are not monitored), and to alert anesthesia and cardiopulmonary bypass personnel if the anesthesia ventilator is turned off when weaning the patient from bypass. Other device interconnectivity and safety interlocks continue to be explored with mixed results. More successful have been advances in arrhythmia detection algorithms in physiologic monitors and the enhanced linkage of those monitors to alarm systems that successfully address the cognitive limitations of health care staff.

Medical device accidents caused by user error have decreased significantly due to an increase in the device industry's focus on enhancing human factors design and usability testing. This has proven true for capital equipment (e.g., physiologic monitors, defibrillators, infusion pumps, anesthesia machines, imaging and radiation therapy equipment), surgical instruments, and clinical laboratory and pharmacy equipment. Devices commonly used in the home (e.g., glucose monitors, insulin pumps, portable ventilators, nerve stimulators) have become much safer to use because of better human factors designs that take into account the limitations of the patient or lay caregiver using the device.

Finally, devices have been made "user friendly" and more tolerant of users' errors through critical analysis of the four device interfaces (device-user, device-patient, device-accessories, device-environment). Semi-intelligent software in electromedical devices has reduced errors and enhanced user skill. Virtual user manuals embedded in equipment are instantly viewable via

wireless personal area network links to the user's computer, vidcom, or PDA and have also served to significantly reduce errors.

Simulation

David Gaba. Over the next 20 years, health care will have caught up with the rest of society's high-hazard undertakings, such as commercial aviation and nuclear power, and adopted a comprehensive strategy of intensive training and periodic performance assessment for health care personnel. The system in place in 2008 emphasizes an initial period of "book learning" followed by apprenticeships—work with real patients with varying levels of supervision. Once a clinician achieves full staff status, there is only a modicum of recurrent training and even less assessment of skill. In the future, there will be an integrated system of "learning by doing" and checking of performance, much of it taking place away from real patients. These activities will be required periodically for all clinicians—as individuals, teams, work units, and whole institutions—regardless of years of experience. A variety of modalities will be used in these efforts, including verbal simulation or role playing, network-based multiplayer virtual worlds, standardized patient actors, part-task and procedural trainers, and mannequin-based or virtual reality replications of complete patients.

Training and performance assessment are not panaceas and must act synergistically with process improvement and design in order to improve patient safety. Simulation also has a role to play in these approaches. In the future, medical equipment (and user interfaces) will be tested in advance using simulations. Clinical processes will be probed with *in situ* simulations in actual clinical environments. Simulation will be used, not only for clinicians, but also for health care executives, regulators, and legislators.

Simulation is a "technique," not a technology, to replicate important aspects of the real world, to amplify them, or to replace them for the appropriate purposes. It facilitates training and assessment in ways that cannot be accomplished in real patient care. In particular, simulations can:

- Be scheduled as needed to accomplish key goals.
- Be targeted to the personnel in need of training or assessment.
- Be about routine processes and events or about unusual and critical events.
- Be intense whenever desired.
- Address issues ranging from psychomotor performance on invasive procedures to cognitive and behavioral performance as individuals and teams.
- Require clinicians to interact with a variety of medical equipment and a diversity of personnel and personalities.
- Facilitate intrusive and detailed recording and assessment of performance.
- Present no risk to patients.

How will this revolution in health care be accomplished? It will be implemented by the same institutions that already oversee the operations of health care, such as professional societies,

professional schools, liability insurers, risk managers, clinical payers, and accrediting organizations. They will, in turn, be “driven” by a variety of forces, all of which translate the demands of the public, the ultimate driver.

Transitions of Care

Robert Wears. Here in 2025, it is hard to recall that around the turn of the century, transitions in care were uniformly viewed at best as disorganized ramblings that badly needed to be standardized and “rationalized,” or at worst, as unmitigated hazards that needed to be reduced or eliminated. The value we place on transitions today differs dramatically from the offhanded casualness with which we considered them not too long ago.

In fact, today we would not even speak of “transitions” as a single entity, anymore than we would speak of “inflammations” as being representative of anything in particular. Although the episodes that were once called “transitions” are still united in that they involve transfers of authority, responsibility, and yes, information, today’s appreciation of the variegated and heterogeneous nature of these episodes—necessarily resulting from the variegated and heterogeneous nature of human physiology, of illness and injury, and of clinical work—does not allow us to think of, say, shift changes, as having anything in common with interservice transfers (e.g., from the ward to the intensive care unit), which in turn, have nothing in common with transitions into or out of the hospital. Each of these events has its own context, characteristic problems, opportunities, affordances for recovery, and social dynamics, such that we treat them each quite differently. In fact, even within these broad classes, many distinctions, both overt and nuanced, remain.

“Transitions in care,” to use the old term, are dramatically better today than they were in 2008, but the improvements did not come from interventions that were thought important back then; most of those (e.g., standardized templates, written turnover documents, and fads like SBAR [Situation-Background-Assessment-Recommendation]) fortunately died quiet deaths along the way, unmourned victims of new ways of thinking that led to better understanding.

To develop those new ways of thinking and better understanding, three fundamental changes must occur: demedicalization, increased understanding of technical work, and changed views of transitions.

Although there is general agreement that safety problems in health care are problems of psychology and engineering, not problems of medicine, patient safety research and improvement efforts today are dominated by health care professionals, mostly physicians. This dominance of safety work by socially powerful groups within a field of practice is strikingly different from other high-hazard industries.

Health care professionals and human performance experts have highly divergent views of transitions that derive from differences in the scientific and philosophical underpinnings of their fields. Health care professionals commonly see transitions as excessively variable, *ad hoc* procedures badly in need of standardization. Human performance experts see them more appreciatively, as exquisitely situated in context, and worry about the consequences that might follow well-intended mandates for standardization. Bringing experts in human performance to

the forefront of safety research—in substantive and sustained collaborations with clinical experts—is an essential first step toward producing anything of value.

The detailed study of technical work in health care is just beginning, but an early surprising result has been the recognition of the role that transitions play in recovery from adverse events in-the-making. The combination of a deep and well-grounded understanding of technical work in context, combined with the insight that imposing a simple structure on a complex process does not result in simplicity, will ultimately lead to interventions that mitigate weaknesses in transitions without placing what is good at risk or driving it underground.

Finally, a fundamentally different understanding of transitions is needed. Rather than being the unidirectional movement of chunks of information, they must be viewed as conversations aimed at jointly constructing shared understandings under important constraints. Instead of the goal of comprehensiveness (transmission of complete, standardized data sets for each patient), the new goal should be saliency (what must we pay attention to based on the complexity of the situation, the extent of common ground among participants, the time available, and competing goals).

Complex Systems

Paul Schyve. By 2025, evidence-based safe practices will be rapidly and universally adopted in and between clinicians’ offices, hospitals, and other health care organizations. Risk of unintended harm will be rare, quickly identified, and successfully mitigated. But this transformation can only be achieved when health care delivery is recognized as being composed of complex systems, the characteristics of complex systems are understood, and systems thinking guides change.

Health care delivery is composed of complex systems. The macrosystems of health care organizations and the microsystems of patient care teams and patients—even at the level of the practitioner’s office—are all complex. And, these systems are open systems—that is, other systems (e.g., educational, financing systems) provide inputs to them.

Fortunately, complex systems exhibit characteristics that can be leveraged to improve safety. First, they are “adaptive”; they self-adjust in response to internal changes and external inputs. Second, small changes at one point in the system can result in large changes elsewhere. Third, they defy comprehensive modeling (complexity), face unanticipated situations (contingency), and contain decision points for which the correct choice is unclear (uncertainty). This complexity, contingency, and uncertainty are helpful reminders to participants to be appropriately cautious, and humble, in creating change.

Unfortunately, these same characteristics can also increase the risk of harm in health care. First, the adaptive nature of complex systems can lead to undesirable changes; self-adjustments are not necessarily guided by participants’ values and priorities. Second, the disconnect between the magnitudes of a cause and its effect can result in a minor “tweak” in one part of a system and lead to a catastrophe elsewhere. Third, failure to appreciate the complexity, contingency, and uncertainty in complex systems can lead to ineffective redesigns with unintended consequences.

How can the recognition that health care delivery is composed of complex systems and an understanding of the characteristics of complex systems be harnessed to transform health care delivery for 2025?

First, clinicians, administrators, and policymakers who want to improve safety and prevent harm must think of health care delivery as complex systems. Systems thinking does not come naturally but must be learned and practiced. People prefer simplicity to complexity, predictability to contingency, and certainty to uncertainty.

Second, clinicians and administrators must apply systems thinking to designing and implementing evidence-based changes that are specifically targeted toward reducing unintended harm in health care. If clinicians are to fulfill the ethical obligation to “first, do no harm,” they must invest in systems change, not just in their personal competence and commitment. Administrators and clinicians must recognize that the implementation of an evidence-based safe practice usually requires more than adding a new process to an existing system. Rather, it often requires a system redesign, with new forcing functions and incentives, if the implemented change is to be effective, efficient, reliable, and sustained.

Third, before being widely implemented, in order to identify potential unintended consequences, proposed changes should be subject to prospective evaluation, such as failure modes and effects analysis and computer-based simulation.

Fourth, because prospective evaluation cannot predict all the unintended consequences, vigilance must be built into the system. Vigilance must be the responsibility of each person in the system—practitioners, administrators, patients, patients’ families—and the system itself must be imbued with continuous self-measurement of processes and outcomes and mining of the measurement databases to identify early indicators of unexpected change.

Clinicians’ offices, hospitals, and other health care organizations, and the United States health care system itself, are all complex systems. With the help of systems thinking, they can become dramatically safer; without it, many of the efforts to improve safety will be wasted.

Concluding Comments

This exercise has generated eight separate visions of patient safety as their originators would like it to be in 2025 from their assigned vantage points. While the coauthors recognize a need for considerable change in their assigned domains, the level of analysis across the different domains varies from the most macro of levels, as in Leape’s national, regional, local, and institutional levels; Hamilton’s design of the physical environment; and Bates’s widespread implementation of health information technology; to a more micro-oriented focus on individual patients and families by Sheridan; improvements in medical device safety by Bruley; and different forms of simulation training and performance assessment by Gaba. Both Wears and Schyve call for new ways of thinking and a more in-depth understanding of transitions of care and systems complexity, respectively.

The first six visions place emphasis on design or redesign efforts, whether they are clinical processes, the physical environment, health information technology, patient-centeredness, devices, or simulation training. However, the last two pieces urge caution and underscore the

need to understand technical work in context and to avoid the temptation of simply adding a new evidence-based safe practice on top an existing system.

None of the coauthors suggest that their idealized visions will come easy. Many of the challenges exist at the ultra-macro level, including political willpower to overcome vested interests, Federal involvement, professional education in safety science, continued funding of evidence-based research, and realignment of misdirected incentives for decisionmakers, just to mention a few.

Finally, although the coauthors were asked to confine their visions to given areas of expertise to which they have contributed, none of the eight perspectives, in isolation from other salient factors, could be viewed as a panacea. Safety does not exist in any one component of the health care system. Instead, it emerges from multiple and intricate interdependencies among broad-based forces external to the care setting, the design of the physical spaces, the clinical work processes performed, the deployment of technology and devices, the types of training experienced by providers, our views of patients, and prevailing modes of thought.

Through a somewhat unconventional exercise, we have attempted to expand prevailing modes of thought for a safer care environment and provide some of the guideposts to a journey well worth the uncertainty and effort in taking. To be sure, vast stretches of the journey remain unmarked. The ultimate task will be up to readers—playing a significant role in shaping tomorrow’s health care—to provide the missing guideposts.

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What Exactly Is Patient Safety?

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Abstract

We articulate an intellectual history and a definition, description, and model of patient safety. We define patient safety as a discipline in the health care professions that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. We also define patient safety as an attribute of health care systems that minimizes the incidence and impact of adverse events and maximizes recovery from such events. Our description includes: why the field of patient safety exists (the high prevalence of avoidable adverse events); its nature; its essential focus of action (the microsystem); how patient safety works (e.g., high-reliability design, use of safety sciences, methods for causing change, including cultural change); and who its practitioners are (i.e., all health care workers, patients, and advocates). Our simple and overarching model identifies four domains of patient safety (recipients of care, providers, therapeutics, and methods) and the elements that fall within the domains. Eleven of these elements are described in this paper.

Introduction

A defining realization of the 1990s was that, despite all the known power of modern medicine to cure and ameliorate illness, hospitals were not safe places for healing. Instead, they were places fraught with risk of patient harm. One important response to this realization has been the growth of interest in patient safety. It is increasingly clear that patient safety has become a discipline, complete with an integrated body of knowledge and expertise, and that it has the potential to revolutionize health care, perhaps as radically as molecular biology once dramatically increased the therapeutic power in medicine.

Patient safety is now recognized in many countries, with global awareness fostered by the World Health Organization's World Alliance for Patient Safety. And yet there continue to be significant challenges to implementing patient safety policies and practices. One fundamental requirement for adopting any new approach is a clear articulation of its premises and manifestations. Components of patient safety have been expressed by thought leaders, and models have been presented. However, a single rendition that can help a thorough adoption of patient safety throughout health care has not been available. This paper aims to offer that. After introducing salient points in the intellectual history of patient safety, we offer a definition, a description, and finally, a model of patient safety. We call on organizations to adopt a definition and model for patient safety.

Intellectual History of Patient Safety

Critical assumptions in health care were rewritten by patient safety thinking. How to understand why people make errors that lead to adverse events shifted from a single cause, legalistic framework to a systems engineering design framework, and in so doing, it changed forever the way people think about health care delivery.

Limiting Blame

The first quantum leap defined patient safety's entry into health care thought. The realization that adverse events often occur because of system breakdowns, not simply because of individual ineptitude prompted the change. The traditional approach assumed that well-trained, conscientious practitioners do not make errors. Traditional thinking equated error with incompetence and regarded punishment as both appropriate and effective in motivating individuals to be more careful.

The use of this kind of blame had a toxic effect. Practitioners rarely revealed mistakes, and patients and supervisors were frequently kept in the dark. Low reporting made learning from errors nearly impossible, and legal counsel often supported and encouraged this approach in order to minimize the risk of malpractice litigation.¹ This mind-set lent a wary, antagonistic backdrop to the therapeutic interaction.² It also created a locked-in paralysis for all concerned when failure did occur.

Thinking began to change in the 1990s in response to several kinds of new information. First, medical injury was acknowledged as occurring far more often than heretofore realized, with most of these injuries deemed preventable. Second was the idea that “active” errors at the “sharp end”—where practitioners interact with patients or equipment—result from “latent” errors, as demonstrated by James Reason.³ Latent errors are upstream defects in the design of systems, organizations, management, training, and equipment (“blunt end”) that lead individuals at the sharp end to make mistakes. To punish individuals for such mistakes seemed to make little sense, since errors are bound to continue until underlying causes are remedied.

Systems Thinking

Thought leaders in health care offered persuasive arguments that errors could be reduced by redesigning systems and processes using human factors principles. These could reduce mistakes through design features, including standardization, simplification, and the use of constraints. One such constraint is a “forcing function,” which is a design characteristic that makes error impossible (e.g., incompatible connectors that prevent connecting an anesthetic gas to the oxygen port of an anesthesia machine).

Another corollary quantum leap to view health care as a system took place as people applied engineering design concepts to health care. Some of these systems changes were related to tools and technology, such as using better intravenous pumps or computerizing physician medication prescribing. Others were related to organizations and people, such as training doctors and nurses to work better in teams or including a pharmacist in the team during rounds. Some were more

successful than others, but the important change was that people were thinking of health care delivery in terms of systems.

Interestingly, in earlier phases of medical history, different forms of systems thinking were dominant. However, these forms focused on the biologic systems within the individual patient, rather than on care and interactions between individuals in the environment of care. The notion of humors and the understanding of the circulatory system are two examples from the period prior to the modern scientific era. As the scientific era dawned and the field of medicine began applying the scientific method with success, systems thinking within physiology continued. Perhaps this was helpful, as clinicians took on a systems understanding of the delivery of health care as well.

Initially, perhaps, blunt-end factors were typically thought of as organizational policies and processes that shaped the behavior of individuals at the sharp end-point of service. However, an awareness also emerged of extra-organizational blunt-end factors, including regulators, payers, insurance administrators, economic policymakers, and technology suppliers. These parties often influence and shape incentives and demands within the health care organization. Thus, health care had to be seen as an open, not closed, system, and policy too began to be thought of as a feature of the system.

Transparency and Learning

The idea that adverse events could yield information was not new, but as it was newly applied in health care, it acquired a new potency. The notion that sharing information about medical errors was essential for effective patient safety outcomes became urgent. Commentators asserted that the more error-related information was shared, the better lessons could be implemented industry-wide.⁴ The possibility that knowledge of systems might require an understanding of how things go wrong was demanding attention.

Culture and Professionalism

Clinicians, governing boards, executive leaders, and middle managers of health care delivery organizations were being increasingly encouraged to think in terms of building high-reliability organizations. This required a culture change to one that refrained from assigning “sharp-end” blame for mistakes; that incentivized learning by fully disclosing information about mistakes, failure, and near misses; that trained and provided support to clinicians involved in inherently risky work; and that disclosed all relevant facts to injured parties.^{5, 6}

These transformations in thinking resulted in approaches that were remarkably well-rooted in the essential ethical underpinnings of the profession. The call for safety went directly to the central medical professional imperative to “above all, do no harm.” The value at issue was nonmaleficence. As a matter of justice, human rights, or the fiduciary obligations intrinsic to the unequal power structure of the provider/patient relationship, the call for systemwide transparency coexisted with fundamental professional standards requiring honesty and disclosure of material facts to the patient.^{7, 8, 9}

Accountability for Delivering Effective, Safe Care

Early Western medical traditions were organized through guilds that kept the special knowledge and skills involved in medical practices a secret.¹⁰ At a time when many medical methods were of dubious foundation, rarely beneficial, and frequently harmful, the challenge of securing the trust of society was significant.¹¹ The primary method was to root out the charlatans. As modern concepts of negligence developed, emphasizing litigation to deter substandard behavior and individual accountability for procedures and actions causally linked to adverse outcomes became embedded in both medicine and law.

In an important parallel development, as treatments became increasingly effective, the medical field began to establish methods for accountability, and the profession's credibility in society rose. The scientific method was essential in that development, and with good reason, medicine has adhered to it. The three-phase approach to establishing the efficacy and safety of new medical therapies—Phase 1, clinical trials to assess safety; Phase 2, clinical trials to ascertain efficacy; and Phase 3, trials to compare it with another standard intervention—was essential, too. The dependence on the randomized clinical trial as the touchstone of the scientific method was critical to that process. The goal was to be sure that medicine was, and was seen as, a clinical research-driven, reliable practice. The effort was successful; society recognized that medicine merited its standing as a profession with specialized expertise to use powerful methods applied appropriately. Consequently, these scientific and clinical research methods and their associated ways of thinking became well entrenched.

The growth of medical sciences also changed standards in medical education, licensure, and peer review. The early apprenticeship model was supplemented by requirements for a phase in which didactically acquired knowledge was transmitted prior to the apprenticeship. As specialties developed, these sought to codify and legitimize their expertise through testing and certification. With the development of safer and more effective surgery, medical care delivery systems began focusing on hospitals; standards for these delivery systems were understood to be necessary. Certification of hospitals and other health care delivery systems followed, often with professional groups, such as the Accreditation Council for Graduate Medical Education (ACGME) and the Joint Commission, serving quasi-government oversight and public protection roles.

The nascent realization that health care, including the clinician and other components, also needed to be accountable for learning from error was harder to grapple with. Faltering moves were made toward tort reform and institutional accountability for safety practices. A model for accountability of clinicians that included accountability for continuous learning set the stage for, but stopped short of, a full rendition of what accountability for understanding and optimally designing safe health care systems required.

Health Care as an Industry

Beginning in the first half of the 20th century, the industrial era phased into the service industry era. Systems thinking was an established part of industrial engineering and applied in production lines and service industries. Yet medicine maintained a separation from these changes. This may have been possible mainly due to medicine's standing as a revered profession with a privileged

relationship to society, but in part, it also may have occurred because both providers and patients protected the one-to-one model of the doctor-patient relationship. Thus, the health care paradigm remained focused on the patient-physician relationship and on a therapy's point of application, rather than on the systems of application. The practitioner was trained and certified to apply therapy at the point of the illness-causing disorder. Even in the more expansive bio-psychosocial model, safety-oriented systems thinking was missing, even though the roles of the patient's immediate relationship circle and of the community and society were acknowledged.

Rising and apparently uncontrollable health care costs, coupled with increasing evidence of poor quality, ushered in the managed care era, along with demands from the public for accountability. Additionally, increased media exposure of preventable medical errors raised troubling questions that propelled a search for new solutions. Leape's earlier publication of the theoretical possibility of applying industrial human-factors engineering concepts to health care,¹² and the subsequent demonstration with Bates and colleagues⁶ of the utility of systems analysis in understanding medication error later that year, provided that new type of thinking. The first conference on patient safety and systems error at the Annenberg Center for Health Sciences in 1996 was a natural next step toward a new type of thinking.

Rethinking Risk

Thought leaders from medicine and policymakers began to carve a new way of understanding risk, new ways to reaffirm relationships with patients, and a new way of addressing the shocking realities that epidemiologic studies, such as Leape's 1994 landmark study, *Error in Medicine*, had presented.¹² A decade earlier, anesthesiology had made substantial improvements by applying systems thinking translated from methods used in aviation and mechanical engineering, but the rest of medicine had failed to generalize it. Quality improvement and risk management had both developed as disciplines within health care, with an emphasis on health services delivery research and measurement. These and other developments produced a readiness for looking at what might be learned and adapted from other high-risk industries and complex organizations.

Emphasizing Teamwork as Well as Dyadic Relationships

Early attempts at systems change revealed one Achilles heel of implementation: dysfunctional relationships between clinicians and other workers. Mirroring some of the developments in aviation—in which a focus on teamwork complemented attention to refinement of mechanical systems—health care began to recognize the importance of team functioning, particularly for communicating across authority gradients. Training in teamwork became a foundational building block for the new field of patient safety.

The discipline of patient safety rejected the concept of health care delivery as an exclusive dominion of the medical profession over the patient-physician relationship. The vision was more inclusive and demanding. It included patient-centered care and the biomedical model, and it focused on interdisciplinary teams and families. It also included the technical and administrative aspects of health care delivery in a complex system.

Defining Patient Safety

As the intellectual history of patient safety developed, it became increasingly important to define patient safety. Thought leaders began to examine their different assumptions. Is patient safety a way of doing things—i.e., a philosophy (with its own explanatory framework, ethical principles, and methods) and a discipline (with a body of expertise)? Or is it an attribute—i.e., a goal and a condition (being safe), a property that emerges from the system? Existing definitions seemed to vary on the question.

Although the Institute of Medicine (IOM) defined safety as “freedom from accidental injury,” patient safety as a discipline or field of inquiry and action has not been fully defined to date in the major consensus statements of the organizations that have propelled its existence. Part of the challenge lies in distinguishing safety from quality, a line that remains important to some, while being dismissed by others as an exercise in semantics. In 1998, the IOM convened the National Roundtable on Health Care Quality, which adopted the following definition of quality that was widely accepted: “Quality of care is the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”¹³

Health care quality problems were classified into three categories: underuse, overuse, and misuse, all of which the evidence shows are common. Misuse was further defined as the preventable complications of treatment. Although the IOM Roundtable was careful to distinguish misuse from error (the latter may or may not cause complications), the misuse category became a common reference point for conceptualizing patient safety as a component of quality.

In 2006, Leape and Berwick observed that, as attention to patient safety has deepened, the lines between the overuse, underuse, and misuse categories have blurred. “It seems logical,” they wrote, “that patients who fail to receive needed treatments, or who are subjected to the risks of unneeded care, are also placed at risk for injury every bit as objectionable as direct harm from a surgical mishap.”¹⁴

The National Patient Safety Foundation identified the key property of safety as emerging from the proper interaction of components of the health care system, thereby leading the way to a defined focus for patient safety, namely systems.¹⁵ Its goal has been defined as: “[t]he avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the process of care.”¹⁶

Our Definition of Patient Safety

We use the following definition of patient safety:

Patient safety is a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the incidence and impact of, and maximizes recovery from, adverse events.

This definition acknowledges that patient safety is both a way of doing things and an emergent discipline. It seeks to identify essential features of patient safety.

The Why, What, Where, How, and Who of Patient Safety

Going farther with the definition, each of its components is expanded here to offer a deeper description of patient safety:

Why does the field of patient safety exist? Patient safety as a discipline began in response to evidence that adverse medical events are widespread and preventable, and as noted above, that there is “too much harm.” The goal of the field of patient safety is to minimize adverse events and eliminate preventable harm in health care. Depending on one’s use of the term “harm,” it is possible to aspire to eliminate all harm in health care.

What is the nature of patient safety? Patient safety is a relatively new discipline within the health care professions. Graduate degree programs are currently being introduced in recognition of patient safety as a discipline. It is a subject within health care quality. However, its methods come largely from disciplines outside medicine, particularly from cognitive psychology, human factors engineering, and organizational management science. That, however, is also true of the biomedical sciences that propelled medicine forward to its current extraordinary capacity to cure illnesses. Their methods came from biology, chemistry, physics, and mathematics, among others. Applying safety sciences to health care requires inclusion of experts with new source disciplines, such as engineering, but without any divergence from the goals or inherent nature of the medical profession.

Patient safety is a property that emerges from systems design. Patient safety must be an attribute of the health care system. Patient safety seeks high reliability under conditions of risk. Illness presents the first condition of risk in health care. Patient safety applies to the second condition: the therapeutic intervention. Sometimes the therapeutic risk is audacious, such as when a patient’s heart is lifted, chilled, cut, and sewn during cardiac transplantation surgery. Risk and safety are flip sides of the therapeutic coin.

Patient safety demands design of systems to make risky interventions reliable. Two tenets of complexity theory apply: First, the greater the complexity of the system, the greater is the propensity for chaos. Second, in open, interacting systems, unpredictable events will happen. The better the therapeutic design, the more resilient it is in the face of both predictable and unpredictable possible or impending failures, so they can be prevented or rescue can be achieved.¹⁷ Safety systems include design of materials, procedures, environment, training, and the nature of the culture among people operating in the system.

Berwick and others have collaborated with Amalberti to apply Shewhart’s notion of statistical quality or error levels to health care.¹⁸ Systems are categorized by their level of adverse events. Barriers to progression from one level to another are identified. Interestingly, leaders of high-reliability organizations in other industries view the level of adverse events in medicine as so high that many of them would consider the health industry as existing in a state of chaos. The patient safety discipline seeks systems that can move health care to higher and higher levels of safe care.

Patient safety is a property that is designed for the nature of illness. High-reliability design is a concept that was not originally developed for health care. However, health care has some essential features in common with how high-reliability design has evolved. While often complex and unpredictable, it can have the ultimate high-stakes outcome: preservation of life.

A unique feature of patient care is its highly personal nature. Provision of care almost always requires health care workers to cross significant personal boundaries, both psychological and physical. To protect patient integrity, the health professions have developed codes of professional ethics that guide how best to provide health care without doing dishonor to the ill person. Patient safety designs must allow for these important restrictions, which include confidentiality, physical privacy, and others. At times, these needs conflict directly with the transparency and vigilance needed for optimal patient care, including safety.

Another unique feature is the natural progression of illness. By definition, when illness care begins, something has already gone wrong. Thus, in many medical situations, failure to provide the correct intervention causes harm to the patient. A missed diagnosis of meningococcal meningitis, for example, usually results in patient death. The patient safety discipline acknowledges the need to include harm due to omission of action, as well as the obvious harm due to actions taken.

The vast diversity of possible etiologies and manifestations of illness makes systems design in health care a unique challenge. Nonetheless, the reality is that most conditions are common and of common etiology, which allows for optimal design, if not infallible outcomes. If most patients with a condition such as breast cancer are best treated according to protocol but some require off-protocol, tailored treatment, systems can be designed to meet that need for the majority of protocols with tailoring options.

Patient safety is a property dependent on open learning. Patient safety has another inherent feature that derives directly from its dependence on errors and adverse events as a main source of understanding. It depends on a culture of openness to all relevant perspectives in which those involved in adverse events are treated as partners in learning. In this sense, patient safety espouses continuous cycles of learning, reporting of adverse events or near misses, dissemination of lessons learned, and the establishment of cultures that are trusted to not cast unfair blame. The patient safety field marries principles of adult education and effective behavioral learning with the traditional approaches of the medical profession. Known from its early days as the field that seeks to move “beyond blame” to a culture trusted by all to be just patient safety, patient safety pioneers have pushed for a much deeper understanding of the mechanisms of errors that often lie beyond the actions or control of the individual.

Patient safety advocates turn away from the traditions of the guild in which social standing and privileged knowledge shielded practitioners from accountability. They also reject the defensive posture of old risk management approaches in which physicians and leaders of health care organizations were advised to admit no responsibility and to defend all malpractice claims, whether or not they were justified. Patient safety embraces organizational and personal accountability, but it also recognizes the importance of moving beyond blame in both its

organizational and its personal dimensions, while maintaining accountability and integrity in interactions with patients and families who have suffered avoidable adverse events.

Trustworthiness is essential to the concept of patient safety. The health care system designed for patient safety is trustworthy. This is not because errors will not be made and adverse events will never happen, but because the health care system holds itself accountable to applying safety sciences optimally. Patient safety (as an attribute) prevents avoidable adverse events by paying attention (as a discipline) to systems and interactions, including human interactions, and allowing learning by all parties from near misses and actual adverse events. Through a concerted, conscientious effort, all those involved act to minimize the extent and impact of unavoidable adverse events by creating well-designed systems and well-motivated, informed, conscientious, and vigilant personnel, and by seeking to repair damage honestly and respectfully when it occurs.

Where does patient safety happen? The ultimate locus of patient safety is the microsystem. That is, the immediate environment in which care occurs—the operating room, the emergency department, and so on. It is in the microsystem where the “sharp end” resides, where patient-caregiver interactions occur, where failures of safety emerge, and where patients are harmed. Breaches in safety may have occurred in many blunt-end components, and as described above, events constitute properties of interacting components of the overall system. Therefore, patient safety is irreducibly a matter of systems. Nonetheless, as the setting where the patient receives health care, the microsystem is the locus where the successes or failures of all systems to ensure safety converge.

At the same time, patient safety must be concerned with the entire system. Importantly, patient safety recognizes that the microsystem is inherently unpredictable. Although it takes a mechanistic view of causation, patient safety acknowledges that each microsystem is open in that it can be influenced by another microsystem. This may result in something unpredictable. Thus, for instance, the microsystem of concern in surgical safety might be the operating suite, but if a local emergency demands that two members of the surgical team leave the operating room, the microsystem has been unpredictably affected.

How is patient safety achieved? A number of mechanisms are involved in achieving patient safety, including:

High-reliability design. The fundamental mechanism by which patient safety can be achieved is high-reliability design, which includes many components. Thus, the irreducible unit of patient safety delivery is multifaceted; all components of health care delivery must be integrated into a system that is as reliable as possible under complex conditions.

A unique feature of high-reliability design comes from complexity theory, which notes that open, interacting systems will produce some level of chaos or inherently unpredictable events. High-reliability designs are resilient even when unpredictable events occur.

Additional design features that guide health systems engineers include “lean process” and a notion of breaking through reliability boundaries in leaps from one safety level to another. These

levels of reliability are often known as sigma levels—through the use of simplified and better processes.

The concept of a multilayered system, in which the failures within each of the layers must be aligned for an error to occur, is known as the “Swiss cheese” model of accident causation.¹⁹ The components that make up the system include the institution and its organization, the professional team and the individuals it includes, and the technology in use.

Error traps (i.e., unpredictable situations in which error is highly likely) are another vivid concept on which safety sciences focus. The notion is that health care delivery is not only complex; it is also an open interacting system, in which illness is also a given, so the opportunities for making errors are many and endemic. Health care workers and health systems designers must therefore take this into account.

Safety systems design in health care is early in its development. Practical approaches to design for safety have been pioneered by the Institute for Healthcare Improvement (IHI), the Agency for Healthcare Research and Quality (AHRQ), and the World Health Organization’s (WHO) World Alliance for Patient Safety (see also “Applying the Patient Safety Model,” below), among others. For instance, patient safety designs can be thought of as falling into two types: those that are for types of routine care that vary little and can best be managed with protocols allowing for little deviation, and those that are for unique situations where on-the-spot innovation and significant deviation from protocol are required.

Safety sciences. The term “safety science” refers to the methods by which knowledge of safety is acquired and applied to create high-reliability designs. The objective is to design systems that approach “fail-safe” conditions—i.e., those that ensure proper execution. The ideal design is one in which the operator cannot perform the function improperly. Short of that ideal, much of the effort in the past has been directed toward developing defenses, which are barriers that prevent an unsafe act from resulting in harm. Over the years, health care has developed many of these barriers, and usually several must be breached for patient harm to occur.

Acquisition of objective knowledge is a matter of science. Patient safety uses methods that are appropriate to the purpose, and these can be drawn from a range of disciplines. Some, such as understanding human error, come from human physiology and psychology. Some, such as systems analysis and quality improvement, come from engineering and management. Others, such as organizational behavior, come from the social sciences. Still other methods come from health services research. The disciplines that contribute to safety use the methods that are appropriate to each field. These include controlled experiments, repeat tests, and other traditional scientific methods. Human factors engineering is built on, as appropriate, randomized controlled trials of human performance, anthropometry, anatomy, physiology, physics, and mathematics.

A strong claim can be made that although safety sciences are scientifically grounded, the fundamental drive toward and the cutting edge of inquiry in patient safety uses the narrative; i.e., the stories of adverse events yield insights and drive adjustments. Stories provide pattern recognition for patient safety practitioners. Stories of patient safety, like other stories, are

specific and yet have insights that can be applied to other settings. This feature is well suited to the need for dealing with events that might be either familiar or entirely unpredictable.²⁰

Importantly, however, one of the founding contributors to the safety sciences had a critical reason and unique standing to claim the term “science” for the safety sciences. Philosopher Karl Popper—famous for his work in defining the scientific method—working with MacIntyre, identified error (and by extension, one can include systems failures more generally) as analogous to data that refute a hypothesis in the scientific method.²¹ Sciences, such as chemistry or biology, use as their core method a cycle that comprises observation, hypothesis generation, testing, and hypothesis verification or alteration, depending on the results of testing. Deviation from this method causes the knowledge to be unreliable and the deviant methods to be discarded as unsound.

The patient safety discipline uses an analogous cycle—observation, design, testing, then use—as its method, and system adjustment is based on analyzing how adverse events came about. This, in turn, is based on Deming’s assertion that making a change is a key source of knowledge for systems.²² The rather close analogue of method warrants the use of the term “science” in the safety sciences.

To understand how human performance slips up, psychology, physiology, or social science must be used. To understand how a machine fails, engineering methods must be used. Each method must be used with its full insistence on rigor so that the new knowledge is as reliable and objective as possible. However, in contrast to the application of the scientific method in the physical sciences, for ethical and practical reasons, in patient care there rarely can be a control or a repeat of the same event to check for reproducibility, except in a simulated environment. Nonetheless, when the analytic method has yielded to the best of its capacity a new insight, then this—like the new data in the process of science—generates a new cycle of adjusted design, testing, and use. In short, the analytic method must be unique to the adverse event, but then the safety sciences use the insight generated to create a new cycle of improved understanding and system design.

In short, patient safety applies many methods and techniques. However, two analytic methods have become widely associated with the field. One is retrospective. The analysis of what went wrong when an adverse event has occurred is known as “root cause analysis” (RCA). Perhaps the close identification (probably excessively so) of patient safety with RCA is a result of heightened attention that occurs after a bad event. RCA is an approach to finding out what underlying features of a situation contributed to an adverse event. Adopting the idea that the immediate cause of an event is almost always the end result of multiple systems failures, RCA seeks, by review of data and interviews, to identify and understand all contributing causes in order to redesign the systems to make them safer in the future.

The other characteristic method of patient safety is prospective. Attempting to anticipate and prevent adverse events through safety design is known as “failure modes and effects analysis” (FMEA). FMEA is an engineering approach, usually taken early in the development of a product, that seeks to imaginatively identify potential failures and their effects. Knowledge from past failures might contribute to a designer’s ability to foresee potential failures in their design.

Designs are then adjusted to make failure less likely. FMEA is used in analyzing every aspect of a system's design, including the system's global functioning, its components and their interactions, the functioning of equipment, the programming of equipment, and the procedures for activities.

Nevertheless, no one method is enough to produce the range of knowledge and types of understanding required for patient safety. In contrast to the clinical sciences in which the randomized controlled trial is the research method of choice, patient safety eschews the notion that the field can have confidence in a single "gold standard." In patient safety, contributions are sought from engineering, social sciences, psychology, psychometrics, health services research, epidemiology, statistics, philosophy (theories of justice, accountability), ethics, education, computer sciences, and more. Each discipline uses its own particular methods; patient safety takes each on its own merits and selects the method most suited to the topic or question at hand.

Measurement remains an important area for development in patient safety. Many needed measures have not yet been developed. The IHI talks of three types of measurement: process, outcome, and balance.²³ Process measures may need to be developed and validated for a complete bundle of carefully selected procedures for a given clinical setting. Outcome measures might need to be developed for the particular outcome in question, but they might also need to be used in a fashion that has been developed to allow for balance—i.e., to look at the impact of intervention in one place in the system on other places in the system.

Methods for causing change. With its emphasis on making changes in health care workers' actions, patient safety seeks to engage methods to bring about improvements that go beyond transmission of knowledge and acquisition of skills to the effective implementation of appropriate skills. In this regard, patient safety builds on the insights and techniques of quality improvement. By its nature, separation between acquisition of new knowledge and service delivery is minimal.

Rapid cycles of feedback and response methods for institutional improvement were pioneered in health care by Berwick and others.²⁴ These processes are derived from continuous quality improvement methods originally designed by Deming²² and others. The methods focus on the systems of health care delivery more than on the medical issues and the knowledge that the rapid cycles produced are of the specific local system. The methods are designed to improve services in areas where a gap between acknowledged standards and actual practices exists. Usually, a guideline or protocol that has already been endorsed by an expert medical body or bundle of established practices is to be applied. The rapid cycles tend to keep the guideline or protocol or bundle the same, altering its application only to optimize its full use in the local system. Once the implementation is done, quality indicators are monitored to maintain the new standards.

Patient and family voice is important throughout. Adverse events are subjected to analysis, which feeds into redesign or adjusted design of the systems of care. More traditional health services research and other methods of acquiring understanding are also fed into the recomposition of the systems.

Dissemination of change is not a characteristic of the approach that uses rapid cycles or of quality improvement more generally. This is in great part because the methods are designed to be tailored to the local system; therefore, they do not readily generalize, and measures of success might vary for the same reason. However, approaches that standardize measures and quality improvement methods are being used, which will allow for better dissemination.²⁵ Alternatively, more traditional campaigns to get individual health care sites to each do their own improvement work can be used, as has been done by the IHI.

Who is a patient safety practitioner? Most health-related disciplines are characterized by specialists who devote themselves to the full-time practice of the discipline. Similarly, patient safety is emerging as a specialty in which education at the masters' level is offered and to which patient safety offices and patient safety officers devote their full-time effort.

However, patient safety requires that all members of the health care service delivery team be "patient-safety minded." It also depends on both hands-on patient safety practices and leadership within every discipline in health care. As a quintessentially collaborative activity, patient safety needs leaders in each area of clinical administration and in each clinical discipline—including doctors, nurses, pharmacists, and others—in addition to information management, equipment and plant management, and other areas. Patient safety practitioners truly include everyone in health care.

For those who have an advanced degree in patient safety or a role determined by patient safety, it could be a primary professional identity. For most, it will be a personal and professional commitment—a part of their identity, but not their primary identity, which will remain cardiology or plant management, etc. Nonetheless, since all in health care should acquire the characteristics needed for practicing safety, it is important to know what characteristics a patient safety practitioner (whether by primary or secondary identity) should have.

What skills or unique characteristics should a patient safety practitioner possess? A professional who provides direct care needs to have a kind of wariness or patient safety vigilance. This quality is most often informed by a rich knowledge about adverse events and how to help avert them or minimize their damage. This kind of practical wisdom or "safety savvy" grows continuously from experience and an ability to recognize when something is not right. Often an adverse event that is about to unfold can be averted or its impact minimized if it is caught in action.

Patient safety practitioners are well storied. The role of narrative in patient safety has been emphasized, both as a vehicle for acquiring safety-relevant knowledge and as a vehicle for becoming, what Weick has called, mindful or safety wary.²⁶ They understand that health care systems are full of "error traps," and they are vigilant in foreseeing and preempting, mitigating, and rescuing patients from them. Reason envisions a future for patient safety in which its practitioners share many true stories of adverse events in their training and educational venues.²⁰ He sees this as the normative method for making members of the health care community "safety wise." For example, studies of pediatric cardiac surgeons found that those surgeons—who were inclined to detect their errors and fix them, even at the price of having a longer and less elegant operation—had the best outcomes and reputations.

Patient safety practitioners must also become excellent team members, whether they are natural leaders or better in other roles. They must be able to substitute for one another and appreciate the other's perspective. Importantly, since vigilance is essential for patient safety and is also tiring, working in teams during shift work is essential.²⁷

A Patient Safety Model of Health Care

With the above aspects of patient safety lined up, it is possible to see a simple model of patient safety. While good models of patient safety have been constructed, we seek an overarching model that is simple, fully authentic to the subject matter, and compatible with the good existing models. At the same time, it should be simple enough that it can be seen in a readily sketched diagram and stated in a simple, short sentence that can be easily recalled. Only such a simple model can ubiquitously permeate the interstices of daily thought among all the necessary people throughout health care.

We offer the following simple model with which to view patient safety. It divides health care systems into four main domains:

- Those who work in health care.
- Those who receive health care or have a stake in its availability.
- The infrastructure of systems for therapeutic interventions (health care delivery processes).
- The methods for feedback and continuous improvement.

These four domains are represented graphically in Figure 1. Each domain interacts with the other domains and with the environment, as depicted by the semipermeable divisions (dotted lines) between them and at their outer edges. The result is a core, overarching model for patient safety.

The model is consistent with the descriptors of patient safety stated above: *What...?* and *Where...?* correspond to the third domain, i.e., “Systems for therapeutic action.” *How...?* corresponds to the fourth, “the Methods”; *Who...?* corresponds to the first and second, i.e., “people who work in health care” and “people who receive it or have a stake in its availability.”

The model is also consistent with existing frameworks of thinking that underpin patient safety. Each framework defines categories or elements that fall coherently within one or more of the four domains, as displayed in Table 1.

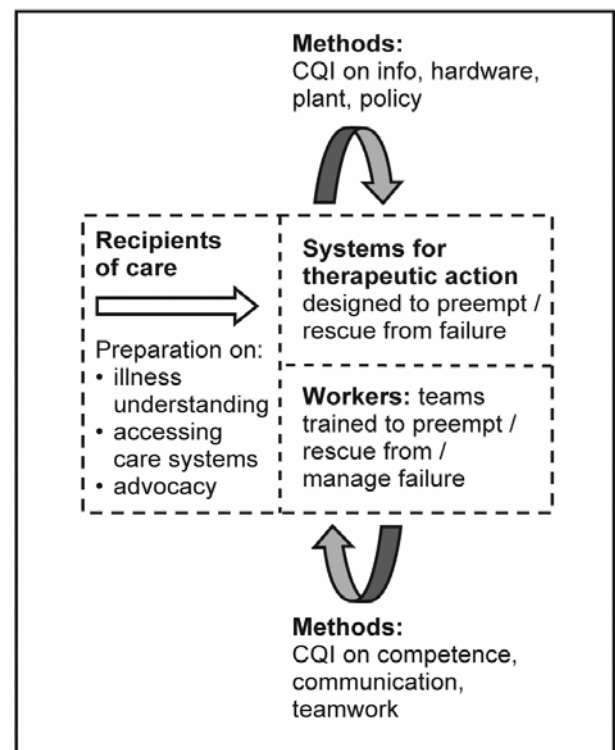


Figure 1. A patient safety model of health care.

Table 1. How domains and elements relate in the patient safety model

Domain	Systems for therapeutic action	People who work in the health care system	People who receive health care or have a stake in its availability	Methods
Content areas	• Structure • Process • Outcome			
	• Organization & management • Work environment • Task factors • External environment	• Team factors • Individual factors	• Patient characteristics	• System knowledge • Understanding of variation • Understanding of how change yields knowledge • Psychology

Deming's²² notion of “deep knowledge” of quality design required an understanding of (1) the system; (2) variation in its performance; (3) how to use change as a source of knowledge; and (4) the psychology of people in the organization. All of these elements drive quality improvement, and they belong within the domain of “methods.”

Donabedian divided health care into structure, process, and outcomes for the purpose of measurement.²⁸ It is also a helpful way of categorizing the health system for the purposes of understanding how elements of the system interact. For this reason, the categories can be thought of as cutting across all four domains in the patient safety model.

Vincent¹⁶ identified seven elements that influence safety:

1. Organization and management factors.
2. Work environment factors.
3. Team factors.
4. Task factors.
5. Individual factors.
6. Patient characteristics.
7. External environment factors.

These factors distribute among the three domains: systems for therapeutic action, the people who work in health care, and the people who receive it or have a stake in its availability.

Carayon and colleagues proposed a Systems Engineering Initiative for Patient Safety (SEIPS) model for design in health care.²⁹ In the SEIPS model, elements are helpfully depicted with intersecting arrows that illustrate how the elements can interact with one another, so indicating the notion of emergent properties.

The above 11 elements do not represent an exhaustive list. In addition, elements can be subdivided into their content areas, which is not attempted here. For instance, external environment has been divided into physical, social, and biologic areas.³⁰ The elements can also be categorized in different ways. For example, team factors could be included within work environment. The purpose of this simple, broad model of domains is to capture the largest category of essential components in patient safety and their interaction with one another.

The fashion in which this or any patient safety model applies must vary by setting as dramatically as the settings vary. The nature of the illnesses and social setting, the nature of the therapies, the nature of the human resources, and the nature of the physical infrastructure all will contribute to defining the very different systems. These systems must be analyzed and options identified for improvement. However, the fundamental concepts in any good patient safety model are applicable to most settings.

What is the utility of this model and of the other models with which ours is built to be compatible? Our model and other models provide a way of seeing the component elements involved in patient safety and how they interact. So, when designing a system, improving a system, analyzing an adverse event, researching an issue, or measuring a new intervention, such models provide a ready map of matters that should be considered. Given the human tendency to limit the scope of focus, models provide a countervailing stimulus to include the whole universe of domains and their elements that could be involved in the patient safety issue at hand.

Conclusion

The field of patient safety has emerged in response to a high prevalence of avoidable adverse events. However, many do not use a clear definition or have a clear model of understanding of the field. We call on organizations to adopt a definition and model for patient safety. To assist the process, we provide a definition and describe the nature of the field by going through each component in the definition. We identify its primary focus of action as the microsystem and its essential mechanisms as high-reliability design and the use of safety sciences and other methods for causing improvement, including cultural change. We describe key attributes of those who practice safety, and we identify its practitioners as all involved in health care. To provide an easy-to-recall, overarching model of patient safety, we offer one that identifies four main domains of patient safety (1) people who receive health care, (2) people who provide it, (3) systems of therapeutic action, and (4) methods and elements within each domain. We hope that this description, definition, and model will assist the integration of patient safety practices throughout health care.

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References

1. Ferlie EB, Shortell SM. Improving the quality of health care in the United Kingdom and the United States: A framework for change. *Milbank Q* 2001; 79: 281-313.
2. Schoenbaum SC, Bovbjerg RR. Malpractice reform must include steps to prevent medical injury. *Ann Intern Med* 2004; 140: 51-53.
3. Reason J. *Human error*. Boston: Cambridge University Press; 1990.
4. Sexton JB, Thomas EJ, Helmreich RL. Error, stress, and teamwork in medicine and aviation: Cross-sectional surveys. *Br Med J* 2000; 320: 754-759.
5. McElhinney J, Heffernan O. Using clinical risk management as a means of enhancing patient safety: The Irish experience. *Int J Health Care Qual Assur Inc Leadersh Health Serv* 2003; 16: 90-98.
6. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. *JAMA* 1995; 274: 35-43.
7. Levinson W, Roter D, Mullooly JP, et al. Physician-patient communication: The relationship with malpractice claims among primary care physicians and surgeons. *JAMA* 1997; 277: 553-559.
8. Gallagher TH, Waterman AD, Ebers AG, et al. Patients' and physicians' attitudes regarding the disclosure of medical errors. *JAMA* 2003; 289: 1001-1007.
9. Beachamp T, Childress J. *Principles of medical ethics*. 4th ed. New York: Oxford University Press; 1994.
10. Starr P. *The social transformation of American medicine*. New York: Basic Books; 1982.
11. Baker RB, Caplan AL, Emanuel LL, eds. *The American medical ethics revolution: How the AMA's code of ethics has transformed physicians' relationships to patients, professionals, and society*. Baltimore: Johns Hopkins University Press; 1999.
12. Leape LL. Error in medicine. *JAMA* 1994; 272: 1851-1857.
13. Chassin MR, Galvin RW. The urgent need to improve health care quality. Institute of Medicine National Roundtable on Health Care Quality. *JAMA* 1998; 280: 1000-1005.
14. Leape LL, Berwick DM. Five years after "To Err Is Human." What have we learned? *JAMA* 2005; 293: 2384-2390.
15. Cooper JB, Gaba DM, Liang B, et al. The National Patient Safety Foundation agenda for research and development in patient safety. *Med Gen Med* 2000; 2: E38.
16. Vincent C. *Patient safety*. London: Elsevier; 2006.
17. Hollnagel E, Woods D, Leveson N. *Resilience engineering: Concepts and precepts*. Burlington, VT: Ashgate Publishing; 2006.
18. Amalberti R, Auroy Y, Berwick D, et al. Five system barriers to achieving ultrasafe health care. *Ann Intern Med* 2005; 142: 756-764.

19. Reason J. Managing the risks of organizational accidents. Burlington, VT: Ashgate Publishing Company; 2000.
20. Reason J. Foreword. In: Runciman B, Merry A, Walton M, eds. Safety and ethics in healthcare: A guide to getting it right. Aldershot, UK: Ashgate; 2007: p. xi-xiii.
21. McIntyre N, Popper K. The critical attitude in medicine: The need for a new ethics. *Br Med J* 1983; 287: 1919-1923.
22. Deming WE. Out of the crisis. Cambridge, MA: MIT Center for Advanced Engineering Study; 1986.
23. Institute for Healthcare Improvement. Measures. Available at: <http://www.ihf.org/IHI/Topics/OfficePractices/Access/Measures>. Accessed July 2, 2008.
24. Millenson ML. Demanding medical excellence: Doctors and accountability in the information age. Chicago: Chicago University Press; 1997. p. 233-267.
25. Emanuel L. Crossing the classroom-clinical practice divide in palliative care by using quality improvement methods. Commentary. *BMJ clinical evidence handbook*. Spring 2008. Available at: http://clinicalevidence.bmj.com/ceweb/about/onlineaccess_uhf.jsp. Subscription required. Accessed July 2, 2008.
26. Coutu DL. Sense and reliability: A conversation with celebrated psychologist Karl E. Weick. *Harvard Bus Rev* 2003;81: 84-90.
27. Samkoff JS, Jacques CH. A review of studies concerning effects of sleep deprivation and fatigue on residents' performance. *Acad Med* 1991; 66: 687-693.
28. Donabedian A. The quality of care. How can it be assessed? *JAMA* 1988; 260: 1743-1748.
29. Carayon P, Hundt AS, Karsh B, et al. Work system design for patient safety: The SEIPS model. *Qual Safe Health Care* 2006; 15(Suppl 1): i50-i58.
30. Brasel KJ, Layde PM, Hargarten S. Evaluation of error in medicine: Application of a public health model. *Acad Emerg Med* 2000; 7: 1298-1302.

Reporting Systems

Improving the Value of Patient Safety Reporting Systems

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Abstract

Use of patient safety reporting systems (PSRS) to identify and mitigate risks to patients who are harmed by medical care has been a national priority for nearly a decade. Yet, most reporting systems are still new and focus on reporting events. To improve the value of PSRS, we must use the data to identify safety hazards, prioritize where to focus resources, develop interventions to mitigate these hazards, and evaluate whether the interventions reduced harm. We developed and implemented a Web-based PSRS and discuss in this paper the benefits, limitations, and challenges we encountered. First, we discuss the benefits of PSRS as part of a patient safety learning community. The remainder of the paper focuses on the challenges we faced that still need to be resolved to improve the value of reporting systems. We address these challenges as follows: what to report, how to minimize reporting burden and costs, how to conduct expert reviews and prioritize safety efforts, how to place incidents into taxonomies, how to know that the reporting system actually improved patient safety, and who should be responsible for attempting risk mitigation.

Introduction

The Institute of Medicine (IOM) recommended using patient safety reporting systems (PSRS) to evaluate why patients are harmed by medical care.^{1, 2, 3} In response, 22 States have legislation requiring reporting systems, The Joint Commission requires that hospitals report mistakes (www.jointcommission.org), and a law including incident reporting was enacted in 2005.⁴ Under the auspices of the Agency for Healthcare Research and Quality (AHRQ), the United States will launch a national error reporting system.

Despite diligent efforts, most reporting systems are relatively new and focus on collecting events. In addition, stakeholders disagree about the goal of reporting. Should the goal be to improve patient safety or to ensure individual and institutional accountability?^{5, 6} Little attention has centered on analyzing reports and assessing how to use the data to improve patient safety.^{7, 8, 9} Thus, health care organizations struggle to prioritize improvement efforts and evaluate whether patient safety has improved.

Our efforts to develop and implement a Web-based patient safety reporting system, called the Intensive Care Unit Safety Reporting System (ICUSRS), revealed various potential benefits and challenges.^{10, 11, 12, 13} The purpose of this paper is to discuss the strengths, limitations, current challenges, and future directions in using patient safety reporting systems to improve safety.

Potential Benefits of Patient Safety Reporting Systems

Web-based patient safety reporting systems (PSRS), such as the ICUSRS, provide a means to efficiently identify and, hopefully, mitigate hazards.¹⁴ Many participating sites in the ICUSRS project stated how this reporting mechanism helped them improve patient safety. For example, one hospital identified insufficient staff knowledge as the main cause of events related to the use of intracranial pressure monitoring devices. This recognition led to an improved staff training program. Nevertheless, most of the evidence regarding the benefits of PSRS is anecdotal. While health care has traditionally relied on quantitative methods to understand the epidemiology of diseases and other health-related issues, anecdotal stories provide the context in which an incident occurred.^{5, 15} The information pulled from these stories can help shape future interventions to mitigate harm.

A well-functioning PSRS should collect events (incidents) that could or did lead to patient harm. While there is wide variation relative to how harm is classified,^{16, 17} we believe harm can be biological, physiological, or psychological in nature. An event that causes harm is typically called an adverse event (e.g., retained surgical instrument); an event without ensuing harm is called either a near miss or a close call (e.g., wrong medication identified before administration). Ideally, a patient safety learning community would use PSRS data to identify safety hazards, prioritize where to focus their resources, develop interventions to mitigate these hazards, and evaluate whether the interventions reduced harm.

In this community, learning should occur on multiple levels. A local patient care area can reduce risks that are unique to it; a hospital can reduce risks that span multiple units; and the broader health care community can learn from risks that span multiple health care organizations. Recently, AHRQ solicited proposals for a Patient Safety Organization (PSO) Network and national patient safety database (NPSD), which could provide the structure for this learning community.

Nevertheless, current approaches to mitigating risks are probably neither efficient nor effective. Local hospitals develop interventions to mitigate risks that have a low probability of achieving success. For example, errors involving devices are common, and the local intervention is generally staff re-education. The collective costs of re-education across the United States would be substantial. A more effective and efficient approach would be to redesign the devices. Yet, individual hospitals and health care systems cannot do this alone. A collaborative effort is needed.

Limitations of PSRS

In a previous commentary, we discussed the dilemma of using PSRS as a means to evaluate progress in patient safety.⁹ Selection bias and other uncertainties preclude the feasibility of interpreting PSRS data as rates or trends in rates. To calculate a valid rate, you need a reasonably accurate numerator (event) and denominator (population at risk of the event). However,

definitions of events vary widely, and determining a population at risk for most events is opaque at best. Also, many in health care debate the issue of preventable harm vs. inevitable complications. In addition, PSRS suffer an unknown degree of underreporting, given that reporting is voluntary and spontaneous, and a systematic surveillance system is not feasible. Yet many, particularly those using reporting systems for accountability, wrongly interpret PSRS data as valid rates of errors or as a valid measure of patient safety. The inferences from these interpretations will project an inaccurate or incomplete picture of patient safety.

Because reporting bias varies over time, amongst hospitals and clinical areas, by event type, and by perceived harm, the noise (measurement error) generated inevitably drowns out any signal. Due to these biases, reports from PSRS should be interpreted as a nonrandom sample of identified hazards from a larger unknown universe of hazards that can focus our efforts on improving patient safety. In essence, incidents should be used as golden nuggets of data to address and fix a specific hazard in a clinical area or hospital. PSRS data cannot be used to measure rates or monitor progress in improving patient safety.

Challenges Facing PSRS

The focal point of most reporting systems is submission of events. Consequently, many health care organizations suffer from data overload. For example, The Johns Hopkins Hospital implemented a PSRS and received about 11,000 reports in year 1 and about 14,000 in year 2.^a Much of our comprehension from PSRS thus far has come from individual case review, not aggregate data analysis. This is because individual cases are readily understood, and learning methods are better established.¹⁸ Yet, our ability to use aggregate data to prioritize improvement efforts across the institution and to evaluate whether these efforts improved patient safety are limited.

We must decide how to use data from reporting systems to prioritize and mitigate hazards. Below we discuss several fundamental, yet unanswered, questions that must be addressed to enhance the efficiency and effectiveness of PSRS to help improve safety.¹⁹

What to report? What should be reported is an important and fundamental question. Our decisions likely drive the amount and level of detail reported about an incident, the time required to report, and ultimately the usefulness of the data. In the ICUSRS project, there was variability in the volume and content of incidents submitted from the 18 intensive care units participating in the first year.¹⁰ Text descriptions ranged from meticulous in detail to telegraphic facts. In addition, discrepancies were sometimes found between text descriptions and structured data for the same incident. For example, the text description from one event reported that the patient died, but “no harm” was checked in the harm classification section. This was one of many cases found when the ICUSRS team reviewed incidents to evaluate underreporting of harm and contributing factors. In fact, over 30 percent of cases had additional contributing factors evident in the free text that were not checked in the structured response categories.

^a Personal communication, Lori Paine, RN, MS, June 12, 2008.

Previous studies have shown that visibility of the event and/or its outcome, the reporter's comprehension of the definitions of harm and contributing factors, a culture that is cognizant of safety, and discernible followup actions all influenced reporting activities.^{2, 20, 21, 22} A clearer definition of reportable events is needed. For example, double-checking insulin doses is a standard process of care. If the second nurse finds an error, is this a reportable event? While safety culture influences a clinician's willingness to report events, there is still uncertainty about the relative value of text vs. structured data and of reporting any event vs. specified events.

A second but related question is, What type of events should be reported? In addition, given that health care organizations generally take action only on harmful events, the relative value of reporting a large number of near misses should be explored. While it is generally agreed that no-harm events contain identifiable hazards, reporting these incidents increases the burden on reporters and subsequent investigators. As the IOM noted, the value of "near miss" reporting needs to be demonstrated in health care.³ We must identify which events will facilitate improvements in patient safety. For example, if harm is a condition for action, the value of near miss reporting is questionable. Given the limited resources for patient safety, few near misses are investigated and even fewer are used to institute improvement efforts.

How can reporting burden and costs be minimized? Incident reporting incurs costs for those reporting, analyzing incidents, resolving hazards, and evaluating the impact of hazard reduction efforts. As reporting systems proliferate nationwide, so will the costs of incident reporting. Most hospitals (87 percent) participating in the ICUSRS used multiple reporting systems, and integrating these systems did pose challenges.¹³ However, the ICUs submitting the highest volume of reports used the ICUSRS as their primary mechanism for reporting incidents to their unit manager and/or risk manager. To avoid duplicate efforts and wasted resources within and among hospitals, organizations should consider coordinating reporting systems. The AHRQ-sponsored PSO Network to establish a national patient safety database (NPSD) is a good example of coordinating efforts. This PSO Network will develop a national database to collect and analyze events and then report information and provide resources that can be used to improve patient safety. Ideally, hospitals should have a single reporting system that would route events to multiple stakeholders.

How to conduct expert reviews and prioritize safety efforts? Conducting expert reviews presents multiple challenges. Expert reviews are costly, and gaining consensus regarding preventability of an incident is a challenge.²³ In addition, experts must be able to comprehend the nascent field of patient safety in the context of their clinical disciplines. They must also commit sufficient time to review each incident, understand what happened and why, and formulate a plan to prevent a recurrence. Reporting systems that collect all types of incidents will face challenges in recruiting multiple experts to review all incident types. In addition, while PSRS may contain information about events and contributing factors, acquiring more detailed information about events requires a more thorough investigation, such as a root cause analysis (RCA). Events submitted to a reporting system often trigger or initiate an RCA. Thus, linking a reporting system to professional societies or a national agency might increase its strength and probability of success. As patient safety develops and uses a standardized taxonomy to code incidents, the ability to use and interpret data in PSRS will increase.

Because of the accumulation of a large number of events, health care tends to investigate many events superficially and few thoroughly. As the volume of reports increases, health care organizations must learn to analyze aggregate data and also develop strategies to prioritize improvement efforts.²² Strategies to prioritize patient safety efforts using aggregate data are underdeveloped. Severity scoring (i.e., severity of patient injury and frequency of occurrence) is one approach to prioritizing efforts.²² However, we do not know how reporting bias influences what event types are reported, how harm varies among event types, and whether severity scoring to prioritize interventions will result in fewer harmful events. Also, scant data exist regarding the most useful format to report findings to caregivers and risk managers.

One promising approach to prioritize risks identified by PSRS data is the Harm Susceptibility Ratio (HSR), which is informed by the Risk Resiliency Ratio developed by Carl Macrae.²⁴ The HSR is intended to prioritize events that have a low probability of being “trapped” or defended. That is, the odds that an event will result in harm. Mathematically, it models the odds of harm in a specific work area or event type, divided by the odds of harm averaged among all work areas or event types. The HSR can be interpreted as an odds ratio with vulnerability indicated by any number >1. In addition, we can look at the distribution or dispersion of events among organizations. If events are distributed among many organizations, the solution might be more effective and efficient to occur at a regional, State, or county level, depending on the clustering of events. More research is needed to help develop methods to prioritize data in reporting systems and to determine the appropriate level for interventions.

How to place incidents into taxonomies? Understanding incidents in the aggregate requires a classification of those incidents. However, what is comprised by a meaningful taxonomy for medical incidents is debatable.²⁵ In addition, many taxonomies have been developed independent of each other and range from broad to specific. The Applied Strategies for Improving Patient Safety (ASIPS) Victoroff taxonomy, for example, targets the primary care setting,²⁶ while the ICUSRS was developed for critical care.

In the United Kingdom, the National Reporting and Learning System (NRLS) collects and categorizes events in both inpatient and outpatient settings. Though it is far from perfect, the NRLS is perhaps the most mature, country-level PSRS in existence. This national effort has one reporting system and taxonomic classification that could be emulated in the United States. However, the NRLS is currently faced with an unwieldy volume of reports and an unclear mechanism for prioritizing events, designing interventions, and evaluating their impact. The United States could learn much from the successes and shortcomings of the NRLS. In particular, they could make better use of professional societies in analyzing events and designing interventions.

Nevertheless, three types of taxonomies have been applied to incident reporting: conditional risk, classifying event types and contributing factors, and process maps.³ All three taxonomies have challenges. Few health care researchers have judged the conditional risk of incidents because it has low inter-rater reliability and introduces bias.²⁷ Moreover, the type of events and contributing factors coded can significantly influence the results obtained. For example, most taxonomies include mistakes (e.g., prescribing errors) and the outcome of mistakes (e.g., patient falls, decubitus ulcers) as event types. However, falls and decubitus ulcers are visible harms (outcomes) that might have resulted from failure to monitor patients or an inaccessible bedpan

(process) that occurred earlier in the delivery of care. When examining the proportion of incidents in the ICUSRS with harm identified, it is not surprising that falls and decubitus ulcers were among the highest.

Lack of clear process maps is one reason why some event types are classified by the outcome, not the underlying process or mistake. For example, the process map for medication errors is clear and understood—prescribing, documenting, dispensing, administering, and monitoring. When a patient receives the wrong medication, the steps upstream from the drug administration are visible to staff.¹⁹ Without lenses to see process maps and the factors (e.g., teamwork, supervision) that contribute to mistakes at each step in the process, caregiver reports would likely be incomplete and biased. A generic process map could include three steps: diagnose, treat, and monitor. Within each step would be three parts: the decision to do something, the process of doing it, and interpreting the results. Clear process maps would help prioritize patient safety improvement efforts.

How do we know that the reporting system actually improved patient safety? As mentioned previously, health care has struggled to answer whether patients are safer.⁸ The number of events reported to patient safety reporting systems will not provide the answer.²⁸ One measure of safety could be whether we learned from the mistake, intervened, and reduced the probability that another patient would be harmed from a similar event. A tool was developed to investigate individual incidents and then plan and carryout a strategy to prevent the mistake from recurring.²⁹ This tool is being used at The Johns Hopkins Hospital in clinical areas and as part of morbidity and mortality conferences.

To better understand the impact of interventions, we can classify them from strongest (most likely to reduce future harm) to weakest (least likely to reduce harm). Strong interventions include strategies to eliminate or prevent a mistake. For example, the field of anesthesiology redesigned their equipment to prevent the connection of oxygen tubing to nitrous oxide canisters. Unfortunately, such strong interventions are rare in health care. A mediocre intervention would make a mistake visible. For example, clinicians could place an ‘epidural only’ sticker on epidural tubing to prevent inadvertent connection to an intravenous catheter. A weaker intervention would mitigate harm. For example, The Joint Commission recommended removing “concentrated” potassium from care areas.³⁰ While we can still overdose a patient with potassium, the risk for harm is reduced. The weakest but most common intervention would be to create a policy or procedure or to educate staff. Although multiple interventions are often used, a strong intervention is clearly the most desirable.

Evaluating the effectiveness of an intervention is inversely related to the intervention’s strength; strong interventions need limited evaluation, while weak interventions need rigorous evaluation. In general, there are three methods to evaluate whether the risk for harm is reduced. We can measure the presence of a policy or program (the most common method), the staff’s knowledge of the policy or program, or the appropriate use of the policy or program.⁸ If the policy or program involves communication among caregivers, the most valid method to measure the intervention’s effectiveness is to observe team behavior. For example, if a preprocedure briefing is recommended to improve teamwork, it would be more reliable to observe the effectiveness of the discussion than to review a chart documenting the briefing. Additional research is needed to

learn how to effectively and efficiently evaluate whether interventions generated by PSRS data have reduced a patient's risk for harm.

Who should be responsible for attempting risk mitigation? What level(s) of the health care industry should be responsible for addressing a safety issue? For example, should the local nursing unit, the department, the hospital, the health care system, or a medical manufacturer be responsible for mitigating hazards? The most effective interventions eliminate or prevent the mistake; the least effective interventions encourage vigilance, educate staff, or institute a policy. The highest level possible should attempt to mitigate the risk. For example, if an equipment design flaw caused an event, it is more efficient and effective to have the manufacturer fix the flaw than to try to educate staff at every hospital about the design flaw.

Health care lacks a process for determining what level or levels should attempt mitigation of hazards. Nevertheless, some degree of centralization would be cost effective. For example, mistakes involving central line placement are common, costly, and distributed among multiple specialties.^{31, 32} While individual departments within health care organizations may lack the resources to develop training programs for proper placement of central catheters, a centralized program with input from clinical and educational experts would be effective and efficient. Many types of mistakes commonly occur across institutions that would benefit from a central method for addressing common hazards. In light of these issues, a national organization capable of exercising national policy and working with manufacturers to implement broad-based interventions might be more effective and efficient than current approaches in which individual hospitals design their own solutions and which have a low probability of reducing risks to future patients.

Health care could create an organization similar to the aviation industry's Commercial Aviation Safety Team (CAST).³³ CAST is a public-private partnership made up of three core teams: a joint safety analysis team, a joint safety implementation team, and a joint implementation measurement data analysis team. Operators, manufacturers, labor organizations, and the government appoint members to support these teams. The strength of CAST lies in its extensive membership, its proactive commitment to safety, and its ability to design and broadly implement strong system changes. They have been credited with reducing fatal airline crashes by 65 percent over the past 10 years.

Future Directions

Until these challenges can be addressed, regulators and accreditors could standardize methods of evaluating whether specific types of events recur. For example, hospitals could determine whether they have a behavior-specific policy for preventing wrong site surgery, assess staff knowledge about this policy, and use an audit tool to evaluate whether the policy is implemented appropriately. Until the science of PSRS advances, its value will derive from surfacing and reducing hazards. The challenge is to migrate from investigations that go a mile wide and an inch deep, to an inch wide and a mile deep.

A research agenda to advance this science could include understanding the bias in reporting, developing tools to use information in PSRS to prioritize patient safety efforts, and developing

measures to evaluate whether safety actually improved. Health care must spend its resources more efficiently. The need to improve patient safety is too great and the resources too scarce not to evaluate what works and at what cost.

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References

1. Brennan T, Leape L, Laird N, et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. *Qual Saf Health Care* 2004; 13: 145-152.
2. Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: Building a safer health system*. Washington DC: National Academies Press; 1999.
3. Institute of Medicine. *Patient safety: Achieving a new standard for care*. Washington, DC: National Academies Press; 2004.
4. Patient Safety and Quality Improvement Act of 2005. Available at: [frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ041.109](http://www.webgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_public_laws&docid=f:publ041.109). Accessed May 1, 2008.
5. Leape L. Reporting of adverse events. *N Engl J Med* 2002; 347: 1633-1638.
6. Weingart S, Wilson R, Gibberd R, et al. Epidemiology of medical error. *Br Med J* 2000; 320: 774-777.
7. Leape L, Berwick D, Bates D. What practices will most improve safety? Evidence-based medicine meets patient safety. *JAMA* 2002; 288: 501-507.
8. Pronovost P, Holzmueller C, Sexton J, et al. How will we know patients are safer? An organization-wide approach to measuring and improving patient safety. *Crit Care Med* 2006; 134: 1988-1995.
9. Pronovost P, Miller M, Wachter R. Tracking progress in patient safety. An elusive target. *JAMA* 2006; 296: 696-699.
10. Holzmueller C, Pronovost P, Dickman F, et al. Creating the web-based Intensive Care Unit Safety Reporting System (ICUSRS). *J Am Med Inform Assoc* 2005; 12: 130-139.
11. Wu AW, Holzmueller CG, Lubomski L, et al. Development of the ICU Safety Reporting System. *J Patient Safety* 2005; 1: 23-32.
12. Lubomski L, Pronovost PJ, Thompson D, et al. Building a better incident reporting system: Perspectives from a multisite project. *JCOM* 2004; 11: 275-280.
13. Thompson D, Lubomski L, Holzmueller C, et al. Integrating the intensive care unit safety reporting system with existing incident reporting systems. *Jt Comm J Qual Saf* 2005; 31: 585-593.
14. Pronovost P, Thompson D, Holzmueller C, et al. Toward learning from patient safety reporting systems. *J Crit Care* 2006; 21: 305-15.

15. Newman T. The power of stories over statistics. *Br Med J* 2003; 327: 1424-1427.
16. Classen D, Metzger J. Improving medication safety: The measurement conundrum and where to start. *Int J Qual Health Care* 2003; 15: 41-47.
17. Pronovost P, Nolan T, Zeger S, et al. How can clinicians measure safety and quality in acute care? *Lancet* 2004; 363: 1061-1067.
18. Vincent C. Understanding and responding to adverse events. *N Engl J Med* 2003; 348: 1051-1056.
19. Pronovost P, Holzmueller C, Young J, et al. Using incident reporting to improve patient safety: A conceptual model. *J Patient Saf* 2007; 3: 27-33.
20. Leape L. A systems analysis approach to medical error. *J Eval Clin Pract* 1997; 3: 213-222.
21. Uribe C, Schweikhart S, Pathak D, et al. Perceived barriers to medical error reporting: An exploratory investigation. *J Healthc Manag* 2002; 47: 263-279.
22. Gandhi TK, Graydon-Baker E, Huber Neppel T, et al. Closing the loop: Follow-up and feedback in a patient safety program. *Jt Comm J Qual Patient Saf* 2005; 31: 614-621.
23. Itoh K, Andersen HB. Analysing medical incident reports by use of a human error taxonomy. In: Spitzer C, Schmocker U, Dang VN, eds. *Proceedings of the International Conference on Probabilistic Safety Assessment and Management (PSAM 7 – ESREL '04)*, Berlin; 2004 Jun 14-18, Vol. 5. Berlin: Springer; 2004. p. 2714-2719
24. Macrae C. Harnessing hindsight. *Risk Regulation* 2006; 11: 10-11.
25. Battles J, Kaplan H, Van der Schaff T, et al. The attributes of medical event reporting systems: Experience with a prototype medical event reporting system for transfusion medicine. *Arch Pathol Lab Med* 1998; 122: 231-238.
26. Pace W, Staton E, Higgins G, et al. Database design to ensure anonymous study of medical errors: A report from the ASIPS Collaborative. *J Am Med Inform Assoc* 2003; 10: 531-540.
27. Lawthers A, McCarthy E, Davis R, et al. Identification of in-hospital complications from claims data. Is it valid? *Med Care* 2000; 38: 785-795.
28. Kaplan HS, Battles JB, Van der Schaaf TW, et al. Identification and classification of the causes of events in transfusion medicine. *Transfusion* 1998; 38: 1071-1081.
29. Pronovost P, Holzmueller C, Martinez E, et al. A practical tool to learn from defects in patient care. *Jt Comm J Qual Patient Saf* 2006; 32: 102-108.
30. High-alert medications and patient safety. Sentinel event alert. Issue 11, November 19, 1999. Oakbrook Terrace, IL: The Joint Commission; 1999. Available at: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_11.htm. Accessed June 11, 2008.
31. Burke JP. Infection control - a problem for patient safety. *N Engl J Med* 2003; 348: 651-656.
32. Mermel L. Prevention of intravascular catheter-related infections. *Ann Intern Med* 2000; 132: 391-402.
33. CAST (Commercial Aviation Safety Team). Washington, DC: Air Transport Association of America; 2008. Available at: <http://www.airlines.org/NR/exeres/DB95EAE2-3BC2-4589-8D0F-49518A73AD0E.htm>. Accessed June 11, 2008.

The Association Between Pharmacist Support and Voluntary Reporting of Medication Errors: An Analysis of MEDMARX® Data

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Abstract

Objective: We used MEDMARX®, the national medication error-reporting program, to compare medication errors reported by critical access hospitals (CAHs) to those reported by non-Federal, general community hospitals. **Methods:** We used the availability of pharmacist support to represent the structure and process of medication use and within-cluster resampling to account for the correlation of error reports within hospitals. **Results:** CAHs with 15 or fewer hours of pharmacist support per week were significantly less likely to report “near miss” errors—a characteristic of high-reliability organizations—than general community hospitals with 24-hour pharmacist support. **Conclusion:** The severity of voluntarily reported medication errors is associated with the structure and process of medication use as indicated by the availability of pharmacist support. MEDMARX is a potential data source for patient safety organizations (PSO). PSOs must consider varying structure and process within reporting organizations and account for the correlation of data within clusters.

Introduction

The Risk from Medication Errors

Medication errors are the most common source of risk to hospitalized patients.¹ On average, a hospitalized patient experiences one medication error per day.² This lack of reliability in hospitals’ medication use practices results in 400,000 preventable medication-related injuries costing \$3.5 billion annually.² The Institute of Medicine’s (IOM) publication, *Preventing Medication Errors*, summarizes research and the work of the Joint Commission and the National Quality Forum to establish an action agenda for health care organizations to systemically improve the safety of medication use.² This agenda includes actions for prescribers, pharmacists, and nurses. Furthermore, the agenda identifies evidence-based safe medication practices, including dispensing medications in unit-dose or unit-of-use form, using standardized abbreviations, identifying “high alert” drugs, reading back verbal orders, standardizing labeling, and integrating pharmacists throughout the medication use process.

The Role of Voluntary Reporting and Patient Safety Organizations in Medication Safety

The IOM recommends mandatory reporting of adverse events and voluntary reporting of nonharmful errors to facilitate learning about and preventing systems-level sources of errors.¹ Successful voluntary reporting programs allow organizations to learn from their experience by providing independent, expert analysis focused on systems rather than on individuals.³ Reporting programs—whether mandatory or voluntary—do not determine the actual incidence of errors and adverse events.^{4, 5, 6} Estimating the incidence of errors requires a multimodal approach, including voluntary reporting, direct observation, and chart review.⁷ The Patient Safety and Quality Improvement Act of 2005 calls for the creation of patient safety organizations (PSOs) that collect, aggregate, and analyze confidential reports of errors and near misses from multiple organizations in a standard format. The ultimate goal of PSOs is to identify patterns of system failures and to recommend measures that will mitigate the risks and hazards patients encounter in the health care system.⁸

MEDMARX[®], the Nation's first Internet-accessible and largest voluntary medication error reporting program,⁹ was established in 1998 by the United States Pharmacopeia (USP), affirming safe medication use as a national priority. MEDMARX is an anonymous medication error-reporting program that subscribing hospitals and health care systems participate in as part of their ongoing quality improvement initiatives. Nationally, data from MEDMARX contribute to knowledge about the causes and prevention of medication errors. Over 870 hospitals and health care systems have submitted reports of more than 1.3 million medication errors to MEDMARX. Analyses of voluntary medication error records from large patient safety databases, such as MEDMARX, can identify system sources of error and lead to the establishment of safe medication practices.

The Agency for Healthcare Research and Quality (AHRQ) has had an important role in patient safety and medication error reporting. In July 2005, the University of Nebraska Medical Center (UNMC) received one of 17 Partnerships in Implementing Patient Safety (PIPS) grants from AHRQ to fund the project, *Implementing a Program of Patient Safety in Small Rural Hospitals*. The primary aim of this project was to develop the organizational infrastructure for voluntarily reporting and analyzing medication errors in small rural hospitals that is necessary for identifying system sources of error. Given the limited technologic and human resources in these hospitals, UNMC used MEDMARX as the tool for 35 small rural hospitals to report and analyze medication errors in a standardized format. In March 2007, with funding from AHRQ, USP sponsored a conference for users of MEDMARX and other reporting programs. Participants shared successful strategies for reporting and learning from medication errors, a process consistent with the objectives of a PSO.

Structure and Process as Determinants of Medication Safety

Analyses from large patient safety databases typically aggregate reports from all hospitals, regardless of differences in structure or process. Structure refers to the capacity for work and encompasses the human resources, the equipment, and the environment in which care is provided. Process refers to the health care activities—i.e., what was done with the structure. The causal relationship between structure, process, and outcome must be established by scientific

evidence.^{10, 11} Hospitals that lack the structures of computerized medication administration records, automated dispensing devices, barcoding technology, or pharmacist review of medication orders are likely to have different latent system sources of error than hospitals with these structures and processes. Medication error reporting is also likely to differ based on the structure and process of medication use within hospitals. Little has been published regarding the effect of medication use structure and process on voluntary medication error reporting.

Differences in hospital structure and process are evident in a comparison of Critical Access Hospitals (CAHs) with larger hospitals. CAHs are a category of limited-service hospitals created in 1997 as part of the Balanced Budget Act to maintain access to care in rural areas by providing cost-based reimbursement. CAHs, the Nation's smallest hospitals,¹² are limited to 25 inpatient beds for acute care and have an average inpatient length of stay of 96 hours. As of May 2007, there were 1,283 CAHs,¹³ representing approximately one-fourth of the general community hospitals in the Nation.¹⁴

A primary difference in medication use between CAHs and larger hospitals is the amount of pharmacist support. Survey research suggests that approximately 40 percent of CAHs have a pharmacist available for fewer than 20 hours per week.¹⁵ When integrated into the medication use process, pharmacists are available to consult with prescribers, to review and interpret medication orders, and to prepare, dispense, and monitor medications.

Pharmacists who regularly review medication orders are, by training, able to identify, intercept, and report medication errors that originate during prescribing or dispensing. The limited availability of pharmacists in CAHs limits pharmacists' ability to intercept medication errors before reaching the patient (e.g., near-miss errors); it also limits their participation in the medication error-reporting process.¹⁶ While research has shown that limited financial resources, low patient volume, and lack of accreditation by the Joint Commission are all associated with having limited pharmacist support in small rural hospitals,^{15, 16} little has been published comparing error-reporting patterns of the Nation's smallest community hospitals to those of larger hospitals and health care systems.¹⁶

The structure and process of a hospital's medication use system is responsible for latent system sources of error. The purpose of voluntary medication error reporting is to identify these sources of error. Consequently, it may be particularly useful for a hospital to review and learn from error reports submitted by organizations with similar structures and processes, in addition to reviewing all aggregated reports. The purpose of this study was to compare the medication errors reported by the 35 CAHs that participated in our patient safety project to those reported by non-Federal community hospitals (NFCHs) with 24-hour pharmacist support.

The amount of pharmacist support was used as an indicator of differences in the structure and process of the medication use system. We sought to determine whether the proportion of errors classified as near misses was associated with the structures and process of medication use as represented by the amount of pharmacist support. We used reporting of near misses as our dependent variable of interest because reporting and analyzing near misses is a characteristic of high-reliability organizations (HROs) that are preoccupied with failure. HROs include nuclear power plants, aircraft carriers, and air traffic control operations, all of which have complex, tightly coupled operations with the potential for catastrophic failure and yet have fewer accidents

than expected. HROs pay attention to near misses as small failures that provide free lessons about sources of poor system reliability.¹⁷

Methods

Study Design and Population

We identified medication error report variables and hospital characteristics from the 35 CAHs, which had varying levels of pharmacist support, and from 147 NFCHs with 24-hour pharmacist support. We used the query-building functions of Crystal Reports, Ver. 9 (Crystal Decisions, Inc., San Jose, CA), to connect to the MEDMARX Oracle database with open database connectivity drivers. These software drivers allowed the Crystal Reports application to access the data stored within the various data tables (regardless of the underlying database management system). We identified and exported two data sets (CAH and NFCH) in worksheet format that contained all reported medication errors from these two groups of hospitals (Table 1). Next, we imported these data sets into SAS[®] Ver. 9.1 (SAS Institute, Cary, NC).

Hospital Characteristics

MEDMARX subscribers receive a unique, anonymous, identification number, known as a facility ID number (FID). Each subscriber completes a facility profile that describes the type of facility, owner, size, and level of pharmacist support. The facility profile also contains variables that describe the extent of implementation of structures that support safe medication use. These variables describe the use of computerized prescriber order entry, automated dispensing devices, and computer-generated medication administration records. We used the FID to link each medication error report to the hospital submitting the record.

Medication Error Report Data

The MEDMARX program assigns a unique record number to each error report, which includes information about the severity, phase of the medication use process in which the error originated, type, and cause of error. The MEDMARX program uses the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) *Index for Categorizing Medication Errors* to assess the severity of the error.¹⁸ The NCC MERP scale assigns an alphabetical category, A through I, to describe the severity of the error based on the outcome for the patient (Table 2). The index has a reported kappa value of $\kappa = 0.62$.¹⁹ Category B errors are actual errors that were intercepted before they reached the patient and are frequently referred to as “near misses.”

The phase of the medication use process refers to the steps required to process a medication order. The process begins when the medication is procured by an organization. Next, a licensed prescriber orders the medication. This order is transcribed from the patient’s medical record for processing. Next, a pharmacist reviews the order and dispenses the medication for use by another health care professional (typically a nurse). This health care professional administers and monitors the medication’s effects on the patient.⁹ The type of error is the basic description,

Table 1. Characteristics of hospitals by pharmacist availability

Hospital characteristics	Pharm available 0 – 15 hrs/wk N (%)	Pharm available 32 – 76 hrs/wk N (%)	Pharm available 24 hr/day, 7 days/wk N (%)
Type of hospital			
Critical Access	18 (100.0)	16 (100.0)	0
General community	0	0	143 (100.0)
Average occupied bed size			
1 – 10	13 (72.2)	4 (25.0)	0
11 – 24	5 (27.8)	12 (75.0)	0
25 – 49	0	0	1 (0.7)
50 – 99	0	0	3 (2.1)
100 – 199	0	0	31 (21.7)
200 – 299	0	0	51 (35.7)
300 – 399	0	0	28 (19.6)
400 – 499	0	0	12 (8.4)
>500	0	0	17 (11.9)
Owner/operator of facility			
Government, non-Federal (State/city/county)	12 (66.7)	2 (12.5)	13 (9.1)
Nongovernment, nonprofit	6 (33.3)	14 (87.5)	130 (90.9)
Average doses dispensed per month			
<9,999	17 (94.4)	13 (81.2)	2 (1.4)
10,000 – 19,999	1 (5.6)	2 (12.5)	3 (2.1)
20,000 – 29,999	0	1 (6.2)	0
30,000 – 99,999	0	0	42 (29.4)
100,000 – 149,999	0	0	36 (25.2)
150,000 – 199,999	0	0	22 (15.4)
≥200,000	0	0	38 (26.6)
Computerized prescriber order entry			
Used in all clinical areas	0	1 (6.2)	11 (7.7)
Used in some clinical areas	0	4 (25.0)	9 (6.3)
Not in use	18 (100.0)	11 (68.8)	123 (86.0)
Computer-generated medical administration record			
	2 (11.1)	7 (43.8)	129 (90.8)
Automated dispensing system in use			
Centralized + decentralized system	0	2 (12.5)	68 (47.6)
Centralized system	2 (11.1)	1 (6.2)	12 (8.4)
Decentralized system	0	3 (18.8)	58 (40.6)
Not in use	16 (88.9)	10 (62.5)	5 (3.5)
Pharmacist primarily prepares inpatient IV admixture products & solutions			
	0	8 (50.0)	140 (97.9)

Note: No facilities had a pharmacist available 16 - 31 hrs/wk.

Table 2. Comparison of medication error reports by pharmacist availability

Severity category all error reports	% Pharm available 0 – 15 hrs/wk (N = 2,586)	% Pharm available 32 – 76 hrs/wk (N = 5,501)	% Pharm available 24 hr/day, 7 days/wk (N = 159,519)
A Circumstances or events that have the capacity to cause error	28.4	22.6	6.0
B Error occurred but it did not reach the patient	14.9	23.9	40.9
C Error occurred that reached the patient but did not cause harm	53.6	49.8	43.4
D Error occurred that reached the patient and required monitoring to confirm that it resulted in no harm and/or required intervention to prevent harm	2.7	3.4	8.0
E Error occurred that might have contributed to or resulted in temporary harm to the patient and required Intervention	0.4	0.2	1.4
F Error occurred that might have contributed to or resulted in temporary harm or required initial or prolonged hospitalization	0.0	0.1	0.3
G Error occurred that might have contributed to or resulted in permanent patient harm	0.0	0.0	0.0
H Error occurred that required intervention necessary to sustain life	0.0	0.0	0.0
I Error occurred that might have contributed to or resulted in patient's death	0.0	0.0	0.0
Characteristics of actual error reports by severity (Categories B - I)	% (N = 1,851)	% (N = 4,260)	% (N = 149,978)
B (near miss)	20.8	30.8	43.5
C - D (reached the patient, no harm)	78.6	68.7	54.7
E - I (harm)	0.6	0.5	1.8
Phase of medication use process	% (N = 1,851)	% (N = 4,260)	% (N = 149,978)
Prescribing	5.8	8.8	18.0
Documenting	29.1	29.5	25.6
Dispensing	6.4	10.1	21.2
Administering	57.3	50.2	33.5
Monitoring	0.6	0.9	1.3
Procurement	0.8	0.6	0.3

Table 2. Comparison of medication error reports by pharmacist availability (continued)

	Pharm available 0 – 15 hrs/wk	Pharm available 32 – 76 hrs/wk	Pharm available 24 hr/day, 7 days/wk
Error types	N = 2,002 ^a (%)	N = 4,652 ^a (%)	N = 158,812 ^a (%)
Omission	35.8	32.4	29.4
Improper dose/quantity	19.5	21.1	18.4
Prescribing error	3.8	6.2	13.3
Unauthorized/wrong drug	10.8	15.3	13.2
Wrong time	11.4	8.1	7.7
Extra dose	8.4	7.6	6.1
Wrong patient	1.5	1.8	4.3
Wrong route	2.0	1.5	1.6
Wrong administration technique	1.5	1.3	1.6
Drug prepared incorrectly	0.9	1.2	1.3
Wrong dosage form	2.7	1.8	1.3
Mislabeled	1.2	1.5	1.1
Expired product	0.4	0.2	0.4
Deteriorated product	0.0	0.1	0.2

Note: No facilities had a pharmacist available 16-31 hours per week.

a The number of error types exceeds the number of reports for severity Categories B – I because error type is a multi-select field in MEDMARX; each error report may be categorized as more than one error type.

regardless of the cause, that characterizes an error within the medication use process. There are 14 types of errors within the MEDMARX program (Table 2).⁹

Statistical Analyses

We excluded from this analysis hospitals submitting fewer than 10 reports during the data collection period of 2005 through 2006. We divided the data into three groups based on the hours of pharmacist support available within a hospital each week: (1) CAH with a pharmacist available for ≤15 hours/week, (2) CAH with a pharmacist available >32 hours/week but not available 24 hours/day, and (3) NFCH with a pharmacist available 24 hours/day. No CAHs had a pharmacist available 16 to 31 hours/week. We used descriptive statistics to compare hospital characteristics and medication error report data across the three groups of hospitals. We used logistic regression to evaluate the association between the likelihood of reporting Category B errors (dependent variable) and the three levels of pharmacist support (independent variable). NFCHs with 24-hour pharmacist support served as the reference group.

Reports submitted to MEDMARX are clustered by hospital, which means that the reports submitted by each hospital are correlated and cannot be treated as independent outcomes. Generalized estimating equations (GEE) are typically used to account for the correlation of data within clusters. However, the GEE methods assume that cluster size is not related to the outcomes of interest.²⁰ In our analysis, cluster size was the number of reports submitted by a hospital; cluster size was significantly associated with our outcome of interest—i.e., reporting

near misses. Specifically, the volume of medication errors reported by the hospitals was positively associated with reporting errors of severity Category B ($P < 0.0001$). Because CAHs tended to submit fewer error reports than the NFCHs, we could not ignore the differences in cluster size in our analysis. To achieve a valid estimate of the standard error in the presence of this difference in cluster size, we used a within-cluster resampling method to account for the nesting of error reports within hospitals. This method remains valid when cluster size is informative.^{20, 21} One error report was randomly drawn from each of the 177 hospitals included in the analysis. Because the 177 error reports from each sample were independent, a logistic regression was used to estimate the association between pharmacist support and the likelihood of reporting Category B errors. This sampling procedure was repeated 1,000 times with replacement, and logistic regression was conducted for each sample. The odds ratio and 95 percent confidence interval for the odds ratio were estimated from the results of the 1,000 samples using the method provided by Hoffman.²¹

Results

Sample Characteristics

The 35 CAHs from the UNMC PIPS grant and the 147 NFCHs reported 167,632 medication errors to MEDMARX during the calendar years 2005 and 2006. After excluding the five hospitals that reported 10 or fewer errors during this period, there were 34 CAHs that reported 8,087 medication errors and 143 NFCHs that reported 159,519 errors (Table 2). The number of error reports submitted by the 177 hospitals varied from 11 to 8,309. There were varying levels of pharmacist support among the CAHs: 18 (53 percent) had a pharmacist available ≤ 15 hours/week and reported 2,586 medication errors. The remaining 16 CAHs (47 percent) had a pharmacist available 32 to 76 hours per week and reported 5,501 medication errors

The hospital groups differed in structures other than pharmacist availability (i.e., bed size, ownership, and volume of doses dispensed) that could also influence the medication use process (Table 1). They also differed in the prevalence of other technologically based structures and processes that support safe medication use. Only five CAHs with a pharmacist available 32 to 76 hours per week and 20 NFCHs with 24-hour pharmacist support used computerized prescriber order entry (CPOE) in any area. The two categories of CAHs without 24-hour pharmacist support were less likely to use a computer-generated medication administration record (11 percent and 44 percent vs. 91 percent) or automated dispensing systems (11 percent and 37 percent vs. 96 percent) than the NFCHs. The CAHs were far less likely to report that intravenous solutions were prepared primarily by a pharmacist than were the NFCHs (0 percent and 50 percent vs. 98 percent).

Medication Error Severity

The severity of medication errors varied by the availability of pharmacist support (Table 2). Specifically, the CAHs reported a higher proportion of circumstances that had the capacity to cause an error (Category A) than did the NFCHs (28 percent and 23 percent vs. 6 percent). When considering actual medication errors (Categories B - I), the CAHs reported a lower proportion of near misses (Category B) (21 percent and 31 percent vs. 44 percent) and a higher proportion of

errors that reached the patient but did not cause harm (Categories C or D) (79 percent and 69 percent vs. 55 percent) than did the NFCHs. Harmful errors (Categories E - I) accounted for approximately 2 percent of reported errors from the NFCHs and <1 percent of reported errors from the CAHs. Only the NFCHs reported fatal medication errors during the 2005 to 2006 reporting period.

After accounting for the clustering of error reports within a hospital by using the within-cluster resampling technique, we found that CAHs with ≤ 15 hours of pharmacist support were significantly less likely to

report Category B errors than were hospitals with 24-hour pharmacist support [odds ratio (OR) 0.64; $P = 0.048$, 2-tailed test] (Table 3). No significant difference in the likelihood of reporting near misses was found between CAHs with 32 to 76 hours of pharmacist support and NFCHs (OR 0.98; $P = 0.91$).

Table 3. Association between pharmacy support and the likelihood of reporting Category B errors

Pharmacist support	OR	95% CI	P-value ^a
Available 0-15 hr/wk ^b	0.64	0.42 - 0.9978	0.048
Available 32-76 hr/wk ^b	0.98	0.70 - 1.39	0.91

Note: No facilities had a pharmacist available 16-31 hours a week.

a 2- tailed z-test.

b The reference category is pharmacist available 24 hours a day.

Medication Use Process

The CAHs were less likely than the NFCHs to report errors that originated in the prescribing phase (6 percent and 9 percent vs. 18 percent) and dispensing phase (6 percent and 10 percent vs. 21 percent) of the medication use process and more likely to report administering errors (57 percent and 50 percent vs. 34 percent) (Table 2). Analysis of the phase of the medication use process by error severity indicated that CAHs were less likely to report near misses in the prescribing phase (53 percent and 64 percent vs. 82 percent) and dispensing phase (38 percent and 51 percent vs. 58 percent) than were NFCHs (Table 4). The proportions of reported near-miss errors in the administration phase were similar (9 percent and 6 percent vs. 9 percent) (Table 4). The small numbers of monitoring and procurement errors reported by the CAHs prevent meaningful comparisons to those reported by the NFCHs (Table 2).

Type of Error

Omission and improper dose/quantity were the two most frequently reported error types, regardless of the amount of pharmacist support within a hospital (Table 2). The proportions of all reported error types were similar across the three groups of hospitals, with the exception of prescribing errors. Specifically, the CAHs reported a smaller proportion of prescribing errors than did the NFCHs (4 percent and 6 percent vs. 13 percent) (Table 2). With the exception of omission errors, an analysis of the type of error by severity revealed that CAHs with 1 to 15 hours of pharmacist support per week reported the smallest proportion of all types of errors as Category B (Table 5). Prescribing errors were more likely than any other error type to be reported as Category B across the three groups of hospitals.

Table 4. Phase of origination and severity of actual (Categories B - I) medication error reports by pharmacist availability

Phase of medication use process	Pharm available 0 – 15 hrs/wk (N = 1,851)	Pharm available 32 – 76 hrs/wk (N = 4,260)	Pharm available 24 hr/day, 7 days/wk (N = 149,978)
Prescribing reports	(N = 108)	(N = 375)	(N = 26,998)
Severity category:			
B (%)	52.8	63.7	81.6
C - D (%)	46.3	35.5	16.9
E - I (%)	0.9	0.8	1.5
Documenting reports	(N = 539)	(N = 1,256)	(N = 38,473)
Severity category:			
B (%)	34.3	57.4	51.0
C - D (%)	64.9	42.3	47.8
E - I (%)	0.7	0.3	1.2
Dispensing reports	(N = 118)	(N = 430)	(N = 31,748)
Severity category:			
B (%)	38.1	51.4	57.6
C - D (%)	61.0	48.1	41.4
E - I (%)	0.8	0.5	1.1
Administering reports	(N = 1,061)	(N = 2,138)	(N = 50,290)
Severity category:			
B (%)	8.9	5.8	8.8
C - D (%)	90.7	93.7	88.4
E - I (%)	0.5	0.5	2.8
Monitoring reports	(N = 11)	(N = 37)	(N = 1,953)
Severity category:			
B (%)	0.0	10.8	32.0
C - D (%)	90.9	86.5	61.8
E - I (%)	9.1	2.7	6.3
Procurement reports	(N = 14)	(N = 24)	(N = 516)
Severity category:			
B (%)	28.6	25.0	44.4
C - D (%)	71.4	75.0	54.5
E - I (%)	0.0	0.0	1.2

Note: No facilities had a pharmacist available 16-31 hours/week.

**Table 5. Type and severity of actual medication error reports
(Categories B - I) by pharmacist availability**

Type of medication error	Pharm available 0 – 15 hrs/wk (N = 2,002 ^a)	Pharm available 32 – 76 hrs/wk (N = 4,652 ^a)	Pharm available 24 hr/day, 7 days/wk (N = 158,812 ^a)
Omission error reports	(N = 717)	(N = 1,507)	(N = 46,657)
Severity category:			
B (%)	14.5	13.5	29.8
C - D (%)	84.7	86.2	68.5
E - I (%)	0.8	0.3	1.8
Improper dose/quantity reports	(N = 391)	(N = 983)	(N = 29,239)
Severity category:			
B (%)	32.0	42.9	44.7
C - D (%)	67.5	56.4	52.7
E - I (%)	0.5	0.7	2.6
Prescribing error reports	(N = 76)	(N = 286)	(N = 21,102)
Severity category:			
B (%)	55.3	66.1	83.3
C - D (%)	43.4	32.9	15.4
E - I (%)	1.3	1.0	1.3
Unauthorized/wrong drug reports	(N = 217)	(N = 711)	(N = 21,044)
Severity category:			
B (%)	26.3	38.3	44.1
C - D (%)	73.3	61.6	54.0
E - I (%)	0.5	0.1	1.9
Wrong time reports	(N = 229)	(N = 376)	(N = 12,224)
Severity category:			
B (%)	8.3	22.3	29.5
C - D (%)	91.7	77.4	69.5
E - I (%)	0.0	0.3	1.1
Extra dose reports	(N = 169)	(N = 356)	(N = 9,652)
Severity category:			
B (%)	26.6	38.2	32.7
C - D (%)	72.8	61.2	65.5
E - I (%)	0.6	0.6	1.8
Wrong patient reports	(N = 30)	(N = 83)	(N = 6,836)
Severity category:			
B (%)	10.0	56.6	47.5
C - D (%)	90.0	43.4	51.5
E - I (%)	0.0	0.0	1.0

**Table 5. Type and severity of actual medication error reports
(Categories B - I) by pharmacist availability (continued)**

Type of medication error	Pharm available 0 – 15 hrs/wk (N = 2,002 ^a)	Pharm available 32 – 76 hrs/wk (N = 4,652 ^a)	Pharm available 24 hr/day, 7 days/wk (N = 158,812 ^a)
Wrong dosage form reports	(N = 54)	(N = 86)	(N = 2,038)
Severity category:			
B (%)	24.1	38.4	48.2
C - D (%)	75.9	61.6	50.3
E - I (%)	0.0	0.0	1.5
Other reports	(N = 119)	(N = 264)	(N = 10,020)
Severity category:			
B (%)	21.0	48.1	45.7
C - D (%)	78.2	50.0	51.4
E - I (%)	0.8	1.9	3.0

Note: No facilities had a pharmacist available 16-31 hours/week.

a The number of error types exceeds the number of reports for severity Categories B – I because error type is a multi-select field in MEDMARX; each error report may be categorized as more than one error type.

Reporting of Errors by Pharmacy Personnel

Of the 156,089 actual errors reported (Categories B - I) from the 177 hospitals, information about the level of staff discovering the error was available in 111,622 records. This variable is not a required field in the MEDMARX reporting program. Pharmacy personnel (pharmacist, pharmacy technician, nonspecific pharmacy personnel) reported 36,672 (33 percent) of the 111,622 records.

The participation of pharmacy personnel in medication error reporting varied among the three groups of hospitals: in CAHs with ≤15 hours of pharmacist support per week, pharmacy personnel were identified as the staff discovering the error in 3.3 percent (55/1,658) of submitted reports; in CAHs with 32 to 76 hours of pharmacist support per week, pharmacy personnel were identified as the staff discovering the error in 28.4 percent (1,211/4,088) of submitted reports; and in NFCHs, pharmacy personnel were identified as the staff discovering the error in 31.8 percent (31,168/97,893) of submitted reports.

Of the 32,434 actual errors (Categories B - I) discovered by pharmacy personnel across the 177 hospitals, 55 percent originated in the prescribing phase of the medication use process, 21 percent in documenting, 13 percent in dispensing, 9 percent in administering, 2 percent in monitoring, and 0.5 percent in procurement. However, the phase of origination of reported errors that pharmacy personnel discovered differed among the three groups of hospitals: in CAHs with ≤15 hours of pharmacist support per week, 3.6 percent of errors discovered by pharmacy personnel originated in prescribing, 25.5 percent in documenting, and 65.5 percent in administering. In CAHs with 32 to 76 hours of pharmacist support a week, 17.3 percent of errors discovered by pharmacy personnel originated in prescribing, 40.7 percent in documenting, and 33.9 percent in administering. In NFCHs, 56.6 percent of errors discovered by pharmacy

personnel originated in prescribing, 20.6 percent in documenting, and 7.4 percent in administering.

Finally, the severity of reported errors that pharmacy personnel discovered differed among the three groups of hospitals: in CAHs with ≤ 15 hours of pharmacist support a week, 16.4 percent of actual errors discovered by pharmacy personnel were Category B; in CAHs with 32 to 76 hours of pharmacist support a week, 47.7 percent were Category B; and in NFCHs, 78.6 percent were Category B.

Discussion

Key Findings

These results illustrate differences in the severity of medication errors voluntarily reported by 177 hospitals to a national medication error-reporting program. These differences were associated with the structure and process of medication use, as represented by the number of hours a pharmacist was available each week. As PSOs develop, they will aggregate and compare data from multiple organizations. However, analysis of aggregated data results in the loss of information and an inflated Type I error rate if the data are correlated within clusters. We used the computationally intensive method of within-cluster resampling to account for this correlation and the important differences in the sizes of our clusters. Future analyses of aggregate PSO data will be more likely to result in meaningful improvements in patient safety if data are clustered by differences in the structure and process of care within hospitals. However, appropriate statistical analyses must be used to account for the likely correlation of the data within these clusters.

Structure is the major determinant of the average quality of care a system is able to offer. The relationship between structure, process, and outcome is linear, such that differences in structure result in differences in process, which in turn, affects the outcome of care.^{10, 11} A significant difference between the structure of medication use in CAHs and larger community hospitals is the availability of pharmacist support. Pharmacists affect all phases of the medication use process. These results demonstrate that, after accounting for the correlation of reports within a hospital, those hospitals with ≤ 15 hours of pharmacist support are significantly less likely to report near-miss errors than are hospitals that have pharmacists available 24 hours per day. This pattern is stable across all phases and types of voluntarily reported medication errors. In addition, the more time a pharmacist is available within a hospital, the more likely it is that he or she will report errors and intercept errors that originate in the prescribing phase. For example, “no 24-hour pharmacy” support was selected as a contributing factor in 3 percent of a 5-year aggregation of all MEMARX reports.²² In contrast, in a 2-year aggregation of data from all CAHs reporting to MEDMARX, those with 1 to 10 occupied beds selected “no 24-hour pharmacy” as a contributing factor in 20 percent of reported errors (*USP data on file*).

The complexity of medication use requires that pharmacists play a central role in an interdisciplinary system of independent double-checks that places more than one provider between the drug and the patient.^{1, 23, 24} When reviewing medication orders, clinical pharmacists verify the appropriateness of the drug and dose as ordered by the prescriber. The importance of this review is reflected by the fact that harmful medication errors are most likely to originate in

the prescribing phase of medication use.²⁵ When a pharmacist is not present to dispense a medication, the entire responsibility for correct selection of drug, quantity, and dosage form falls on the nursing staff. Specifically, standards of nursing practice require a nurse to verify that the correct drug, quantity, and dosage form is being given to the correct patient, at the correct time, and by the correct route. In a nationally representative sample of CAHs that we surveyed in 2005, 41 percent reported that nurses always or frequently selected and administered a newly ordered medication without an independent double-check by another provider.²⁶

Clinical pharmacists also serve an important role in the monitoring and procurement phases of the medication use process. They frequently monitor a patient's response to the prescribed medication regimen for both effectiveness and safety. It is standard practice for clinical pharmacists who work full time at a hospital to manage the procurement phase of medication use and thus control the hospital's formulary. Formulary management is a proven safe medication practice.²³

Similar to other studies,^{15, 16} we found that the structures of computer-generated medication administration records and the presence of automated dispensing systems were more likely to be available in large community hospitals than in CAHs. These technology-based structures affect the process of medication use and reduce the number of opportunities for error. Computer-generated medication administration records minimize the need to manually copy these forms. Automated dispensing systems minimize the need for nurses to enter the pharmacy and limit the number of medications to which they have access. Barcode medication administration (BCMA) is a technology that can intercept medication errors at the point of care.²⁷

The MEDMARX facility profile does not identify which hospitals have implemented BCMA. We did not observe differences in the low proportions of near-miss errors intercepted in the administering phase across the three groups of hospitals. It is likely that this costly but effective intervention will become common in large hospitals, but adoption of BCMA is likely to lag in CAHs with limited financial resources. In our 2005 survey of small rural hospitals, 4 percent of CAHs had implemented BCMA.²⁶

These results demonstrate that the structure of pharmacist availability is significantly associated with patterns of voluntary medication error reporting. However, a possible argument against aggregating error reports by similarities in structure and process, particularly for CAHs, is that the voluntary reporting system may be insufficient to identify errors and determine system vulnerabilities across all phases of medication use. Specifically, the proportions of errors originating in the prescribing and dispensing phases were much lower in the CAHs than in the NFCHs. Hospitals without the structures and processes to review medication orders are unlikely to identify errors that originate in prescribing. In addition, nurses are not licensed to dispense medications. In those hospitals where pharmacists are not dispensing, errors that originate in the pharmacy as a nurse selects a drug are reported as originating in the administration phase. Hospitals that do not have pharmacists to dispense medications are less likely to identify errors that originate when the drug is selected than hospitals with dispensing pharmacists, simply because an opportunity for an independent double-check is removed. Since prescribing and dispensing errors are under-represented in the voluntary reporting of CAHs, to become high-reliability organizations and intercept errors before they reach the patient these CAHs must learn

from the reporting of other hospitals or implement additional error-detection strategies, such as telepharmacy and BCMA.

Limitations and Strengths

There are several limitations to this analysis. First, the voluntarily reported medication errors in this study come from organizations that self-selected to participate in a national medication error-reporting program. In addition, the 35 CAHs in this analysis were part of an AHRQ-funded patient safety program that emphasized the importance of learning from all errors, especially near misses. Thus, these hospitals might not be representative of all hospitals of similar size or degree of pharmacist support.

Second, errors reported by the NFCHs may be misclassified. We verified the accuracy of error categorizations reported by the CAHs as part of our grant-funded activities. However, no effort was made to verify this accuracy in the NFCHs. While MEDMARX provides a glossary of terms, it is the user who submits the record who must ensure accurate error classification. We do believe, however, that it is unlikely that misclassifications of errors occurred to an extent large enough to explain the differences observed.

A third limitation in this analysis is our use of one characteristic—amount of pharmacist support—to represent differences in the medication use systems across hospitals of different sizes. Other structures, such as CPOE, computer generated Medication Awareness Reporting Systems (MARs), automated dispensing systems and BCMA, significantly influence the medication use process. Data for three of these factors were available for our sample. These additional structural variables were not included in a multivariate analysis due to their collinearity with pharmacist support and the complex resampling methodology. We do not believe that inclusion of additional structure or process variables in the analysis would affect our overall finding that differences in structure and process result in differences in the severity of medication errors that are voluntarily reported by hospitals.

The strength of this analysis is its demonstration that large databases of voluntary error reports generated by future PSOs can be a source of information about hazards to patient safety for hospitals of all sizes. We also demonstrate that hospitals seeking to be high-reliability organizations will need to be able to interpret information provided by PSOs in the context of the structures and processes in use in reporting organizations. Finally, we demonstrate how within-cluster resampling can be used to account for the correlated nature of data that will be reported to PSOs.

Conclusion

These results demonstrate that after accounting for the correlation of reports within a hospital, CAHs with ≤ 15 hours of pharmacist support per week were significantly less likely to report intercepting medication errors before they reached patients than were hospitals that have pharmacists available 24 hours per day. The differences in reporting patterns observed between hospitals across the phases and types of voluntarily reported medication errors were associated with their differences in structure, as indicated by the availability of pharmacist support.

Knowledge of the variation in the structure and process of care in organizations that report to PSOs will enhance an understanding of how this variation contributes to error and will, thus, improve the likelihood that recommended changes to the structure and processes of care will improve patient safety. If PSOs are to appropriately analyze data from reporting organizations, they must be able to account for the correlation of the data within these hospital clusters. If appropriate statistical methods that account for the correlation are not used, the variance of mean summary statistics will be underestimated in the presence of positive correlation. This underestimation may result in false positive reporting (i.e., the reporting of differences that do not exist). Finally, as PSOs develop and disseminate recommendations to improve patient safety based on aggregated data analysis, future research must examine the impact of their recommendations on patient outcomes.

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References

1. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: Building a safer health system. Washington, DC: National Academies Press; 2000.
2. Institute of Medicine. Preventing medication errors. Washington, DC: National Academies Press; 2007.
3. Leape LL. Reporting of adverse events. N Engl J Med 2002; 347: 1633-1638.
4. Ashish K, Kuperman GJ, Teich JM, et al. Identifying adverse drug events: Development of a computer-based monitor and comparison with chart review and stimulated voluntary report. JAMA 1998; 5: 305-314.
5. Bates DW, Boyle DL, Vander Vliet MB, et al. Relationship between medication errors and adverse drug events. J Gen Intern Med 1995; 10: 199-205.

6. Classen DC, Pestotnik SL, Evans RS, et al. Computerized surveillance of adverse drug events in hospital patients. *JAMA* 1991; 27: 2847-2851.
7. Flynn EA, Barker KN, Pepper GA, et al. Comparison of methods for detecting medication errors in 36 hospitals and skilled nursing facilities. *Am J Health Syst Pharm* 2002; 59: 436-446.
8. The patient safety and quality improvement act of 2005. Available at: www.ahrq.gov/qual/psact.htm. Accessed April 29, 2008.
9. Stevenson JG. Medication errors: Experience of the United States Pharmacopeia. *Jt Comm J Qual Saf* 2005; 31: 106-111.
10. Donabedian A. Evaluating the quality of medical care. *Milbank Q* 1966; 44: 166-206.
11. Donabedian A. An introduction to quality assurance in health care. New York: Oxford University Press; 2003.
12. Mueller KJ. The Medicare prescription drug, improvement, and modernization act of 2003 (P.L. 108-173): A summary of provisions important to rural health care delivery. Omaha. RUPRI Center for Rural Health Policy Analysis; 2004. Policy Paper P2004-1.
13. Flex Monitoring Team Site. A complete list of Critical Access Hospitals. Available at: www.flexmonitoring.org/documents/CAH_LIST_08_06_07.xls. Accessed April 29, 2008.
14. American Hospital Association. AHA hospital statistics. Chicago: Health Forum, LLC; 2006.
15. Casey MM, Moscovice IS, Davidson G. Pharmacist staffing, technology use, and implementation of medication safety practices in rural hospitals. *J Rural Health* 2006; 22: 321-329.
16. Jones KJ, Cochran G, Hicks RW, et al. Translating research into practice: Voluntary reporting of medication errors in critical access hospitals. *J Rural Health* 2004; 20: 335-343.
17. Weick KE, Sutcliffe KM. Managing the unexpected: Assuring high performance in an age of complexity. San Francisco: John Wiley & Sons; 2001.
18. Index for categorizing medication errors. National Coordinating Council for Medication Error Reporting and Prevention; 2001. Available at: www.nccmerp.org/pdf/indexBW2001-06-12.pdf. Accessed June 10, 2008.
19. Forrey RA, Pedersen CA, Schneider PJ. Interrater agreement with a standard scheme for classifying medication errors. *Am J Health Syst Pharm* 2007; 64: 175-181.
20. Follmann D, Proschan M, Leifer E. Multiple outputation: Inference for complex clustered data by averaging analyses from independent data. *Biometrika* 2003; 59: 420-429.
21. Hoffman EB, Sen PK, Weinberg CR. Within-cluster resampling. *Biometrika* 2001; 88: 1121-1134.
22. Hicks RW, Becker SC, Cousins DD. MEDMARX data report. A chartbook of medication error findings from the perioperative settings from 1998-2005. Rockville, MD: USP Center for the Advancement of Patient Safety; 2006.
23. Cohen MR. Medication errors: Causes, prevention, and risk management. Sudbury, MA: Jones and Bartlett Publishers; 2000.
24. Shojania KG, Duncan BW, McDonald KM, et al. Making health care safer. A critical analysis of patient safety practices. Evidence report/technology assessment no. 43. Rockville, MD: Agency for Healthcare Research and Quality; 2001. Available at: www.ahrq.gov/clinic/ptsafety/pdf/front.pdf. Accessed May 2, 2008.
25. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA* 1995; 274: 29-34.
26. Cochran, GL, Jones KJ, Xu L, Mueller K. Prevalence of evidence-based safe medication practices in small rural hospitals. Omaha. Nebraska Center for Rural Health Research; April 2008. Brief No. 2008-1. Available at: <http://www.unmc.edu/ruprihealth/Pubs/IssueBrief2008-1.pdf>. Accessed July 17, 2008.
27. Heinen MG, Coyle GA, Hamilton AV. Barcoding makes it mark on daily practice. *Nurs Manag* 2003; 18-20.

Proactive Postmarketing Surveillance: Overview and Lessons Learned from Medication Safety Research in the Veterans Health Administration

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Abstract

This report is an overview of the medication safety studies conducted by the VISN (Veterans Integrated Service Network) 8 Patient Safety Center of Inquiry (PSCI), Tampa, FL, over the past 5 years. The Center has been developing the research capacity to conduct national Veterans Health Administration (VHA) proactive medication safety surveillance studies as part of its research focus on patient falls and mobility issues in elderly veterans. The Center's research findings describe new directions and alternative approaches based on a paradigm shift in how proactive medication safety surveillance can be conducted using the VHA's comprehensive health care utilization data. These studies are primarily hypothesis-generating and enhanced signal-detection studies on a national level. The lessons learned from the Center's studies may help to inform the current Congressional debate on Food and Drug Administration (FDA) legislation Prescription Drug User Fees Act (PDUFA IV) that affects the nature and rigor of U.S. postmarketing drug safety studies.

Introduction

Considerable controversy exists concerning the sufficiency of current programs that ensure the safety of drugs in the U.S. health care system.^{1, 2, 3} The U.S. Food and Drug Administration (FDA) has come under increased scrutiny for safety issues associated with approved drugs.^{2, 3, 4, 5} The FDA requires drug manufacturers to do extensive safety and efficacy testing of proposed new medications during the approval process.⁶ However, after FDA approval, knowledge gaps exist in its postmarketing safety system.^{2, 3, 4, 5, 6, 7} These gaps include concerns that the current postmarketing reporting system fails to detect drug safety risks in a timely fashion, challenges in its ability to monitor drug safety in populations that were not included in the drug approval process (e.g., children, pregnant women, and the elderly), and safety issues with off-label medication use.⁶ Because of its sophisticated health information technology system, the Veterans Health Administration (VHA) has a unique opportunity and capacity to provide a model system for proactive postmarketing surveillance of medications.

Proactive medication safety surveillance does not necessarily rely on reports of adverse events (AEs) associated with drugs to initiate an investigation.⁸ Historically, voluntary spontaneous reporting systems have focused on adverse drug reactions, defined as responses to a drug that are noxious and/or unintended at doses normally used for treatment.⁹ The VHA Patient Safety Center of Inquiry (PSCI) in Tampa, FL, has undertaken a series of proactive medication safety surveillance studies that have focused on adverse health outcomes where the literature has identified medications as a risk factor. These studies have used multivariate analyses focused on the adverse outcome as the dependent variable in the study and temporally linked selected medications as an independent variable to the adverse outcome. These AEs included adverse drug reactions and other adverse outcomes, such as fall-related fractures, that occurred while patients were prescribed a category or class of medication.¹⁰ This article provides an overview of these VHA proactive medication safety surveillance studies and discusses the lessons learned from these studies within the context of the current FDA postmarketing surveillance policy debate.

Current U.S. Initiatives

Potential postmarketing medication safety issues in the United States are largely identified by various AE reporting systems.¹¹ Medication safety incidents are reported to the FDA from several major sources: as manufacturer reports (AEs that result in serious injury and for which a medication error might be a component), direct contact reports (MedWatch),¹² reports from the U.S. Pharmacopeia (USP, e.g., U.S. Pharmacopeia MEDMARX[®] Program),¹³ and the Institute for Safe Medication Practices (ISMP).¹⁴ With other adverse drug event reporting systems (e.g., VHA Patient Safety Reporting System)¹⁵ or mandatory State serious AE reporting systems,¹⁶ events may or may not be reported to the FDA.¹⁷ Commentators have noted that problems with the FDA's postmarketing surveillance program include the need for more population-based data on medication usage and better use of existing data.^{7, 18, 19, 20}

Additionally, other issues raised have included the FDA's inability to require and enforce timely clinical studies of postmarketing drug safety, the limitations of the voluntary MedWatch reporting system, and limited resources currently devoted to the FDA's Office of Drug Safety.^{1, 7} The recent Institute of Medicine (IOM) study on drug safety underscored that two decades of studies have made recommendations addressing these same deficiencies in drug postmarketing surveillance programs in the United States.²

A fundamental recommendation from recent studies of the FDA's postmarketing surveillance system is the need for large-scale health care datasets to conduct population-based safety studies.^{2, 7} The recent General Accounting Office (GAO) and the IOM reports recommend that the FDA obtain large-scale datasets for postmarketing studies in order to enhance FDA medication safety activities.^{1, 2} A major finding of the GAO (2006) report was that the FDA needs to gain access to and analyze large-scale datasets from more diverse patient populations, over a longer period, through a postmarketing safety surveillance system utilizing electronic health care data systems.¹ The FDA has recognized the need for analyses of large-scale health care utilization datasets and has contracted with outside providers—largely managed care organizations and research institutions—to conduct them.^{6, 21}

Health care information in the United States is largely fragmented, so the ability to link medications to adverse outcomes of interest is limited. No U.S. organization exists that actively collects and analyzes national, population-based data on the linkage of medication use with a broad range of potential patient harms that span adverse drug reactions, injuries, and other serious medical conditions, such as strokes and acute myocardial infarctions (AMIs). Several countries, the World Health Organization (WHO), and the European Union (EU) have been actively developing more population-based medication safety surveillance systems.^{22, 23, 24, 25} These developing international systems are possible because they occur in countries with nationally financed health care systems that have the ability to link pharmacy and health care utilization data.

In recent years, the VHA has conducted postmarketing safety surveillance primarily through several mechanisms. These include an affiliation with the Research on Adverse Drug Events and Reports Project (RADAR),²⁶ the national VHA Center for Medication Safety,²⁷ and health services research. The RADAR project, partially funded by the VHA, focuses on identifying, evaluating, and disseminating information concerning serious adverse drug reactions.²⁶ This project primarily uses clinical event reports from investigators and other clinicians to initiate an investigation and then obtains data from other sources, which may include FDA case reports and literature reviews.²⁶ The VHA currently has a very robust medication safety program administered by its Pharmacy Benefits Management system (PBM), which conducts drug utilization reviews and maintains the sophisticated national health information technologies associated with its computerized prescribing and barcoded medication administration systems. The VHA's Center for Medication Safety, in conjunction with the National Center for Patient Safety, is responsible for coordinating adverse drug event reporting and medication safety administrative programs.²⁷

The VHA health service's research programs have historically supported a broad range of medication safety-related research. Recently, several new PSCIs were established and funded under the auspices of the VHA's National Center for Patient Safety (NCPS). These new Centers will focus their research activities on specific medication safety issues, such as risk assessment of drugs, medication reconciliation, and safer outpatient medication usage. These three new patient safety centers join with the Veterans Integrated Service Network (VISN) 8 PSCI in continuing the VHA's commitment to patient safety research.

Proactive Medication Safety Surveillance Studies at the VISN 8 Patient Safety Center of Inquiry, Tampa, FL

The VISN 8 PSCI was established in 1999 to conduct research on mobility-related safety issues in elderly veterans. It has established an international reputation in the areas of falls and safe patient handling and movement. Because of the recognized chance of certain medications to increase the risk of injurious falls in the elderly, for the past 5 years, the Center has been developing the research capacity for proactive medication safety surveillance studies similar to the Agency for Healthcare Research and Quality's (AHRQ) DEcIDE (Developing Evidence to Inform Decisions about Effectiveness) project.²⁸

The DEcIDE project is developing a database that links administrative data with clinical components from the pharmacy, outpatient, inpatient, physician office, and emergency departments.²⁸ Center studies linking VHA administrative and clinical datasets have demonstrated the utility of using hospital discharge data to develop an injury and AE surveillance system for the VHA.²⁹ The Center's medication safety research over the last 5 years has produced studies that have examined drug-related adverse outcomes in many care settings.^{30, 31, 32, 33, 34, 35, 36, 37, 38} The usefulness of VHA national data for proactive medication safety surveillance, or enhanced pharmacovigilance studies, is based on the ability of researchers to link national data on health care utilization from all VHA datasets across care settings.

Postmarketing medication safety studies have largely relied on spontaneous, passive reporting systems.² Spontaneous reporting systems are limited by the fact that clinicians may fail to identify and report illnesses that they suspect are not due to a drug. This has led to the development of systems in other countries (mainly in the EU) based on reporting all AEs in the initial postmarketing period.^{39, 40} Proactive medication safety studies, with the proper data and methods of analysis, can be expanded beyond adverse drug reactions and recognized adverse drug-drug or drug-disease interactions to encompass a broader range of patient harms and injuries to provide a more robust, proactive medication safety surveillance system.^{29, 34, 38}

These kinds of proactive studies are largely hypothesis-generating and enhanced signal-detection studies that may identify associations between medications and the outcomes of interest over a longer period. However, it must be noted that these studies are primarily aimed at hypothesis testing or enhanced detection of safety signals. These kinds of studies require clinician involvement in their design and interpretation. The ultimate determination of safety issues requires further examination and studies that could include examination of the patients' medical records, consultations with manufacturers, and the involvement of the FDA.

The IOM report recommended that the FDA adopt an approach to drug risk and benefit that extends more comprehensively past the initial approval process.² Another recommendation (IOM recommendation 4.3, 2006) was that the FDA collaborate with public and private organizations and use data from publicly funded health care programs, including the Department of Veterans Affairs (VA) and Department of Defense (DoD), to improve the drug safety system with partial public funding.² The VA and DoD datasets are components of comprehensive electronic health care data systems. This enhances their ability to rapidly and efficiently identify potential medication-related AEs that might merit further analysis using electronic medical records.

Recently, the Centers for Medicare & Medicaid Services (CMS) also recognized the usefulness of large-scale datasets for postmarketing surveillance in a proposed rule.⁴¹ The rule proposes that the new Medicare Part D claims data be used for a variety of purposes, including postmarketing surveillance activities by the FDA. These surveillance activities, according to the proposed rule, could: (1) include monitoring patterns of drug use in the elderly and the disabled with the goal of identifying unsafe or suboptimal patterns of use, (2) be used to identify rare but serious complications more quickly and effectively, or (3) be used to facilitate formal epidemiologic studies examining the nature and magnitude of risk associated with particular medications.⁴¹

When linked to Medicare health care utilization data, these Medicare Part D pharmacy claims data could create a more effective postmarketing medication safety surveillance system. Currently, these kinds of proactive postmarketing studies of medications in specific populations—e.g., a larger group of aged patients with chronic diseases and long-term medication usage—are not widely published in the United States.

Lessons Learned from Center Medication Safety Research

The major lessons learned from developing the capacity for VHA proactive medication safety surveillance research are summarized below:

Large scale pharmacy datasets capable of being linked to health care utilization data are critical for identifying groups of patients who were exposed to a particular medication and the effect of that exposure to the health outcome of interest. This is especially important when the outcome of interest is a very rare event. The VHA maintains national pharmacy datasets that include inpatient and outpatient settings of care. In contrast to individual reports of adverse drug reactions, national pharmacy data allow one to put AEs, or health outcomes of interest, into a population-based context. Large-scale pharmacy administrative datasets that include unique patient identifiers can be used to rapidly identify a population of patients exposed to a particular medication of interest. This provides a “denominator” of patients exposed to the drug and a critical context for determining the subsequent effect of the adverse outcome of interest. The Center’s studies temporally linked these patients to their health care utilization to see which patients had the AE or outcome of interest. An example of this kind of Center study was the research on COX-2 inhibitor usage linked with hospitalizations for an AMI or stroke.³⁸

Proactive medication surveillance systems require detailed information on relatively large numbers of patients who have been prescribed the medication, in addition to comprehensive data on their health care utilization. VHA studies have demonstrated the utility of using clinical datasets to rapidly identify populations exposed to medications of interest to study outcomes of interest that are either relatively common or rare. Without sufficient information on the numbers of potentially affected patients (i.e., a denominator), it is difficult to evaluate the effect on the VHA system of the safety of a medication, especially for very rare AEs. An example is the Center’s study of Viagra[®] use and the potential for patients using the drug to develop ischemic optic neuropathy.⁴²

Linked administrative health care data can be used to identify a broader spectrum of adverse outcomes and associated health care utilization costs beyond adverse drug reactions or adverse drug events. These kinds of studies—which represent a major paradigm shift from the current focus of postmarketing safety studies—greatly expand the scope of medication safety surveillance into new areas, where medications themselves are a risk factor for the occurrence or development of an adverse outcome. This is exemplified by the Center’s studies of hospitalizations and costs for fall-related injuries temporally linked to the use of psychotropic medications.^{29, 30, 32}

These kinds of studies are the logical extension of new initiatives from accreditation activities, such as the Joint Commission’s patient safety goals related to medications and fall-risk

assessment. Recent patient safety initiatives have recognized the importance of patient medication assessments in relation to injury risk profiles. An example is The Joint Commission's use of the patient safety goals to accurately and completely reconcile medications across the continuum of care and to reduce the risk of patient harm resulting from falls through assessments that include patients' current medication profiles.⁴³

Medication safety surveillance employs epidemiologic methods to identify and analyze potential adverse outcomes associated with the use of medications. Adverse outcomes can encompass more than adverse drug reactions. The FDA has defined pharmacovigilance as "all post-approval scientific and data gathering activities relating to the detection, assessment, understanding, and prevention of AEs or any other product-related problems."⁴⁴

"Pharmacovigilance" is defined in a WHO report as "the science and activities relating to the detection, assessment, understanding, and prevention of AEs or any other possible drug-related problems."⁴⁵ Center studies have demonstrated the usefulness of linked datasets to explore the associations of medications with a broader range of AEs, especially in the elderly veteran population.

Proactive medication safety analyses can be used to identify major drug-drug interactions that were associated with AEs temporally and where these interactions were modeled as independent risk factors for adverse outcomes, such as injuries. An example of this kind of Center study is an analysis of concomitant use of benzodiazepines and other medications linked to adverse outcomes, such as fall-related injuries in elderly veterans.³³

Drug-drug interactions are widely evaluated in drug utilization reviews and in studies of potentially inappropriate prescribing for selected subpopulations.^{46, 47, 48} However, few studies have used large-scale, population-based datasets to examine the influence of drug-drug interactions on other relatively common adverse health outcomes, such as fall-related injuries.^{31, 32, 33} These types of hypothesis-generating studies also facilitate the identification of rare, or previously unrecognized, serious AEs that can be further investigated, as suggested in the CMS proposed rule related to the potential uses of Medicare Part D prescription data.⁴¹

The use of large-scale national datasets allows researchers to conduct more sophisticated epidemiologic studies that incorporate multivariate analyses. These kinds of multivariate analyses can inform clinical decisionmaking by empirically specifying the nature and magnitude of the risk of having a particular adverse outcome associated with a medication. The Center's study of benzodiazepines and the risk of injury incorporated a multivariate analysis and provided information to health care providers on the risk of an injury associated with the interaction of benzodiazepine dose and duration, while controlling for other important factors.³¹

By using multivariate models that control for important confounders identified in comprehensive datasets, a more effective postmarketing surveillance system can be developed to protect patients against adverse outcomes and to inform clinical prescribing patterns. Specific information for clinicians, based on empirical research that quantifies the effect of medications on identified risks from more sophisticated multivariate modeling of risk factors, can guide safer prescriptive practices and positively influence patient safety. These kinds of sophisticated

pharmacoepidemiologic studies support the current Federal initiatives for expanded use of Medicare Part D claims data for research recommended in the proposed CMS rule and current AHRQ medication safety research initiatives.⁴¹

Proactive medication safety studies using population-based datasets can be used to develop medication and comorbidity profiles in the elderly linked to specific injuries or other health outcomes of interest. These kinds of studies can promote safer prescribing practices in elderly subpopulations and care settings. Center studies have demonstrated that analyses can be conducted to produce profiles of patients that include summaries of their medication and comorbidity profiles. These profiles have been included in Center analyses that have examined the association of these patient profiles with outcomes of interest such as treatment for outpatient fractures or inpatient hospitalizations for syncope.^{34, 36}

Polypharmacy and multiple chronic diseases are common in the elderly population.^{33, 46, 47, 48, 49, 50, 51} Premarketing medication studies typically do not include patients with multiple comorbidities or patients taking multiple medications. Targeted proactive postmarketing surveillance could be especially valuable for these types of vulnerable populations. This is a recognized limitation of the current FDA drug approval process, noted in a recent IOM report (2006), that could be partially addressed by the proposed CMS rule.^{2, 41} Medication and comorbidity profiles derived from large-scale datasets permit proactive, hypothesis-generating studies of health care utilization and could lead to safer prescribing practices in specific patient cohorts. Proactive medication safety studies that incorporate medication and comorbidity profiles, a common occurrence in the elderly, would be responsive to the proposed uses of national Medicare Part D prescription data under several Federal research initiatives.⁴¹

A proactive medication safety surveillance system can be used on a national level to identify adverse outcomes and events in different settings of care that are associated with selected medications. Center studies have examined national data on adverse health outcomes associated with selected medication usage in long-term care, acute care hospitalizations, and outpatient treatment settings.^{29, 32, 34, 37}

The CMS proposed rule for sharing Medicare Part D data linked to Medicare Parts A and B data would permit more rapid and effective investigations of medication-related adverse outcomes in different populations and care settings, similar to the Center's research and other VHA research.⁴¹

Conclusion

The Center's medication safety studies have demonstrated the utility of conducting research using the VHA's national administrative datasets for proactive medication safety surveillance. The Center's studies have been focused on identifying potential medication-related AEs in different care settings and in specific populations. These studies have explored hypotheses about the association between certain medications and selected health outcomes of interest to the Center and the VHA. The studies have demonstrated the utility of these national comprehensive VHA datasets to enhance proactive medication safety surveillance studies and to enhance signal detection for AEs.

The current policy debate about improving the FDA's postmarketing surveillance activities underscores the importance of regulator and researcher access to large-scale health care datasets to conduct research similar to the VHA's studies. The current Congressional debate on the exact kinds of postmarketing safety study provisions to include in the final legislation concerning the Prescription Drug User Fees Act amendments (PDUFA IV) underscores the public interest in providing for more rigorous and timely postmarketing safety studies.⁵² Large-scale national datasets, although necessary to identify potential medication-related AEs, are not sufficient for a comprehensive medication safety surveillance system.

More definitive studies of medication safety ultimately require access to information usually available only in medical records. Ideally, these should be electronic medical records similar to the VHA's electronic medical record system. The VHA's comprehensive national programs in postmarketing surveillance have been in place for several years and encompass administrative programs and an extensive array of health services research initiatives.⁵³ Recently, the VA and the FDA entered into a memorandum of understanding to allow collaborative safety research initiatives capitalizing on the richness of the VHA's national datasets and expertise.⁵⁴

Many safety research initiatives are currently underway that can inform the direction of the FDA postmarketing surveillance debate in Congress. These include the VHA programs, drug safety surveillance programs in other countries, and health services research being conducted in numerous sites across the United States. The current AHRQ medication safety research initiatives under the DEcIDE program constitute a promising avenue of Federally supported health research in the effectiveness of health care services. Health care systems, providers, and insurers have important contributions to make to the current FDA policy debate based on their own internal data systems and medication safety program initiatives. Medication safety, cost, and effectiveness studies will continue to be important public policy concerns as the Medicare Part D drug prescription program matures in the coming years. New directions and alternative approaches in postmarketing surveillance studies will continue to be an important area for future health services research.⁵⁵

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References

1. Drug safety: Improvement needed in FDA's postmarket decision-making and oversight process. Report No.: GAO-06-402; Washington, DC: US Government Accountability Office; 2006 March.
2. Baciú A, Stratton K, Burke SP, eds. The future of drug safety: Promoting and protecting the health of the public. Committee on the assessment of the U.S. drug safety system, Board on Population Health and Public Health Practice. Washington, DC: Institute of Medicine; 2006.
3. Sibbald B. Rofecoxib (Vioxx) voluntarily withdrawn from market. CMAJ 2004; 17: 1027-1028.
4. Grassley C, Baucus M, Graham D, et al. FDA, Merck and Vioxx: Putting patient safety first? United States Senate Committee on Finance; 2004. Available at: news.publicfindlaw.com/hdocs/docs/vioxx/111804vioxxhrngs.html. Accessed April 10, 2008.
5. Carpenter D, Ting MM. Essay: The political logic of regulatory error. Nat Rev Drug Discov 2005; 4: 819-823.
6. Report to the nation: Improving public health through human drugs. Rockville, MD: U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER); 2005.
7. Gottlieb S. Opening Pandora's pillbox: Using modern information tools to improve drug safety. Health Aff (Millwood) 2005; 24: 938-948.
8. Pharmacovigilance planning: Planning of pharmacovigilance activities. Report No.: CPMP/ICH/5716/03. London: The European Agency for the Evaluation of Medicinal Products (EMA); Report No.: CPMP/ICH/5716/03; 2003 November 20.
9. International drug monitoring: The role of national centres. Technical Report Series No 498. Geneva, Switzerland; World Health Organization; 1972.
10. Aronson JK, Ferner RE. Clarification of terminology in drug safety. Drug Saf 2005; 28: 851-870.
11. Smetzer JL, Cohen MR. Medication error reporting systems. In: Medication errors. 2nd ed. Washington, DC: American Pharmacists Association; 2006.
12. U.S. Food and Drug Administration (FDA). MedWatch; 2006. Available at: www.fda.gov/medwatch/. Accessed April 14, 2008.
13. United States Pharmacopeia (USP). MEDMARX®. Rockville, MD: U.S. Pharmacopeia; 2006. Available at: www.usp.org/products/medMarx/. Accessed April 14, 2008.
14. U.S. Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP) USP-ISMP Medication Errors Reporting Program (MERP); 2006. Available at: www.usp.org/hqi/patientSafety/mer/. Accessed April 14, 2008.
15. Department of Veterans Affairs (VA). Patient safety reporting system. Patient Safety Resources: National Center for Patient Safety; 2006. Available at: www.va.gov/ncps/. Accessed April 14, 2008.
16. Rosenthal J, Booth M. Maximizing the use of State adverse event data to improve patient safety. Portland, ME: National Academy for State Health Policy; 2005.
17. Aspden P, Wolcott J, Bootman JL, et al, eds. Preventing medication errors: Quality chasm series. Committee on Identifying and Preventing Medication Errors. Washington, DC: Institute of Medicine; 2006.
18. Lenzer J. U.S. government agency to investigate FDA over rofecoxib. Br Med J 2004; 329: 935.
19. Rodriguez EM, Staffa JA, Graham DJ. The role of databases in drug postmarketing surveillance. Pharmacoepidemiol Drug Saf 2001; 10: 407-410.
20. Avorn J. Powerful medicines: The benefits, risks, and costs of prescription drugs. New York: Alfred A. Knopf: Distributed by Random House; 2004.
21. FDA awards contracts on databases of adverse effects of marketed drugs ability to monitor approved drugs enhanced. FDA Talk Paper #T05-30. Rockville, MD: Food and Drug Administration; 2005 October 7. Available at: www.fda.gov/bbs/topics/answers/2005/ans01368.html. Accessed April 14, 2008.
22. Assessment of the European community system of pharmacovigilance. Karlsruhe, Germany: Fraunhofer Institute for Systems and Innovation Research; Service Contract No: FIF.20040739; 2006 January 25.
23. Practical pharmacovigilance. In: WHO Collaborating Centre for International Drug Monitoring. Uppsala, Sweden: The Uppsala Monitoring Centre; 2006.
24. de Vries F, de Vries C, Cooper C, et al. Reanalysis of two studies with contrasting results on the association between statin use and fracture risk: The general practice research database. Int J Epidemiol 2006; 35: 1301-1308.
25. Paterson JM, Laupacis A, Bassett K, et al. Using pharmacoepidemiology to inform drug coverage policy: Initial lessons from a two-province collaborative. Health Aff (Millwood) 2006; 25: 1436-1443.
26. Bennett CL, Nebeker JR, Lyons EA, et al. The Research on Adverse Drug Events and Reports (RADAR) project. JAMA 2005; 293: 2131-2140.

27. National Center for Patient Safety. Department of Veterans Affairs (VA); 2006. Available at: www.va.gov/ncps/. Accessed April 10, 2008.
28. Medicare prescription drug data development: Methods for improving patient safety and pharmacovigilance using observational data. DECIDE Projects in Progress; Rockville, MD: Agency for Healthcare Research and Quality; 2006.
29. Campbell R, Bradham D, Sanchez-Anguiano A, et al., eds. Developing a VHA Serious Injury Surveillance System. Advances in patient safety: From research to implementation. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol1/Campbell.pdf. Accessed April 10, 2008.
30. French D, Spehar A, Campbell R, et al. Outpatient benzodiazepine prescribing, adverse events, and costs. Advances in patient safety: From research to implementation. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol1/French.pdf. Accessed April 10, 2008.
31. French DD, Campbell R, Spehar A, et al. Benzodiazepines and injury: A risk adjusted model. *Pharmacoepidemiol Drug Saf* 2005; 14: 17-24.
32. French DD, Campbell R, Spehar A, et al. Outpatient medications and hip fractures in the United States: A national veterans study. *Drugs Aging* 2005; 22: 877-885.
33. French DD, Chirikos TN, Spehar A, et al. Effect of concomitant use of benzodiazepines and other drugs on the risk of injury in a veterans population. *Drug Saf* 2005; 28: 1141-1150.
34. French DD, Campbell R, Spehar A, et al. National outpatient medication profiling: Medications associated with outpatient fractures in community-dwelling elderly veterans. *Br J Clin Pharmacol* 2007; 63: 238-244.
35. French DD, Campbell R, Spehar A, et al. Drugs and falls in community-dwelling older people: A national veterans study. *Clin Ther* 2006; 28: 619-630.
36. French DD, Campbell R, Spehar A, et al. National Veterans Health Administration hospitalizations for syncope compared to acute myocardial infarction, fracture, or pneumonia in community-dwelling elders: Outpatient medication and comorbidity profiles. *J Clin Pharmacol* 2006; 46: 613-619.
37. French DD, Campbell RR, Spehar AM, et al. How well do psychotropic medications match mental health diagnoses? A national view of potential off-label prescribing in VHA nursing homes. *Age Ageing* 2007; 36: 107-108.
38. French DD, Spehar A, Campbell R, et al. A medication surveillance system model to improve patient safety: A national veterans study of cyclooxygenase 2 inhibitors and risks of stroke or myocardial infarction. *J Patient Saf* 2006; 2: 78-82.
39. Coulter D. PEM in New Zealand. In: Mann R, Andrews E, eds. *Pharmacovigilance*. Chichester, UK: Wiley & Sons; 2002.
40. Shakir S. PEM in the UK. In: Mann R, Andrews E, eds. *Pharmacovigilance*. Chichester, UK: Wiley & Sons; 2002.
41. Center for Medicare & Medicaid Services (CMS). Medicare Program; Medicare Part D data, Proposed Rule. *Federal Register* 2006; 71: 61445-61455.
42. Margo C, French D. Ischemic optic neuropathy in male veterans prescribed phosphodiesterase-5 inhibitors. *Am J Ophthalmol* 2007; 143: 538-539.
43. Facts about the 2007 National Patient Safety Goals. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations. Available at: http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/07_npsg_facts.htm. Accessed April 10, 2008.
44. Risk assessment of observational data: Good pharmacovigilance practices and pharmacoepidemiologic assessment. Concept paper. Rockville, MD: U.S. Food and Drug Administration; 2003 March 3; Docket number 02N-0528.
45. The safety of medicines in public health programmes: Pharmacovigilance an essential tool. Geneva, Switzerland: World Health Organization; 2006. ISBN 92 4 159391 1 (NLM classification: QV771). Available at: www.who.int/medicines/areas/quality_safety/safety_of_therapy/Pharmacovigilance_B.pdf. Accessed April 10, 2008.
46. Zhan C, Correa-de-Araujo R, Bierman AS, et al. Suboptimal prescribing in elderly outpatients: Potentially harmful drug-drug and drug-disease combinations. *J Am Geriatr Soc* 2005; 53: 262-267.
47. Hanlon JT, Lindblad CI, Hajjar ER, et al. Update on drug-related problems in the elderly. *Am J Geriatr Pharmacother* 2003; 1: 38-43.
48. Allard J, Hebert R, Rioux M, et al. Efficacy of a clinical medication review on the number of potentially inappropriate prescriptions prescribed for community-dwelling elderly people. *CMAJ* 2001; 164: 1291-1296.
49. Lindblad CI, Hanlon JT, Gross CR, et al. Clinically important drug-disease interactions and their prevalence in older adults. *Clin Ther* 2006; 28: 1133-1143.

50. Perucca E, Berlowitz D, Birnbaum A, et al. Pharmacological and clinical aspects of antiepileptic drug use in the elderly. *Epilepsy Res* 2006; 68 (Suppl 1): S49-S63.
51. French D, Campbell R, Spehar A, et al. How well do psychotropic medications match mental health diagnoses? A national view of potential off-label prescribing in VHA nursing Homes. *Age Ageing* 2007; 36: 107-112.
52. FDA letters transmitted to Congress, March 16, 2007 concerning prescription drug users fees amendments 2007 (PDUFA IV). Available at: www.fda.gov/oc/pdufa/default.htm. Accessed April 10, 2008.
53. Campbell R, French D, Cunningham F. Enhancing post-marketing surveillance: Lessons from the Veterans Health Administration. Presentation at the 3rd Annual Harvard FDA Compliance symposium. Boston, MA. August 24, 2007. Powerpoint presentation available at: www.ehcca.com/presentations/fdasymposium3/campbell_4.ppt. Accessed April 10, 2008.
54. Memorandum of understanding between the Food and Drug Administration and the Veterans Health Administration, Department of Veterans Affairs. MOU number 225-07-4300; 2007 January. Available at: www.fda.gov/oc/mous/domestic/225-07-4300.html. Accessed April 10, 2008.
55. Developing Evidence to Inform Decisions about Effectiveness: The DEcIDE Network: Request for Proposals; 2005 July. Rockville, MD: Agency for Healthcare Research and Quality. Available at: www.ahrq.gov/fund/contarchive/rfp050010.htm. Accessed April 10, 2008.

Medical Product Safety Network (MedSun) Collaborates with Medical Product Users to Create Specialty Subnetworks

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Abstract

The U.S. Food and Drug Administration (FDA) is now in its fifth year of identifying medical device-associated risks through the Medical Product Safety Network (commonly known as MedSun). MedSun has expanded nationally to 350 facilities. These are primarily hospitals, but outpatient clinics, nursing homes, and home health agencies are also represented. The basic reporting team for each participating site comprises primarily risk managers and clinical patient safety officers. MedSun participants receive device-related feedback from the FDA relevant to their reported issues. In particular, the exchange of device-related safety information and reports on adverse events with the clinical community provides the FDA Center for Devices and Radiological Health (CDRH) MedSun program with enhanced understanding of medical device-related problems. In order to reach more deeply into the participating hospitals to obtain incident information from the actual clinical users of the medical devices, MedSun is now implementing targeted surveillance efforts that are directed toward “high-risk” areas of the hospitals. This effort has resulted in the development of subnetworks within MedSun to give attention to the types of products of interest to the FDA. Currently, four subnetworks have either been launched or are under development for data collection that began in 2007. The goal is to build relationships between MedSun/FDA and frontline medical device users so the FDA can work with clinicians to learn about, understand, and solve problems related to the use of medical devices. The FDA is evaluating the impact of developing these reporting relationships on the overall effectiveness of MedSun data collection. The subnetworks also offer the FDA an opportunity to obtain more “real-time” information from subnetwork participants through focus group discussions, teleconferences, and educational offerings.

Introduction

The Medical Product Safety Network, commonly known as the MedSun Program, is a United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) program that works with a sample of hospitals, nursing homes, and other health care facilities (350 sites nationwide) to:

- Rapidly identify and understand problems related to the use of medical devices.
- Provide a “laboratory” for research into understanding problems with these medical products as they are used in the clinical environment.
- Provide actionable feedback to the clinical community.

The key element of MedSun is its relationship with a relatively small, specifically trained, and motivated group of reporters from each MedSun site. These MedSun reporters typically include a risk manager and a biomedical or clinical engineer from each site, but many sites also include quality managers, material managers, patient safety managers, and clinicians on their MedSun teams. They send reports about problems with the use of medical devices through the secure online system into the FDA database. The FDA provides feedback to the MedSun reporters so they can improve patient safety related to the use of medical devices at their sites.

MedSun has used a “train-the-trainer” model, which employs numerous educational tools for MedSun reporters to use with health care professionals throughout the hospital. These tools promote staff recognition of device-related events and encourage notification through the hospital’s in-house reporting system, which the designated reporter then passes on, when appropriate, to MedSun. MedSun sites also help the FDA understand device issues by responding to surveys, participating in focus groups, and providing clinical experts to participate in individual telephone interviews on an as-needed basis.

The specifics of the early years of MedSun, and the concepts used to build the beginning phases of this highly collaborative, interactive, and successful reporting program, were presented in the Agency for Healthcare Research and Quality (AHRQ) 2005 publication *Advances in Patient Safety: From Research to Implementation*.¹

This update provides a brief overview of the program to date and then a lengthy discussion of the newest phase of MedSun, its subnetworks, which target specific clinical specialty areas to obtain information directly from end users of devices and human tissue and cell products.

Update on Current MedSun Program

The FDA has been working with a contractor, Social & Scientific Systems, Inc. (SSS), in Silver Spring, MD, to design and implement MedSun since 1996. Data collection began in February 2002 with 25 sites on the east coast. The cohort reached 350 sites across the continental United States in 2005. As of July 31, 2007, data collection had yielded the types and number of outcome reports shown in Table 1.

MedSun encourages the reporting of medical product problems before a patient is injured or dies because of the use of that medical product. This permits the FDA, the clinical community, and device manufacturers to become aware of and solve problems before patients are injured. The very large percentage of reported problems falling into the “potential for harm” category speaks to the responsiveness of the MedSun sites to this important patient safety agenda.

The most recent MedSun Annual Report, issued in March 2007, demonstrated that MedSun reports have been extremely useful in improving patient safety nationwide.² Here are a few facts concerning actions stemming from the FDA and manufacturer receipt of MedSun adverse event reports:

- Ten device recalls and 39 other manufacturer actions (e.g., letters issued to customers, improving labeling, changing suppliers to obtain parts, and current and future design improvements) came out of review of information provided in MedSun reports.
- Eight CDRH investigatory teams were formed to investigate and solve complex issues, which required a multidisciplinary approach.
- A variety of followup efforts were implemented to learn more about certain medical device issues, including focus groups and surveys of professionals from the MedSun sites.
- Safety tips (five in total) were written. Sometimes the best approach in helping to solve a problem is to develop educational articles for members of the clinical community about safer ways to interact with the devices they use.

Table 1. Patient safety data reported to MedSun through July 31, 2007

Reported outcome	N ^a
Death	184
Serious injury/illness	828
Minor injury	1,132
Potential harm to patients	5,312
Potential harm to health care provider	371
“Other” (e.g., out-of-box failures, reports of poorly designed devices, complaints about manufacturers)	1,371
Total outcomes	9,198

a Total number of reports = 8,767; some reports showed more than one outcome.

Expanding MedSun to Include Subnetworks

The MedSun program is highly successful in generating signals about problems with medical devices. Due to the success of this model, the FDA explored avenues for increasing the number and quality of reports from “high-risk” areas of the MedSun sites. Numerous areas in hospitals utilize devices that are considered “high-risk” or serve highly vulnerable populations. Given that the FDA does not have unlimited resources to investigate and address adverse events with medical devices, the question for the FDA became, “How and where in the hospital should MedSun focus its attention to increase the number and quality of reports?”

The answer to “how” was to create subnetworks within some selected existing MedSun facilities to include, as additional reporters, health professionals who work in areas where high-risk devices are used or where patients may be especially vulnerable. It was anticipated that this approach would increase the likelihood that the FDA would learn about device problems that occur in these selected areas. Also, access to frontline users of devices in these “high-risk” areas would enable the FDA to quickly canvass several users to see if they were having problems similar to those reported by others in the subnetwork. This strategy increased MedSun’s enhanced surveillance to the level of obtaining information in “real-time” when needed.

Selecting the Subnetworks

The idea of “subnetworks” was the easy part. The hard part was selecting the “where” because of the many areas in the reporting facilities where “high-risk” devices are in use. Narrowing the subnetworks to a few areas was important due to the resource-intensive effort necessary to recruit and orient health care professionals in the subnetworks; develop useful feedback to the subnetworks, which the reporters could use to improve patient safety; develop ongoing educational opportunities to keep the reporters engaged in each subnetwork; and to process, analyze, and take action on the large increase in reported issues that was expected.

It was critical to target subnetworks that would provide CDRH with timely information about rare events that is often difficult to obtain from the broader MedSun program, from registries, from the literature, or from other sources. Therefore, the MedSun team announced to CDRH that it wanted to create these subnetworks and asked for input.

In 2004, Steven Gutman, MD, the Director of the Office of In-Vitro Diagnostic Evaluation and Research (OIVD) in CDRH, asked the MedSun team to provide his office with a connection to clinical laboratories within hospitals so that OIVD could have more in-depth and timely reports directly from the laboratories about problems with in vitro diagnostic products and point-of-care devices, such as glucose meters. Thus, LabNet was conceived and created. The lessons learned from LabNet have provided the basis for design of the subnetworks that came afterwards: the Tissue/Cell subnetwork (implemented for our sister FDA Center – the Center for Biologics Research and Development), HeartNet, and KidNet.

In 2005, while LabNet was being launched, FDA’s Center for Biologics Evaluation and Research (CBER) contacted the CDRH MedSun team to explore the inclusion of human cells, tissues, and cellular and tissue-based products (HCT/Ps) as products that certain hospitals would be trained to report about through MedSun. CDRH staff were very interested in collaborating with a sister Center within the FDA to help ensure the safety of additional types of medical products. FDA staff from CDRH and CBER began developing the Tissue and Cell Pilot Project to obtain information from MedSun sites about adverse events and events representing potential for harm associated with various types of tissues, cells and related products.

The concept for HeartNet took hold in 2005 when Thomas Gross, MD, MPH, the Director of the Division of Postmarket Surveillance within CDRH, asked the MedSun team to develop a subnetwork that would collect unanticipated/unexpected problems with devices used in electrophysiology (EP) laboratories [e.g., cardiac pacemakers and implantable cardioverter defibrillators (ICDs), ablation catheters]. ICDs had been the focus of highly publicized recalls in 2005 and 2006, and CDRH receives thousands of reports about these types of devices, so it is well informed about the routine types of problems seen with them. However, rare or unusual problems often go unreported.

Therefore, Dr. Gross asked that electrophysiologists be recruited from within MedSun hospitals who would be highly motivated to report device-related adverse events that, based on their clinical experience, were something they believed to be unanticipated or unexpected. Additionally, he requested that these volunteers be willing to respond quickly to the FDA’s queries about whether they too might have experienced a particular problem about which the FDA needed more information. This would provide the ability to quickly amplify a particular

problem, so that the FDA could ascertain whether a problem might be widespread. This strategy has quickly been incorporated into the other subnetworks as well.

The importance of developing a subnetwork focusing on pediatrics was clear from the early concept development of the subnetworks. Numerous special issues surround medical device use in children. One example is the lack of clinical data on how the pediatric population responds to treatment with many of the medical devices used in the pediatric setting. Clinical trials might have included adults, but once a device is cleared for marketing, it might also be used on children because of the lack of a pediatric version of the product. Since children might react in unexpected ways to devices, it seemed critical for the pediatric clinical community to be aware of the types of problems that could occur.

In 2007, MedSun began planning and developing KidNet. This subnetwork focuses on collecting data from neonatal intensive care units (NICUs) and pediatric intensive care units (PICUs). Participation in this subnetwork is not limited to MedSun pediatric specialty hospitals but extends to all MedSun hospitals with large NICUs and PICUs. This broader inclusion of hospital types provides for larger numbers of reported events. KidNet data collection began in June 2007.

LabNet

CDRH estimates that 80 percent of all professionals' medical decisions are determined from laboratory results, with 15 to 50 billion health care dollars spent on laboratory tests each year. Laboratory tests and their results play a prominent role in the diagnosis of patients' conditions and constitute a foundation of modern medical practice. The primary goal of OIVD is to ensure the safety and effectiveness of in vitro diagnostic (IVD) devices. An important instrument in the FDA's "toolbox" to ensure the safety and effectiveness of IVD devices is the active surveillance of "signals" and of any adverse events associated with their use.

OIVD relies heavily for adverse event data on IVD devices on LISTSERVs™, literature reviews, manufacturer reports, trade complaints, consumer complaints, government reports, and manufacturers' recalls. In early 2006, OIVD wanted to enhance its surveillance efforts to include a more active type of monitoring using the MedSun program. LabNet was then developed as the first MedSun subnetwork in collaboration with OIVD.

LabNet has two principal objectives. The first is to promote health care providers' awareness about IVD devices and their role in patient safety. Thus, staff working in hospital laboratory areas and "sharp-end" clinicians in patient care settings are targeted as candidates for education and training geared toward promoting this awareness. LabNet's training efforts encompass a broad scope of clinicians: hospital laboratory directors and managers, medical technologists, and bench technologists, as well as clinicians in various patient care areas.

LabNet's second objective is to emphasize the importance of adverse event reporting to OIVD about both adverse events and situations indicating the potential for harm related to these devices. LabNet is designed to collect information about devices, whether problems (e.g., with point-of-care devices like glucose meters) have been observed in hospital laboratories or in clinical patient care areas.

LabNet was created after a small MedSun pilot effort in 2004 and 2005 indicated that OIVD could obtain very important reports about problems with diagnostic devices from laboratories. Although the number of reports received was small, the vast majority of the reports provided important information that was the first signal OIVD received about these issues.

The pilot provided lessons that were incorporated into the current design of LabNet. For example, OIVD became aware that laboratories expected direct and timely feedback from the FDA in exchange for their reporting efforts, they required reminders to report, and they needed a system of adverse event reporting that was simple and fairly quick (e.g., using forms that could be completed in less than 15 minutes). Obstacles to reporting adverse events to the FDA were identified as well. For instance, the culture in many hospital laboratories fosters reporting only to manufacturers and not necessarily directly or indirectly to the FDA. Bench and medical technologists, who were in the best position to witness errors, were often unaware of the importance of reporting adverse events (actual and potential) to the FDA. The pilot's participants commented that staff were confused about exactly what products/situations merited reports.

These lessons suggested that LabNet would require an education program at its onset. Such a program would focus on identifying IVD devices and the problems that can occur with them, stressing the importance of reporting to the FDA adverse events and the potential for harm, and highlighting the benefits for public health. Additionally, a successful data collection effort would require useful feedback to the participants and frequent followup efforts on OIVD's behalf.

During the planning effort for LabNet, OIVD staff indicated the kinds of situations that were of interest to them as regulators. These included (but were not limited to) incorrect diagnosis as a result of inaccurate laboratory results, inappropriate labeling, unclear instructions in labeling/packaging, repeated quality control failures, defective sample collection devices, and calibration failures.

In July 2006, OIVD "kicked off" the LabNet network with an informational audioconference for all MedSun participants, including an invitation for MedSun hospitals to participate in the subnetwork. More than 60 individuals called, with 30 sites then committing to LabNet participation. Since OIVD's Director was very interested in learning about the effectiveness of product labeling being made available to laboratories either online or via electronic format, during that same month, drawing upon those interested in the subnetwork, LabNet hosted a telephone focus group discussion concerning electronic labeling.

Within a few months, educational Web-cast orientation sessions were provided for MedSun representatives and laboratory staff members interested in participating in the network. The LabNet orientation provided participants with useful information on the reporting of adverse events involving IVD devices. Examples of laboratory devices were provided, along with a listing of the problems that could occur with such products and report examples.

To date, 50 network participants representing 25 MedSun facilities are involved in the pilot program. OIVD was also interested in increasing IVD device signaling from areas outside the MedSun communities. In 2007, they brought in the National Institutes of Health, which had not previously been participating in MedSun, as a LabNet site.

Roundtable discussions with a major health care system's laboratory managers began in March 2007. Discussion topics have included IVD device reports submitted by the health care system and the FDA's followup, exploration into the health care system's experiences with problems reported into OIVD (thus permitting "amplification" of the signal for OIVD), and an educational session on erroneous troponin results.

Feedback to the FDA about laboratory device reporting from such forums verified a culture of reporting IVD device problems primarily to the manufacturer. The managers did acknowledge that they understood that reporting only to the manufacturers leaves the FDA in the dark. As a common occurrence, many IVD device problems were taken care of by the manufacturers, and reporting to the FDA had usually been reserved for those few instances in which problems were not resolved in this way. All communications with manufacturers are logged in a log book for tracking purposes. With the health care system's permission, LabNet is piloting the use of a MedSun representative to review the log books to determine whether incidents of interest to OIVD can be found there.

All LabNet reports are reviewed by the LabNet team, followup and potential patient safety efforts are discussed, and actionable items are determined by the team. Patient safety actionable items might include placing reports in the MedSun newsletter to share with the general public, creating a safety tip, creating an internal working group to further explore problems, and involving CDRH's pre-market approval or compliance specialists (who work with manufacturers to improve products' safety and effectiveness).

Personal contact with LabNet participants has been critical to the program's success. Through one-on-one discussions with LabNet participants, OIVD has learned about issues pertaining to the lab values for special patient populations and important human factors regarding specific lab products. The MedSun annual conferences have also served as important opportunities for OIVD staff to build relationships with LabNet participants.

Preliminary efforts to measure the program's success demonstrate that for the 6-month period prior to LabNet's introduction, MedSun received eight reports involving in vitro products; for the following 6-month period, 16 reports were received. Although these are small numbers, this represents a 100 percent increase for IVD device reporting since the informational kickoff. During the first year of LabNet, 33 IVD device reports were submitted. The descriptive LabNet reports received by the FDA in this short period have been very useful.

OIVD finds LabNet a valuable resource because of the quality of the signals it generates. The training of staff at sites and the free exchange of information between sites and OIVD have contributed to the fact that LabNet is a particularly important source of post-market information. In addition, OIVD has benefited from two unique features of LabNet. The first is the ability to create, in a streamlined manner, focus groups to address old or emerging problems identified by this network or originating on the outside. The second feature is the ability, as noted above, to make personal connections between OIVD and working laboratory managers and workers. An initial series of information queries to representative members of the LabNet network has clarified OIVD thinking in the arena of patient safety monitoring from the perspective of laboratory services. Candid discussions with high-, moderate-, and low-volume laboratories have reinforced the view that, in general, the current regulatory framework for IVD devices is working

well; manufacturers are able to make and label quality products for routine laboratory use; and with few exceptions, manufacturers are also quite sensitive to needs, questions, and requests raised by the laboratories they supply.

Human Tissue and Cell Subnetwork

Just as CDRH regulates medical devices, CBER regulates human cells, tissues, and cellular- and tissue-based products, including (but not limited to) the following:

- Eye tissue (cornea).
- Sclera.
- Bone.
- Musculoskeletal soft tissue (tendons, fascia lata).
- Skin.
- Heart valves.
- Blood vessels.
- Dura mater.
- Reproductive cells (semen, oocytes, embryos).
- Hematopoietic stem cells (peripheral, cord).

Nonhuman cells and tissues (usually porcine or bovine), which are used in medical care, and human cells or tissues, which have been incorporated into nontissue products (e.g., mesh backings), are generally regulated by CDRH. Collaboration with regard to data collection was seen as mutually beneficial to both FDA Centers. The focus of the FDA Tissue and Cell Subnetwork is on detecting, understanding, and sharing information about adverse events and situations indicating potential for harm from these products.

The timing of this collaboration was especially important for CBER because in May 2005, the FDA implemented regulations that require HCT/P manufacturers to report serious adverse reactions to the FDA, if the reactions are related to their products and involve communicable disease. This regulation was followed by the issuance of a Joint Commission standard for hospitals, effective July 2005, which required hospitals to report to the suppliers of these products any adverse events for human cells, tissues, and related products.³ Under this Joint Commission standard, hospital staff report to the HCT/P establishment. The manufacturer, in turn, reports to the FDA for events required by FDA regulation (i.e., serious events involving communicable disease).

CBER staff wanted to learn more from health care facilities about problems with cells, tissues, and related products, in addition to the problem of infections. A MedSun subnetwork was seen as one way of facilitating that line of communication.

The subnetwork began recruitment in late 2005, at which time the FDA established a goal of enrolling at least 50 MedSun sites. By 2007, 58 sites had agreed to join and had personnel trained to report. An average of 38 sites have been enrolled in the program at any one time over the project's duration, and 99 personnel affiliated with MedSun sites have received training on

reporting HCT/P events through the MedSun Tissue and Cell Subnetwork. Many of these personnel are infection control practitioners, tissue managers, operating room staff with tissue- and cell-related knowledge and responsibilities, or clinical staff from hospital tissue or blood banks. Once they have completed the Web-cast orientation program, they report directly to MedSun through the secure online reporting system or through their risk managers.

Although the number of cell/tissue-related reports from this group has not been large (approximately 40 reports so far), the reports have augmented reporting to CBER for HCT/Ps. The 40 MedSun reports represent one-third of all voluntary (i.e., non-manufacturer-based) reports submitted to CBER during the project's operation and 12.1 percent of all HCT/P reports to CBER during that timeframe. By leveraging the infrastructure of the existing MedSun program, developing the Tissue and Cell Subnetwork has been a cost-effective way to augment the overall number of HCT/P reports submitted to the FDA.

The Tissue and Cell Subnetwork is the first enhanced surveillance program for HCT/P-related adverse events. CBER and CDRH staff are encouraged by the number and quality of the reports they have received and by the link the project provides to the clinical community. Infection-related MedSun reports are routinely investigated by CBER's Tissue Safety Team to detect any product-related disease transmissions. In one case, for example, a MedSun site reported a serious infection in an Achilles tendon. This event was eventually related to a recall by the tissue manufacturer of other tissues from the same donor, as the firm had discovered that another recipient of this donor's tissue had become infected with the same organism. The MedSun report expedited the Tissue Safety Team's investigation of this case.

The Subnetwork also serves as a conduit for participating sites to ask questions and receive feedback from CBER staff on FDA regulations, adverse reaction reporting, and other HCT/P-related concerns.

By not restricting reports to communicable disease-related events, the project broadens the scope of HCT/P reports normally submitted to the FDA. Sites are asked to submit any type of HCT/P related safety information, including noninfectious adverse events and problems with potential for harm, such as damaged products or labeling concerns. These events do not individually initiate FDA regulatory actions (although they might stimulate a response from the manufacturer). However, these reports are qualitatively different from the infectious adverse reactions normally submitted to CBER, and they provide insight for the Tissue Safety Team on the transplantation community's experience with HCT/Ps.

Because the HCT/P manufacturer also receives the report, the project also helps MedSun sites meet the Joint Commission requirement to report to the tissue establishment.

In June 2006, MedSun held an audioconference about this Subnetwork, during which CDRH and CBER learned from participating hospital representatives that the information presented through this Subnetwork was helpful to them, especially for complying with the new Joint Commission requirement for reporting on infections. Participating representatives also indicated that they liked being able to report about cells and tissues and related products using the MedSun system, as they do for medical devices.

MedSun staff provide feedback about the reports they receive and about activities related to this Subnetwork through the MedSun newsletter. In addition, weekly FDA recall information concerning biologics is provided to those MedSun participants who have opted to receive that service. The June 2006 audioconference also provided an opportunity for CBER staff to conduct educational outreach, presenting on the FDA's new regulations concerning adverse reaction reporting for HCT/Ps (21 CFR 1271).

A MedSun representative wrote an article for the MedSun newsletter in 2006 about how the Tissue and Cell Subnetwork has raised awareness about changes to certain procedures needed to remove recalled products from hospital shelves. As with the other subnetworks, educational programs will be developed for relevant staff to learn about the importance of their reports on cells and tissues and related products.

HeartNet and KidNet

HeartNet targets the collection of early warning data on newly emerging or unexpected device-related adverse event problems with diagnostic and therapeutic cardiac ablation, mapping, pacing, and defibrillation device-related adverse events occurring in the electrophysiology (EP) laboratory setting that are:

- Unexpected.
- Not commonly known.
- Not listed in the current labeling of the device.
- Commonly known, but more severe or specific than noted in the labeling.
- Commonly known, but occurring as part of an unanticipated cluster.

KidNet's focus is on identifying and reporting all medical device-related adverse events that occur in PICUs and NICUs and involve death or serious injury, or events that represent a "near miss," "close call," or "potential for harm" if the event is not caught in time in patients, family members, or health care providers. KidNet is particularly interested in problems with medical devices that fail or do not perform optimally in the pediatric patient population because of sizing or fit. Like other subnetworks, HeartNet and KidNet emphasize educating the "hands-on" device user to recognize and report medical device-related adverse events.

Building on the lessons learned with LabNet, the development of the HeartNet and KidNet subnetworks incorporated visits to various types of MedSun sites with EP laboratories or, for KidNet purposes, with ICUs for children and/or for newborns. These visits were undertaken to obtain information on organizational culture, with a special emphasis on reporting barriers that were unique to these clinical areas. Common barriers to reporting include:

- A lack of awareness by clinicians of the need to identify and report device-related problems.
- A perception of reporting being burdensome, since staff are already required to fill out many forms. Reporting needs to be fast, user-friendly, and easily accessible.
- A lack of feedback from the FDA. Such feedback should be easily accessible, convenient in light of staffing and patient care responsibilities, and limited to safety issues of clinical relevance.

To address these concerns, the HeartNet and KidNet Subnetworks collect and share information in three ways:

- Through user-friendly, easily accessible online reporting of adverse events or potential-for-harm events.
- Through discussion groups with CDRH and subnetwork colleagues to share information about medical device safety issues and lessons learned via audioconference, online, and through Web-cast formats.
- Through CDRH posting of “reports of interest” to the HeartNet and KidNet Subnetwork communities, in order to solicit collaborative, interactive feedback on Subnetwork participant experiences with similar device-related adverse events.

Most important, clinicians have the opportunity to learn how to recognize and report medical device-related adverse events within their clinical specialty areas by participating in free educational offerings via audioconference and Web-cast formats with continuing education credit awarded upon successful completion.

KidNet data collection began June 1, 2007, and HeartNet began data collection in the fall of 2007. As of August 2007, a dozen reports had been received from six KidNet participating hospitals on adverse events involving patient injury and device problems associated with intravenous pumps, infusion ports, tubing, catheters, orthopedic screws, and surgical instruments.

Conclusion

CDRH has found MedSun to be very helpful in its efforts to learn about medical device adverse events and situations indicating the potential for harm. However, there is a need for targeting certain kinds of products under the MedSun umbrella by reaching out to specialists in pediatric/neonatal intensive care, hospital laboratories, EP laboratories, and, for both CDRH and CBER, to those who are knowledgeable about tissues, cells, and related products in order to learn about product problems unique to these medical specialty areas.

For this reason, the MedSun subnetworks are being developed with an emphasis on recognizing and reporting adverse events by the health care professionals who use medical products in the clinical setting. Although much work remains, the results of these efforts are expected to increase the number and quality of reports the FDA receives concerning high-priority medical product adverse events and situations indicating potential for harm and to improve the feedback the FDA provides to the clinical community. These efforts should generate communication and collaborative partnerships between clinicians, the FDA, and medical product manufacturers to help ensure the safety and effectiveness of the types of medical products used in the subnetworks. The combined effects of the general MedSun program with the new MedSun subnetworks enhance the FDA’s ability to promote and protect the public health.

Those who may be interested in having their hospital or other health care facility join the MedSun Network should call 1-800-859-9821 or e-mail medsun@s-3.com for more information about this matter.

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References

1. Flack M, Reed T, Crowley J, et al. Identifying, understanding, and communicating medical device use errors: Observations from an FDA pilot program. In: Advances in patient safety: From research to implementation. Vol. 3, Implementation issues. AHRQ Pub. 05-0021-3. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol3/Flack.pdf. Accessed March 19, 2008.
2. CDRH 2006 highlights: October 1, 2005-September 30, 2006. Rockville, MD: Food and Drug Administration, Center for Devices and Radiological Health; 2007. Available at: <http://www.fda.gov/cdrh/annual/fy2006/>. Accessed June 4, 2008.
3. Comprehensive accreditation manual for laboratory and point-of-care testing (CAMLAB). Standards frequently asked questions. Oakbrook, IL: Joint Commission; 2005. See: www.jointcommission.org/AccreditationPrograms/LaboratoryServices/Standards/FAQs/default.htm. Accessed June 4, 2008.

Physician-Reported Adverse Events and Medical Errors in Obstetrics and Gynecology

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Abstract

Objective: To explore the feasibility of a novel method for capturing adverse and potential adverse events within an urban teaching hospital obstetrics/gynecology (OB/GYN) service.

Methods: At morning rounds during two 6-week periods, OB/GYN resident physicians were asked to complete incident reporting cards identifying obstacles to care, injuries or extended hospitalizations, and problems affecting their patients. Responses were coded by type of incident, consequences for the patient, responsible party, process-of-care deficiencies, and preventability of the incident. These were coded by a physician panel and compared with retrospective chart analysis and hospital incident review. **Results:** Eighty-two events were reported during the project period, 56 percent in obstetrics and 44 percent in gynecology, including 7 adverse and 38 potential adverse events. Retrospective chart review corroborated 76 percent of the events with only two noted in hospital incident reports. **Conclusion:** A physician-based voluntary reporting system in OB/GYN complements existing methods for identifying medical errors.

Introduction

Although the extent of medical error has been well characterized among general medicine and surgical patients, less is known about errors and adverse events (AEs) in obstetrics and gynecology (OB/GYN).^{1, 2} Previous studies have identified AE and near miss rates at approximately 5 percent of admissions using a variety of methods. However, detection methods are often expensive, labor-intensive, and difficult to maintain.^{3, 4, 5} Incident reports, required by State health departments and accreditation agencies, fail to detect many AEs.⁶ Investigators have explored alternative or complementary approaches for finding AEs, including the use of physician-based voluntary reporting systems.⁷

Resident physicians in teaching hospitals regularly meet to communicate information about patients. They are intimately aware of impediments to care or errors in management. Resident physicians in medicine—through confidential peer interviews with other frontline providers during routine daily work rounds—were able to detect AEs and near misses in up to 5 percent of admissions.⁸ This approach was particularly well suited for identifying near misses. It was not burdensome, with 5-minute interviews and a high yield per interview. It also provided junior physicians with a better understanding of critical faults in the current system, which may motivate them to find remedies.

Obstetrics and gynecology is a branch of medicine affected disproportionately by medical malpractice. Insurance premiums of \$100,000 per year are becoming commonplace nationally. Bad outcomes in OB/GYN frequently lead to multimillion dollar awards. Although serious AEs are infrequently related to medical errors, relatively little is known about errors in OB/GYN practice. This project was undertaken to assess the ability of resident physicians to identify AEs and medical errors and to characterize these reports.

Methods

Setting

We conducted a prospective, observational project in two 6-week blocks between February 2003 and July 2003 as a peer review activity under the auspices of the Quality Improvement Committee within the department of obstetrics and gynecology. The project site was a 556-bed academic medical center in Boston. During the project year, 554 major and 964 minor gynecologic procedures were performed, as well as 4,755 deliveries. Admissions to the obstetric and gynecologic services were 6,932 and 2,641, respectively. Hospital patients were drawn from the Boston area and its surrounding suburbs. Seventy percent of patients had private insurance, 20 percent belonged to an HMO, and 10 percent were on public assistance.

A senior resident physician led morning work rounds. During rounds, the senior resident reviewed patients cared for at the hospital with house staff from the obstetric and gynecologic services. Additionally, a formal teaching session took place Monday through Friday under the supervision of an attending physician. On the obstetric service, a senior nurse (“resource nurse”) participated in the morning rounds and coordinated all activity on the labor floor during a shift. Nurses on the labor and delivery unit typically functioned with a great deal of autonomy and consulted with supervising physicians when appropriate. Nurses on the unit reported problems they encountered during their shift to the resource nurse.

Interview Protocol

During the 12-week project period, one investigator attended obstetric and gynecologic morning rounds on average three times per week. The investigator asked house officers to complete incident reporting cards to respond to a series of questions:

1. Did you encounter any obstacles to delivering high-quality care?
2. Were any patients injured or hospitalizations extended as a result of our care?
3. If so, what happened? Why? Who were the responsible parties? Were there any consequences for the patient?

House officers were encouraged to fill out cards immediately after reportable events occurred and to place them in collection boxes located prominently on the units. Additionally, cards were collected at the morning rounds, at which time house officers were prompted to submit reports.

Coding and Classifying Errors

Cards were collected in an ongoing manner during the project period, and the information was entered into a spreadsheet. Two obstetricians reviewed each event narrative with a classification scheme developed by one of the investigators for a previous study.⁹ A third physician resolved discrepancies. Responses were coded by the type of incident, consequences for the patient, responsible party, process-of-care deficiencies, severity, and the preventability of the incident. Coders identified the responsible party for the incident from a list of 11 possibilities; the most important process-of-care deficiency from a list of 21 options; and the most serious adverse outcome the patient experienced from a list of five possibilities. The following definitions were used to code the type of event:

- Adverse events were injuries that occurred as a result medical care, rather than the natural course of the illness.
- Potential adverse events were errors where injuries could have occurred but did not, either due to good fortune or corrective action.
- Quality problems that did not meet the definition of AE or near miss were classified separately and typically reflected inefficiencies, inconveniences, or defects in service quality. For example, quality problems (other than AEs and potential AEs) occurred when appropriate instruments were not available for an emergent procedure, or routine lab results did not return in a timely manner.
- Finally, coders judged the preventability of each AE as probably, possibly, or unlikely.

Corroboration of Reports

Events were reviewed independently and compared with retrospective chart reviews and hospital incident reports. The risk management department of the hospital, in accordance with State and Joint Commission requirements, maintains a hospital electronic incident reporting system.

Statistics

We used the kappa statistic to calculate inter-rater reliability among coders, which was substantial. We calculated the rates of AEs, potential AEs, and other quality problems using admissions as a denominator. We used Stata[®] software, version 6.0 (STATA Corp., College Station, TX) for statistical calculations.

Results

Overview

The project was conducted in two 6-week blocks between February 2003 and July 2003. Eighty-two events were reported: 46 in obstetrics and 36 in gynecology. Nine patients experienced two or more incidents.

Demographics

The majority of incidents affected patients over age 40 for gynecologic service and age 31 to 40 for obstetric service. Patients were mostly white, enrolled with a commercial HMO, did not require an interpreter, and saw a hospital-based provider (Table 1).

Adverse Events and Potential Adverse Events

Overall, potential AEs were most commonly identified. The majority of AEs were judged to have significant consequences but a high degree of preventability (Tables 2 and 3). Events characterized as “none of the above” usually involved administrative issues with no clinical consequences (e.g., planned surgery performed later than scheduled). A few events are detailed in the Appendix.

Seven events (9 percent) resulted in patient harm (AEs), while most involved a potential AE (46 percent) or other quality problems (32 percent). The most frequently reported events involved either a delayed diagnosis (39 percent) or delayed treatment (31 percent). The following adverse events were reported:

- Excess administration of intravenous narcotics postoperatively, requiring an ICU admission for monitoring.
- Need for general anesthesia when a scrub technician suffered a syncopal episode during a cesarean delivery, and the regional anesthetic wore off due to a delay in getting a replacement.
- Excessive blood loss, resulting in marked anemia due to a delayed start of an emergent surgical case. An additional operating room team had to be called in, due to high acuity during off hours at the hospital; an attending physician could not be identified for a resident clinic patient; once identified, the attending physician could not enter the changing room.
- Failure to monitor an insulin pump or involve the endocrine staff with management of a diabetic patient. The result was a significant hypoglycemic episode during labor, which required a cesarean delivery, due to a non-reassuring fetal heart rate pattern, and the baby requiring NICU support for glucose control.

Table 1. Patient characteristics

Demographics	N	%
Age (yrs)		
<20	1	2
21-30	16	27
31-40	28	47
>40	15	25
Race		
White	36	60
Asian	10	17
African American	10	17
Hispanic	4	7
Insurance		
Commercial indemnity	21	35
Commercial HMO	25	42
Medicare	4	7
Medicaid	6	10
Uninsured	4	7
Practice group		
Private	7	12
Hospital based	30	50
Community health center	6	10
HMO	8	13
Resident clinic	9	15

Table 2. Types of events and preventability		
vents and preventability	N	%
Adverse events	7	9
Definitely preventable	4	
Probably preventable	3	
Potential adverse event	38	46
Definitely preventable	28	
Probably preventable	9	
Error without injury	26	32
Definitely preventable	32	
Probably preventable	6	
None of the above	11	13
Total	82	100

Table 3. Injury by type and severity		
Injury and severity	N	%
Adverse events	7	9
Life Threatening	1	
Serious	5	
Significant	1	
Minimal/none	0	
Potential adverse events	38	46
Life Threatening	1	
Serious	8	
Significant	29	
Minimal/none	0	
Error without significant injury	26	32
None of the above	11	13
Total	82	100

- Need for a blood transfusion because of excessive blood loss due to poor communication between the radiology, emergency room, and gynecology services, as well as difficulty identifying the attending physician, resulting in the delayed diagnosis and treatment of an abnormal pregnancy. Numerous potential AEs involved lab work delays related to orders not entered, orders not acknowledged by a nurse, phlebotomy staff drawing blood, transport staff bringing the specimen to the lab, and the lab processing the sample or reporting the results.

Other near misses were more straightforward, such as incorrect gloves used with a patient allergic to latex and inadequate supplies to perform a procedure easily.

Responsible Parties

Laboratory staff and support personnel, such as transportation or supply services, were involved in 21 (23 percent) and 15 (16 percent) events, respectively (Table 4). Nurses were involved in 20 events (22 percent), house officers in 11 (12 percent), and attending physicians in 11 (12 percent).

Problematic Processes

A total of 103 problematic processes were identified overall, with 18 cases having more than one process listed (Table 5). The predominant process-of-care issue was related to clinical services in 27/103 cases (26 percent), with failure or a delay in performing tests for the predominant

Table 4. Types of responsible parties

Responsible party	N	%
Laboratory	21	23
Nurse	20	22
Support services	15	16
House officer	11	12
Attending physician	7	8
Emergency services	3	3
Scrub technician	2	2
Other	13	14
Total	92	100

Table 5. Types of process-of-care issues

Process-of-care issues	N	%
Clinical services	27	26
Support services	17	17
Therapy		
Medication-related	14	14
Procedure-related	11	11
Diagnosis	11	11
Other		
Poor communication	11	11
Miscellaneous	9	9
Prevention	3	3
Total	103	100

problem (21/27 cases); 25 cases involved process issues with therapy, 14 cases (14 percent) related to medications and 11 (11 percent) to procedures.

Support services were implicated in 17 cases (17 percent), with inadequate supplies being the most common issue (15/17 cases). Eleven cases (11 percent) involved process issues in making a Diagnosis, and the same number (11 cases) were related to poor communication.

Corroboration of Reports

Seventy-six percent of house officer-reported events were corroborated by retrospective chart review. During this same period, staff submitted 43 hospital incident reports in obstetrics and 16 in gynecology. Only two events were captured by both house officer reports and the usual hospital incident reporting system.

Discussion

Our project describes the types, severity, and preventability of errors detected by house officer voluntary reports on an active OB/GYN service at an academic medical center. In this pilot project, we elicited 82 incident reports from resident physicians during weekday rounds. These included seven AEs (9 percent) ranging from inappropriate medication administration to excessive blood loss from delayed procedures, in some cases requiring a blood transfusion. Potential AEs accounted for the largest percentage of incidents (46 percent), a class of incidents that may offer important lessons about the system's vulnerability to harm. Since near misses do not result in injuries and are, therefore, unlikely to carry medical liability, physicians may be more comfortable in reporting such events. In addition, these potential AEs may represent a more relevant way of detecting errors, since they were derived from direct clinical experiences, where residents felt change should occur.¹⁰

At least one incident report was noted in 73 of the 2,203 admissions during the study period, yielding a rate of 3.3 percent of admissions complicated by a medical error. Using this method, 0.3 percent of admissions were complicated by an AE and 1.7 percent by a potential AE. These findings are somewhat lower but consistent with other studies of AEs, which found that 2.9 to 13 percent of patients admitted to acute care hospitals suffer an injury due to medical treatment that leads to increased length of stay or disability, and that 5 to 10 percent experience a serious medication error.^{5, 11} Consistent with other studies, we found that most errors reported by OB/GYN residents were near-miss errors that (fortunately) did not result in an AE.

The difference in AE rates may be due to the nature of patients admitted to an OB/GYN service. In this study, the majority of admissions were in obstetrics, known for its uniqueness within a hospital population.² Typically, such patients are younger and healthier than those on the average medical or surgical service. Patients are admitted for shorter periods, and the admission is highly structured. Finally, patients in obstetrics spend the majority of time during their admission with a nurse. Physicians tend to get involved primarily for deliveries and when the natural process of labor and delivery goes awry. Since physicians are doing the reporting, this would mean less opportunity for them to notice an error and a tendency to focus more on surgical complications, which are uncommon in obstetrics.

Another distinction noted is that most of the medical errors detected by resident physician reports were not identified by the existing hospital incident reporting system. Other studies have found that hospital incident reporting systems have limited detection rates, and that physician-based reporting may complement this method in the identification of errors.^{6, 9, 12} Although 76 percent of physician-reported events were verified by retrospective chart review, only two of these events were reported through the hospital incident reporting system. Additionally the types of problems encountered, specifically in obstetrics, are often different from the mainstream hospital population and not amenable to traditional methods of detection.^{2, 13} They rarely result in AEs and tend to be more system-based issues, dealing with communication and coordination difficulties that require a detection method not based solely on chart reviews.¹⁴ These differences also may challenge the typical methods of remediation exercised by hospital management.¹⁵

The engagement of physicians in generating reports may account in part for differences in the types of events captured and recorded in each system.¹² The nursing staff enters most incident reports into a computerized system in our existing hospital system, and these primarily relate to falls, medications, and operating room logistics. Residents and attending physicians may not view the use of this system as a key part of their professional responsibilities. The value of educating physicians, house staff, and medical students about patient safety cannot be overstated.^{16, 17} We actively elicited resident physicians' participation by integrating incident reporting into teaching rounds and by presenting this process as a peer review activity. A recent study indicated significant variations of incident reporting amongst the different medical specialties that corresponded with the attitudes and participation of medical staff.¹⁸ Similar to our project, they found physicians were more likely to participate when the method of reporting was integrated within medical, rather than managerial, systems of quality improvement.

We are well aware of the limitations of this study, since hospital incident reports highlighted several errors that escaped detection from our system. First, although residents were welcome to

submit incident reports at any time, these reports were actively solicited only during or after weekday morning rounds. As the total denominator of clinical activities is not known, it is difficult to estimate whether weekend, daytime, or nighttime events might have been under-reported. This also limited the insights into the number of events identified on the obstetric and gynecologic services, although this number roughly corresponded to relative patient volume.

Second, the level of clinical responsibilities and the corresponding available time to devote to error reporting might have played a factor in whether events were reported. A busier clinical service, with a high number of admissions, might preclude residents from having time to report incidents, or alternatively, might have generated a greater number of reports, since more potential events could have occurred. Unfortunately, our data do not allow us to analyze the effect of the number of admissions on the number of incident reports. Finally, the level of individual enthusiasm and motivation to participate in the process will affect the number of incident reports generated.

Future use of this system relies on two major factors. First, time must be allocated during the daily work rounds for this system to continue. Although only a few minutes per day are involved, this time has significant value for busy clinicians, even if it is incorporated into the standard workflow process. Second, those who report incidents must feel their time has been well spent, so it is vital they know the issues they identify are addressed.

Identifying and correcting errors will lead to financial benefits by improving the quality and efficiency of operations, as well as the job satisfaction of those involved, as others have noted.¹⁰ Additionally, outcomes can be measured to assess the overall cost-benefit of this system. In our study, in addition to informal sharing of the events during regular meetings with administrators, we gave formal reports to the departmental Quality Improvement Committee, where incidents were aggregated, analyzed for trends, and examined for root causes that could be remedied. A future opportunity for consideration is for a resident physician on rotation to also serve as a committee member, thereby providing a two-way channel of communication.

Conclusion

This project demonstrates the feasibility of resident physician incident reporting in obstetrics and gynecology, despite the characteristics that make it different from other hospital services. This system was simple to organize and administer and inexpensive, and it complemented the existing incident reporting system. One of the most positive aspects of this system is the involvement of house officers, who are intimately involved in the care of patients and can lead to a new generation that incorporates quality improvement into their daily work. In order for a voluntary system to sustain itself, there must be a cycle of positive feedback developed by addressing these reported barriers to providing good care.

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References

1. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: Building a safer health system. Washington, DC: National Academies Press; 1999.
2. Forster AJ, Fung I, Caughey S, et al. Adverse events detected by clinical surveillance on an obstetric service. *Obstet Gynecol* 2006; 108: 1073-1083.
3. Welsh CH, Pedot RP, Anderson RJ. Use of morning report to enhance adverse event detection. *J Gen Intern Med* 1996; 11: 454-460.
4. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. *JAMA* 1995; 274: 29-34.
5. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. *N Engl J Med* 1991; 324: 370-376.
6. Cullen DJ, Bates DW, Small SD, et al. The incident reporting system does not detect adverse drug events: A problem for quality improvement. *Jt Comm J Qual Improv* 1995; 21: 541-542.
7. Weingart SN, Gordon CE. Finding and fixing medical error: Opportunities for clinicians. *Dis Manag Clin Outcomes* 2001; 3: 67-70.
8. Weingart SN, Callanan LD, Ship AN, et al. A physician-based voluntary reporting system for adverse events and medical errors. *J Gen Intern Med* 2001; 16: 809-814.
9. Weingart SN, Ship AN, Aronson MD. Confidential clinician-reported surveillance of adverse events among medical inpatients. *J Gen Intern Med* 2000; 15: 470-477.
10. O'Neil AC, Petersen LA, Cook EF, et al. Physician reporting compared with medical record review to identify adverse medical events. *Ann Intern Med* 1993; 119: 370-376.
11. Leape L. Error in medicine. *JAMA* 1994; 272: 1851-1857.
12. Chaudhry SI, Olofinboba KA, Krumholz HM. Detection of errors by attending physicians on a general medicine service. *J Gen Intern Med* 2003; 18: 595-600.
13. White AA, Pichert JW, Bledsoe SH, et al. Cause and effect analysis of closed claims in obstetrics and gynecology. *Obstet Gynecol* 2005; 105: 1031-1038.
14. Michel P, Quenon JL, de Sarasqueta AM, et al. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *Br Med J* 2004; 328: 199.
15. Veltman LL. Disruptive behavior in obstetrics: A hidden threat to patient safety. *Am J Obstet Gynecol* 2007;196: 587.
16. Schectman JM, Plews-Ogan ML. Physician perception of hospital safety and barriers to incident reporting. *Jt Comm J Qual Patient Saf* 2006; 32: 337-343.
17. Vohra PD, Johnson JK, Daugherty CK, et al. Housestaff and medical student attitudes toward medical errors and adverse events. *Jt Comm J Qual Patient Saf* 2007;33: 493-501.
18. Waring JJ. A qualitative study of the intra-hospital variations in incident reporting. *Int J Qual Health Care* 2004; 16: 347-352.

Appendix

Sample Narratives and Classification

Event 1. Cesarean hysterectomy performed emergently on patient with *placenta accreta*. Scrub technician and circulating nurse inadequately prepared for procedure, and appropriate instruments were not readily accessible.

Process problem: Procedural delay, loss of sterile technique.

Adverse consequence: Delayed treatment.

Responsible parties: Nursing, scrub technician.

Preventable: Yes.

Event 2. A patient who did not speak English arrived at the hospital in active labor but found entrance locked and no personnel available. Patient and her partner returned to their car and drove to the ER, which then sent them via ambulance to Labor and Delivery. An inadequate evaluation was performed in the ER prior to transfer, and the patient arrived fully dilated and delivered within minutes of arrival.

Process problem: Procedural delay, inadequate evaluation.

Adverse consequence: Delayed evaluation and treatment.

Responsible parties: Parking personnel, ER staff.

Preventable: Yes.

Event 3. Patient identified with an ectopic pregnancy; methotrexate ordered for medical management. After 5 hours, house staff discovered medication had not been administered because nursing staff were awaiting specialized gloves (which were not readily available on the floor) to deliver medicine.

Process problem: Insufficient supplies, inadequate communication.

Adverse consequence: Delayed treatment.

Responsible parties: Support services, nursing.

Preventable: Yes

26,000 Close Call Reports: Lessons from the University of Texas Close Call Reporting System

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Abstract

The 26,000 close call reports collected through The University of Texas Close Call Reporting System (UTCCRS)—funded by the Agency for Healthcare Research and Quality and a research project of The University of Texas Center of Excellence for Patient Safety Research and Practice—are described in this article, as well as a unique approach to increase reporting. The UTCCRS system was designed as a voluntary and anonymous reporting tool to collect valuable information about close calls. Information from close call reports informed the development of targeted interventions and ultimately led to the identification and implementation of quality improvement projects. To date, the system has received over 26,000 reports. Initiatives implemented to increase the number of reports included an innovative Good Catch Program[®] based on a baseball theme. This initiative was recently awarded the 2007 National Patient Safety Foundation's "Stand Up for Patient Safety" Management Award.

Introduction

Although error reporting has been widely substantiated in the literature as an integral part of safety programs, barriers to implementation continue despite substantial efforts to increase reporting. Although close call or near miss reporting is recognized as a proactive means of error prediction, an increase in reporting has not been achieved consistently or sustained in many of the piloted or implemented safety programs in health care.¹

Acquiring, aggregating, and acting on near-miss or close-call reports requires a program of awareness and rewards as demonstrated in the "Good Catch Program." In the experience of this program, a concerted effort to raise awareness is necessary. The Good Catch Program was established in the organizational culture by relating the reporting process to an easily understood, common, and non-threatening sporting event.

In a 2004 patient safety article, Edmondson wrote, "Organizations that systematically and effectively learn from the failures that occur in the care delivery process, especially from small mistakes and problems, rather than from consequential adverse events, are rare."¹ The timely review and rating of close calls can provide valuable diagnostic information for insight into a system's vulnerabilities, facilitate the identification of areas for system improvement, and enable rapid systematic correction.^{2, 3, 4}

The University of Texas Close Call Reporting System (UTCCRS)⁵ was established within the Institute for Healthcare Excellence at the University of Texas M.D. Anderson Cancer Center to

facilitate a proactive approach to preventing errors. The initial low volume of reports submitted by employees was recognized as a barrier to learning from the system. A creative, effective strategy was needed to engage employees in reporting close calls.

Methods

A literature search was conducted to identify strategies to significantly increase reporting. Topics identified from the literature search incorporated into the program design included understanding the role of microsystems within organizations and the importance of engaging frontline employees in safety reporting, understanding why employees do and do not report, identification of essential educational components to facilitate employee participation, the role of executive leadership participation in the program, the feedback process, and employee recognition.

The Importance of Microsystems

Poniatowski and colleagues⁶ described organizations as macrosystems that are built upon many interrelated microsystems. Most actual or potential errors in a hospital setting, which directly affect patient care outcomes and negatively affect patient safety, likely occur at the microsystem level.^{7, 8} Therefore, to capture safety concerns at the time they are identified, it would be necessary for the program to engage frontline employees of inpatient nursing units as reliable sources of information.^{9, 10, 11} However, acquiring reports from the microsystem level has been hindered by several factors. A study of nurses' medication error reporting revealed four factors that explain why employees may not report errors: (1) fear, (2) disagreement over whether an error occurred, (3) administrative responses to errors, and (4) the effort required to report an error.¹²

Fear

In order to overcome employee fears and concerns associated with reporting, a culture of trust must be promoted within an organization.^{7, 8, 9} This can best be accomplished by eliminating the possibility of assigning blame or initiating disciplinary action related to reporting.^{7, 13, 14, 15} Employees must be made to feel safe to report so that safety concerns can be identified and the systems can be strengthened.^{10, 16, 17}

In close call reporting, employees are asked to report situations for which they have already effectively intervened to prevent error. The definition of a close call, as found on the reporting tool, is "a situation that does not cause harm nor reach the patient."⁵ The UTCCRS was designed as an anonymous reporting system to protect employees' identity.¹³ Reports are screened outside the hospital's risk and quality department by an impartial third party group of experts. Names, room numbers, medical record numbers, and any other identifying information are scrubbed from reports (if they have been entered by an employee). The system does not allow individual reporters to be identified or contacted. However, when a report is entered, a unique tracking number is automatically generated. The employee can use this unique tracking number to re-access the system and review followup notes if they desire feedback (Appendix 1).

Defining Actual and Potential Errors

To ensure that appropriate information would be submitted to UTCCRS, it was important to clearly define close calls (“Good Catches”) in the educational component of the program. Hritz, et al.,¹⁸ recommended that reporting systems and improvement interventions continually focus on building an awareness of the occurrence of errors through identification and reporting. To address this recommendation, examples of reports that demonstrated the differences between actual and potential errors were developed, and a list of potential error examples was created as a reference tool. The educational plan incorporated the instruments as exemplars and handouts.

The Importance of Executive Leadership Support

Initiatives led by hospital executives to improve an organization’s culture of patient safety can result in a profound and lasting change in the organization’s safety culture.^{19, 20} Leaders need to visibly guide and support staff through reporting systems that involve recognition and rewards.²¹ Therefore, mechanisms for administrative leaders to show support and motivate employees are essential to the Good Catch Program. Continual recognition of progress, shared safety success stories, and celebrations of achievements were incorporated into the program design. Building recognition and reward from executive leaders, including associated financial support, was therefore identified as another important program component.

Recognition of employees’ personal ability to effect change was also identified. Plans to recognize patient safety champions with safety award certificates and “Most Valuable Player” (MVP) recognition were included in program design. This was recognized as a needed improvement based on feedback from employees and executives after the original launch of UTCCRS. Barriers and interventions to surpass them are summarized in Table 1.

The Good Catch Program

A baseball theme was used to organize inpatient nursing units into teams and group them in one of four Divisions of an Inpatient Nursing League. A report accepted into the UTCCRS resulted in a point for the team. A unit code generated points for each team, while maintaining the reporter’s anonymity. The team and “game” approach engaged frontline staff in a fun, friendly competition on inpatient nursing units as they reported Good Catches identified in daily practice.

As each team joined the league, unit-based in-services were provided using a PowerPoint™ presentation and handouts that included definitions and examples of close calls. Information provided during the educational sessions included definitions of safety and preventable harm; descriptions of a systems view of errors; theories and perspectives about errors in health care; description of UTCCRS with instructions for entering data; and examples of advances in patient safety and human factors in design.

To maintain the program’s baseball theme, close calls were renamed “Good Catches.” Each unit decided on a team name, and representatives from each team served on a workgroup that met as needed to address “game” strategies. Creative team names included: SCRUBS: Safety Created Regularly & Uniformly by Staff; PEDI: People Effectively Decreasing Incidents; OOPS: Outstanding Outcomes in Patient Safety; The Hazard Hunters; STOPS: Staff Thinking of Patient Safety; and The Awareness All-stars.

Table 1. Summary of barriers and interventions

Identified potential barriers to reporting	Intervention
Microsystems within macrosystems	• Use of the baseball theme to organize units into “teams” to engage frontline employees in the reporting process. • Acknowledgment of “patient safety champions,” “most valuable players” on each team. • Promotion of the important role of employees on the frontline of patient safety.
Historical fears of discipline or reprisal for reporting errors	• Changing terminology from near miss or close call to “Good Catch” • Engaging team members in a fun, friendly competition as they report identified safety concerns in daily practice. • Asking unit team members to choose a team name. • Providing positive feedback to assure teams that a higher submission volume of potential error reports demonstrates a greater focus on patient safety. • Providing story-boards for employees to share their experiences with the “Good Catch Program.” • Encouraging employees to take credit for all interventions for patient safety. • Promoting a fair and just culture for error reporting.
Differing definitions of actual and potential error	• Providing unit-based in-services. • Providing definitions and examples of actual and potential errors.
Time/effort required for error reporting	• Implementing the End-of-shift Safety Report. • Giving demonstrations of entering reports in CCRS so it can be viewed as a user-friendly database. • Recognizing employees’ individual, personal abilities to initiate changes that reduce error by reporting. • Promoting “the power of data.” • Awarding one point to a team for every submitted report.
Lack of administrative support	• Enlisting the VP of nursing as the “Inpatient Nursing Good Catch League Commissioner.” • Enlisting directors as “coaches” for each division of teams in the “Good Catch League.” • Arranging unit visits by executive leadership. • Delivering “Safety Champion Award” certificates signed by executive leaders. • Securing administrative budget approval for “Good Catch” pins and other incentives for team members. • Providing a pizza party for winning teams in each “game” (timeframe).
Lack of feedback about what is being done with submitted reports	• E-mailing weekly “Good Catch Scoreboards.” • Publishing updates/progress reports each week in Nursing Newsletter: Reporting themes and action plans to assure time taken to report has been worthwhile. • Providing access codes for employees to locate action plans related to their report submissions.

Quality Improvement Department representatives and administrators of the UTCCRS were included as workgroup members. Team representatives were assigned the important position of Patient Safety Champion and were given responsibilities to facilitate communication of program information to their team members. Weekly scoreboards were e-mailed to representatives for posting on the units. A friendly competition between units was promoted by encouraging team members to submit reports and earn points for their team.

The team in each Division that entered the greatest number of Good Catch reports during a “game” was recognized in the institution’s Nursing News & Information weekly newsletter and awarded a pizza party. In addition, MVPs were identified on each team, and each received a patient safety champion award certificate signed by executive leadership. An Inpatient League World Series is currently in the planning stages. The World Series event will provide a forum for organizational level recognition of employee participation in the Good Catch safety initiative.

Executive Leadership Support

The Vice President of Nursing served as the Inpatient League Commissioner to ensure that executive leadership was provided. Four department directors served as head coaches for each Division to enhance visible administrative support for the program. Every 6 months, a new Division of four to five nursing units was formed. Education and mentorship were provided for all team members until all four Divisions were participating in the program.

The Vice President of Nursing visited each unit approximately 4 months after they joined the program and distributed Good Catch pins to participating team members. Team members prepared patient safety storyboards and shared information about the different types of Good Catches. Several teams had t-shirts made with a team logo and wore baseball caps during the unit visit. One team decorated the staff lounge as a dugout. In addition, incentives for nurses (e.g., “Safety Awards”) were sponsored and promoted by executive leadership to acknowledge individual nurses as patient safety champions during each 6-month game.

Results

The University of Texas Close Call (UTCCRS) reporting system was launched at The University of Texas M.D. Anderson Cancer Center in May of 2003. Dissemination activities included various intranet and e-mailed notices and articles and brief in-services on participating units. In October 2005, the system was opened to all units and became part of the in-service information given to all employees. A single portal icon (named “Safety Reports”) was placed on all computer desktops to allow users to access either the online incident reporting system or to report a close call through UTCCRS.

The Good Catch program was piloted on five acute care units beginning December 12, 2005. Between December 2005 and July 2007, 25,921 reports were received, with a dramatic increase in reporting occurring each time a “season” began or new leagues opened. Each season runs from January to June and from July to December (Figure 1).

Categories Reported in Good Catch

The reporting categories in UTCCRS are not mandatory; the reporter can choose one category or many categories or even not to categorize. The total count of categories (26,622) was higher than the total number of reports received (25,921) because reporters chose several categories in some reports (Figure 2).

Contributing Factors

The contributing factors list in the UTCCRS was developed in an extensive consensus-building exercise as the system was developed¹³ (Appendix 2). The total count of factors identified in Figure 3 (29,273) is greater than the total number of reports received (25,921) (Figure 1) because there are no mandatory reporting fields, and reporters might have chosen more than one (Figure 3).

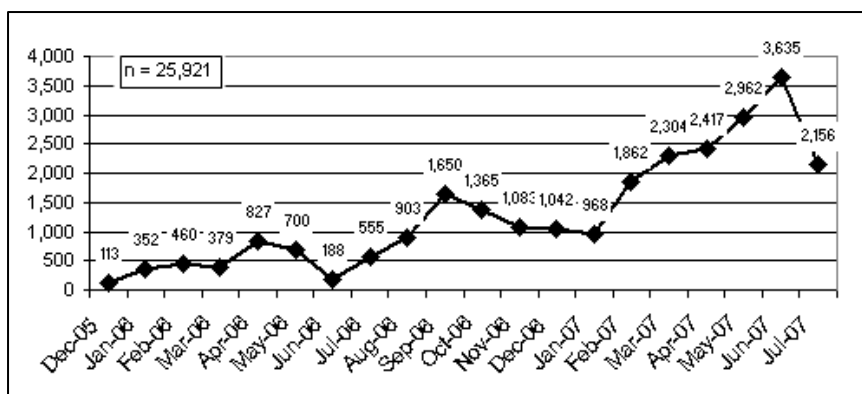


Figure 1. UTCCRS “Good Catch Report,” count by month: December 2005 – July 2007.

Conclusion

Sensemaking of Good Catches

Battles, et al., described safety data as requiring “sensemaking” conversations based on data acquired from detection tools, such as reporting mechanisms.²² Sensemaking also assists in categorizing and prioritizing the risk knowledge that comes from reported events. This essential component of an organization’s safety plan is necessary to create a proactive culture and proactive intervention for safety.¹⁰ Close calls—or

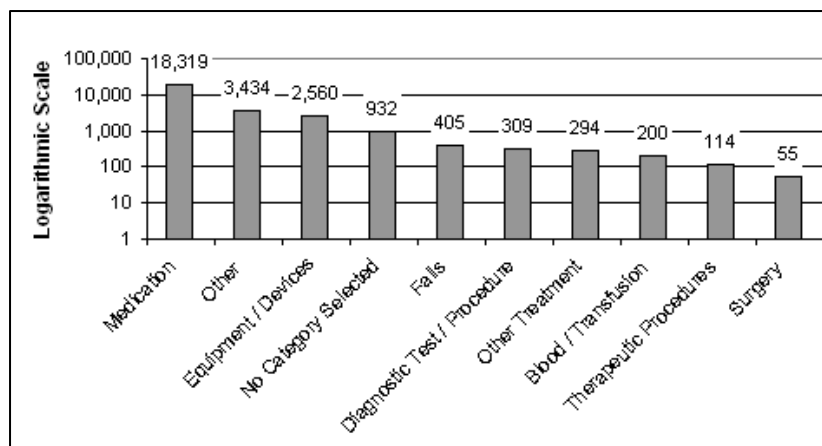


Figure 2. UTCCRS “Good Catch Report,” count by category: December 2005 – July 2007.

good catches—are included in the safety data that contribute to an institution’s safety plan and interventions.

Aggregating themes from the Good Catch Program has informed several quality initiatives. The Good Catch program has generated a number of safety interventions based upon collected data and the “sense” made of these reports. Many of the reports provided data that confirmed

systems mechanisms were in place to prevent actual errors from occurring. Examples of system error prevention mechanisms include: medication administration record (MAR) reconciliation; 8-, 12-, or 24-hour chart checks; and increasing double-checks on reported high-alert medications. Multidisciplinary teams have utilized good catch data to generate short- and long-term quality improvement projects.

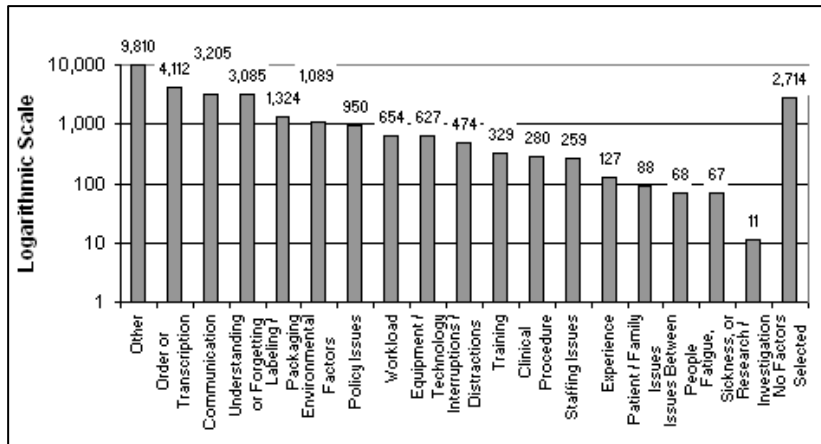


Figure 3. UTCCRS “Good Catch Report,” count by contributing factor: December 2005 – July 2007.

In a health care organization, a large collection of good catches provides challenges. The first challenge is to familiarize the organization with the volume, purposes, and nature of safety reporting. The number of reports is daunting when each one is considered individually, and certainly few organizations maintain the resources to respond equally to each report. Battles, et al., describe the analytical tools necessary to assist staff working with such data to “overcome the limitations of the individual mind” so sense can be made of larger data sets.²² After “sense” has been made, the challenge is to provide interventions based on such reports, so that changes can be made to reduce system-level vulnerabilities found in the data.¹⁰

Challenges

Initially, many of the teams expressed concerns by questioning whether a high number of good catches might “look bad” for a unit. Positive feedback was provided to assure teams that higher numbers of submitted reports supported a greater focus on patient safety. Also, because historically reports were submitted only when an actual error had occurred, a “change in thinking” was required. Some teams raised questions about why units with more submitted reports were being recognized, while units that just “fixed” concerns but did not report them were not being rewarded. This question provided the opportunity to educate employees that although they continually intervened to ensure safe care, the “fixes” needed to be reported so that systems issues could be identified and addressed.

Program coordinators and administrative leadership affirmed that positive recognition was being provided to units that were submitting a high volume of reports. Reports were communicated as “nursing interventions for patient safety” and close call reporting was promoted as an opportunity for employees to document their important role in the front line of patient safety.

By successfully increasing the numbers of reports submitted to the University of Texas Close Call Reporting System, the Good Catch program has provided a supporting mechanism for the organization to systematically and effectively learn from safety interventions implemented on the front line. Gaining insight about areas of potential vulnerability has allowed the organization to be proactive with interventions to eliminate risk for potential errors and to decrease the possibility of an actual error occurring. Each Good Catch has contributed to safer patient care.

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References

1. Edmondson A. Learning from failure in health care: Frequent opportunities, pervasive barriers. *Qual Saf Health Care* 2004; 13 Suppl 2: p. ii3-ii9.
2. Furukawa H, Bunko H, Tsuchiya F, et al. Voluntary medication error reporting program in a Japanese national university hospital. *Ann Pharmacother* 2003; 37: 1716-1722.
3. Mutter M. One hospital's journey toward reducing medication errors. *Jt Comm J Qual Saf* 2003; 29: 279-288.
4. Stump LS. Re-engineering the medication error-reporting process: Removing the blame and improving the system. *Am J Health Syst Pharm* 2000; 57 Suppl 4: S10-S17.
5. The University of Texas Close Call Reporting System; The University of Texas Center of Excellence for Patient Safety Research and Practice. Available at: www.utccrs.org/ccrs/home.jsp. Accessed April 3, 2008.
6. Poniatowski L, Stanley S, Youngberg B. Using information to empower nurse managers to become champions for patient safety. *Nurs Adm Q* 2005; 29: 72-77.
7. Corrigan JM, Kohn LT, editors. *To err is human: Building a safer health system*. Washington, DC: National Academies Press; 2000.
8. Institute of Medicine. *Crossing the quality chasm: A new health system for the 21st century*. Washington, DC: National Academies Press; 2001.
9. Cohen MR. *Medication errors*. Washington, DC: APhA Publications; 2006.
10. Institute of Medicine. *Keeping patients safe: Transforming the work environment of nurses*. Washington, DC: National Academies Press; 2004.
11. Aspden P, Corrigan JM, Wolcott J, et al, eds. *Patient safety: Achieving a new standard of care*. Washington, DC: National Academies Press; 2004.

12. Wakefield DS, Wakefield BJ, Uden-Holman T, et al. Perceived barriers in reporting medication administration errors. *Best Pract Benchmarking Healthc* 1996; 1: 191-197.
13. Martin SK, Etchegaray JM, Simmons D, et al. Development and implementation of the University of Texas close call reporting system. *Advances in patient safety: From research to implementation. Vol 2: Concepts and methodology. AHRQ Pub. 05-0021-2.* Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol2/Martin.pdf. Accessed April 3, 2008.
14. Bagian JP, Gosbee JW. Developing a culture of patient safety at the VA. *Ambul Outreach*, 2000; 25-29.
15. Barach P, Small SD. How the NHS can improve safety and learning. By learning free lessons from near misses. *Br Med J* 2000; 320: 1683-1684.
16. Marx D. Patient safety and the “just culture”: A primer for health care executives. New York: Columbia University; 2001. p. 28.
17. Simpson RL. Winning the “blame game.” *Nurs Manage* 2002; 33: 14-16.
18. Hritz RW, Everly JL, Care SA. Medication error identification is a key to prevention: A performance improvement approach. *J Healthc Qual* 2002; 24: 10-17.
19. Cohen MM, Kimmel NL, Benage MK, et al. Implementing a hospitalwide patient safety program for cultural change. *Jt Comm J Qual Saf* 2004; 30: 424-431.
20. Smith DS, Haig K. Reduction of adverse drug events and medication errors in a community hospital setting. *Nurs Clin North Am* 2005; 40: 25-32.
21. Coyle GA. Designing and implementing a close call reporting system. *Nurs Adm Q* 2005; 29: 57-62.
22. Battles JB, Dixon NM, Borotkanics RJ, et al. Sensemaking of patient safety risks and hazards. *Health Serv Res* 2006; 41(4 Pt 2): 1555-1575.

Appendix 1

Close Call Reporting System Features List

Close Call Gathering:

- ❑ Allows hospital employees a place to anonymously report close calls that they witnessed, took part in, or simply heard about.
- ❑ Employee can enter suggestions on how to prevent this close call from happening in the future.
- ❑ Employee can track the progress of his or her report through a system-generated tracking number and password that only the employee can access.
- ❑ A qualifying question will be asked before reports are entered to detect any occurrence that actually reached the patient; in that case, the employee will be redirected to a form or process defined by each participating hospital.

Reports:

- ❑ Reports entered from any hospital will be available to the administration of that hospital only.
- ❑ Each participating hospital will be assigned a secure Web site for administrators to receive statistics on reports entered from their hospital and do a comparison to all reports entered.

Quality Assurance:

- ❑ Each report entered is reviewed by a member of the Close Call Reporting System project team within 24 hours.
- ❑ Any staff names or ID numbers, patient names, or medical record numbers are removed from records.
- ❑ If a report is found to have data that actually indicate that the occurrence did reach the patient, a designated contact for that hospital will be contacted immediately.

Compliance:

- ❑ System complies with all Americans with Disabilities Act (ADA) requirements.
- ❑ System complies with all HIPAA mandates as followed by the University of Texas system.
- ❑ Some customizations can be made for each participating location to assure localized compliance.

Security:

- ❑ System is set up on dual servers (separate database and Web servers) with the database placed behind a secure firewall.
- ❑ System is monitored 24/7 for unauthorized access or “hacking” attempts.
- ❑ System is protected by the most up to date virus protection available.
- ❑ System has internal monitors set to page support personnel should there be a system failure.
- ❑ Regular backups of the data are performed

Appendix 2 Reporting Tool in Paper form

The University of Texas Close Call Reporting System

Please do not write any identifying information on this form. This report is intended to be anonymous.

I understand the purpose of this study and I have decided to participate in this research project. I understand that I may refuse to answer any (or all) of the questions in the below reporting system. By answering any of the following questions, I am giving my implied consent to participate in this study. Please enter your institution code in the space below.
Institution Code: _____

If you would like to track the progress of this report, please write down or remember the report number in the upper right-hand corner of the this page and enter it in the "Track a Report" section of www.utccrs.org.

Was the action caught before it was carried out and could reach the patient? ☐ Yes ☐ No

If your answer is NO, please do not use this form to report this situation.

Part A. Close Call Information Please answer as many questions below as possible.

Date of Close Call _____ (mm/dd/yy) Time of Day Close Call Occurred _____ am / pm

Location of Close Call _____

How did you become aware of the Close Call ☐ Involved ☐ Witnessed ☐ Heard About It

☐ Other _____

Part B. Reporter Information

What is your current profession? ☐ Dietician ☐ Licensed/Registered Nurse ☐ Pharmacist
☐ Physical Therapist ☐ Physician ☐ Physician Assistant ☐ Radiology Technician
☐ Respiratory Therapist ☐ Other _____

How many years have you worked in this profession? _____ years

How many years have you worked at this institution? _____ years

Part C. Description of a Close Call

Please describe the close call in as much detail as possible. Please DO NOT identify any patients or employees by name, medical record number, or employee ID.

Please provide any suggestions for how we may avoid this close call in the future.

Part D. Type of Close Call

Please place a checkmark next to each term that applies to this particular close call. If the listing below does not contain the type of close call you are reporting, please check "Other" and provide a descriptive word or phrase that best describes this close call.

☐ Medication ☐ Blood/Transfusion ☐ Falls ☐ Equipment/Devices ☐ Surgery
☐ Diagnostic Test/ Procedure ☐ Therapeutic Procedures ☐ Other Treatment
☐ Other _____

Continued on other side

No.

Part E. Close Call Contributing Factors Please place a checkmark next to the factors that may have contributed to this close call. If the listing below does not contain the factor you want to report, please check "Other" and provide a descriptive word or phrase that best describes this close call. Please checkmark ALL sentences that were associated with the close call.

Clinical Procedure Issues

☐ complex procedure
☐ new procedure
☐ procedure was not standard practice
☐ other _____

Environmental Factors

☐ tight space interferes with tasks
☐ poorly organized area
☐ noisy area
☐ area is too hot or too cold
☐ slippery floor
☐ area is not well lit
☐ other _____

Equipment/Technology Issues

☐ equipment not available when needed
☐ equipment malfunctioned during use
☐ incorrect or unclear directions for equipment
☐ poorly designed equipment
☐ equipment was programmed incorrectly
☐ date for use on the equipment had expired
☐ did not have correct accessories for equipment
☐ equipment was a new model which was not familiar
☐ other _____

Communication

☐ someone could not clearly hear the person talking
☐ could not understand communication due to a language difference
☐ information not received because of a technical breakdown (e.g., phone, fax, or email)
☐ inappropriate or unclear directions
☐ illegible handwriting
☐ not enough information available to make a decision
☐ incorrect information
☐ missing information
☐ information not available when needed
☐ patient record not adequately or correctly documented
☐ other _____

Order or Transcription Issues

☐ incomplete order
☐ unclear order
☐ order needed correction
☐ order needed additional authorization
☐ order deleted in error
☐ order not transcribed
☐ order transcribed incorrectly
☐ order keyed into computer incorrectly
☐ other _____

Research/Investigation Issues

☐ patient did not have complete informed consent
☐ patient not registered on the research study
☐ prescriber not authorized under the research protocol
☐ procedure not authorized under the research protocol
☐ other _____

Training Issues

☐ inadequate training on procedure
☐ inadequate training on equipment
☐ incorrect training
☐ incomplete job description
☐ additional training needed
☐ other _____

Patient/Family Issues

☐ patient received unclear information about care
☐ patient did not follow instructions
☐ uncooperative patient
☐ uncooperative family/caregiver
☐ family/caregiver did not follow instructions
☐ other _____

Fatigue, Sickness or Stress

☐ fatigue or being tired
☐ not feeling alert
☐ sick or injured
☐ stress
☐ emotionally distress
☐ other _____

Workload

☐ several patients with a high acuity level
☐ too many admissions/discharges
☐ several complicated patients
☐ emotionally demanding patients and family members
☐ working on several tasks at the same time
☐ working on other tasks in addition to patient care responsibilities
☐ other _____

Issues Between People

☐ strained interactions between workers
☐ not wanting to challenge a person in authority
☐ not having the right to question a superior
☐ fear of being reprimanded if asking for clarification or more information
☐ unclear team assignment
☐ hesitate to take responsibility because of the presence of other team members
☐ someone else should have been responsible for this
☐ no one took charge of the situation
☐ other _____

Experience

☐ asked to work beyond credentialing or certification
☐ new member on the team
☐ recently started working in this institution
☐ have never seen or heard about this before
☐ other _____

Interruptions/Distractions

☐ distracted
☐ interrupted
☐ several emergencies happening at the same time
☐ other _____

Policy Issues

☐ patient did not have complete informed consent
☐ missing policy
☐ policy conflicted with another policy
☐ policy not followed
☐ unclear policy
☐ other _____

Labeling/Packaging

☐ incomplete label
☐ incorrect label
☐ damaged label
☐ damaged package
☐ package looked similar to another product
☐ product name on label looked or sounded like another product
☐ other _____

Staffing Issues

☐ no one took charge of the situation
☐ team lacked adequate supervision
☐ workload not well-distributed across available staff
☐ wrong types of team members available
☐ not enough staff on duty
☐ problems scheduling appropriate staff
☐ too many new staff on duty
☐ other _____

Understanding or Forgetting

☐ not following up on an issue
☐ not paying attention because this event always occurs
☐ this had been reported before, but nothing had been done about it
☐ decision made based on limited information
☐ knew about this at the time, but it slipped someone's mind
☐ misheard something
☐ misinterpreted a written or verbal instruction
☐ misread something
☐ overlooked an important detail
☐ thought it was a routine situation, but it was not, and required a different response
☐ happened many times before, but have become accustomed to it occurring
☐ other _____

Thank you for submitting a report using the UTCCRS!

Using an Anonymous Web-Based Incident Reporting Tool to Embed the Principles of a High-Reliability Organization

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Abstract

High-reliability organizations (HROs) are complex and have the potential for catastrophic failures yet operate with few such defects. Examples include; nuclear aircraft carriers, nuclear power plants, and air traffic control. Health care is also a highly complex industry with many catastrophic defects that would benefit from employing the principles of HROs. HRO reliability results from a capability to discover, manage, and reduce unexpected events. Paper-based reporting systems impede reporting of both actual and near-miss events. In April 2001, Trinity Health designed and implemented an anonymous Web-based reporting tool known as PEERs (Potential Error and Event Reporting System) that was based on the Aviation Safety Reporting System. The goal was to increase the reporting of actual events and near misses, facilitate the management of events, and identify potential safety problems before patients were harmed. Thirty-six Trinity Health hospitals and affiliates are currently using the PEERs system, and over 200,000 reports have been generated. Approximately 80 percent of these reports would have been overlooked in the paper system. The reports are standardized and are immediately available for use by the PEERs coordinator/safety officer. Significant care practice changes have resulted from PEERs reporting. In 2006, 59 root cause analyses were performed as a result of PEERs reports, 16 policies and 123 processes were changed, and an additional 50 policies are undergoing revision. A systemwide council of PEERs Coordinators meets regularly to share lessons learned and best practices related to patient safety. This information is routinely shared with management. The PEERs system nurtures a blame-free environment where reporting is encouraged. It has increased the reporting of events in a manner that allows for timely, efficient, and thorough analysis. PEERs facilitates the discovery, management, and eventual reduction of adverse events.

Introduction

Trinity Health is the 10th largest health care system in the United States and the fourth largest Catholic health care system, based on operating revenue. It is the result of the 2000 merger between the Mercy Health System of Michigan and the Holy Cross Health System of Indiana. Today, Trinity Health comprises 22 ministry organizations and owns and/or operates 45 community inpatient hospitals (30 owned and 15 managed) in urban and rural settings in seven States. Trinity Health employs over 45,000 people and has over 7,000 active staff physicians. During fiscal year 2007, Trinity Health had 400,000 inpatient hospital admissions and more than

3.5 million outpatient visits, excluding visits to the emergency department. Despite its geographic diversity, Trinity Health is a Unified Ministry Organization, with a shared mission, culture, and values. Since its inception, the people of Trinity Health have worked to provide exceptional quality care for all patients. Improving patient safety is a key initiative across the system, as safety is the basis upon which all quality care can be achieved.

Definition of a High-Reliability Organization

In order to consistently achieve high standards for both patient safety and quality, Trinity Health searched for successful models from other industries to emulate. This led to the study of high-reliability organizations (HROs), including the work of Weick and Sutcliffe.¹ HROs are highly complex and have the potential for catastrophic failures, including many deaths, yet they operate with few such defects. An HRO has an exceptional safety record, not merely above average. Examples of HROs include nuclear aircraft carriers, nuclear power plants, and air traffic control systems. Although unique in many ways, health care is also a highly complex industry with many catastrophic defects² that could benefit from employing HRO principles. HRO reliability results from a capability to:

- Discover unexpected events.
- Manage unexpected events.
- Reduce the occurrence of unexpected events.

An HRO has five important attributes that determine an organization's mindfulness of potential errors and defects. These include:

1. **A preoccupation with failure.** An organization must expect error and train staff to recognize and recover.
2. **A reluctance to simplify.** The organization rejects the first impression of the cause of defects and abnormal values. Instead, all staff are trained to investigate the root causes of potential defects.
3. **Sensitivity to operations.** Sensitivity to operations stresses the importance of the frontline employee. All staff are encouraged to address anomalies while still tractable and able to be isolated. This allows defects to be corrected at a point of low intensity.
4. **A commitment to resiliency.** A commitment to resiliency places a high value on staff expertise. Resilient staff have the ability to detect, contain, and mitigate defects and errors.
5. **Deference to expertise.** Deference to expertise requires concentrating decisionmaking with frontline staff, who are authorized to make critical decisions. This HRO attribute is epitomized by the Joint Commission's patient safety standards, which allow any employee involved in a surgical procedure to speak up during the timeout to avoid mistakes that might occur related to wrong patient or wrong site in the operating room suite.

Taken together, these five attributes are the key components of "mindfulness." It is mindfulness that induces the capability to discover and manage unexpected events, which then leads to reliability. The information gleaned from these events is used proactively to reduce future occurrences and to improve the design of suspect processes.

Need for an Event-Reporting System

It is no longer necessary to emphasize the importance of error reduction or the cost of medical errors, both financially and in terms of human suffering.^{3, 4} Everyone is well aware of the need to provide safe and effective health care services. The challenge lies in finding a method to achieve this goal.

Having studied HROs, Trinity Health recognized the need for a better method to discover defects, mitigate harm, and prevent future occurrences. To facilitate the work involved in decreasing error frequency, Trinity Health needed first to collect as much data as possible, examine mistakes, and learn from them to redesign systems and avoid future errors.

The literature indicates that medical errors are severely underreported.⁵ It was determined that traditional paper-based incident-reporting systems, although originally designed to provide information about events, do not meet the needs of an HRO. Too few incidents make it through the paper-based reporting process, and it is nearly impossible to categorize events. Those events that do not result in serious harm frequently are ignored while the focus remains on high-impact events.

We were unable to understand the frequency and cause of events across all of Trinity Health. Nor did our paper-based system foster a preoccupation with errors or encourage mindfulness, one of the key principles of an HRO. Information about “near events” was being lost. Also, incidents tended to be viewed as a means of determining fault, rather than as a way to uncover systemic problems.

Trinity Health needed a tool and a culture that would encourage reporting of all events, so that data could be methodically studied and analyzed. In a culture of blame, the focus is on human error rather than on root causes. In a system that identifies fault and dispenses punishment, events tend to go underreported because the incentive is to hide information. It was Trinity Health’s desire to learn from past events in order to prevent future occurrences.

The Potential Error and Event Reporting System

Trinity Health embarked on a journey to improve reporting of errors and “near events” through the use of an automated reporting system. After much consideration, a decision was made to develop a new tool in-house based on the National Aeronautics and Space Administration’s voluntary Aviation Safety Reporting System. In 2000, this was an innovative approach to event reporting.

Building, rather than buying, such a tool would allow for customization of the tool and provide more control over its content, cost, and configuration. At the time, available commercial tools were expensive and did not meet our need for ease of use. In response to mandatory reporting requirements, the Veteran’s Health Administration has taken a similar approach.⁶

The PEERs questions were developed based on survey responses from physicians, nurses, an attorney, and risk and quality management professionals. After nearly a year of research and development, the Potential Error and Event Reporting System (PEERs) was born. PEERs was intended to:

- Reduce fear of reporting and thus, increase reporting.
- Formulate a database to standardize the information.
- Reduce errors through data tracking, trending, analyses, and targeted improvement projects.
- Reduce errors through prevention.
- Improve quality along with patient and employee satisfaction.
- Reduce costs associated with errors.
- Increase mindfulness and begin the transition toward Trinity Health becoming an HRO.

Development of PEERs

Design

Development of PEERs began shortly after the birth of Trinity Health, and the prototype was ready for a pilot study in April 2001. The PEERs system consists of three interrelated components:

1. **PEERs Survey Tool**, which allows the original reporter to enter an event into the system through a Web-based interface.
2. **Report Management Tool**, which allows the PEERs coordinator/risk manager to review an event, enter additional information, and follow up on the report.
3. **Database of events**, which has reporting capabilities.

The tool was designed to gather input from any staff member with access to a computer within a Trinity Health Ministry Organization. Trinity Health now has 6 years of historical data and over 200,000 records in its PEERs database.

A reporter could enter a PEERs report using a Web-based interface in approximately 5 minutes. The survey tool uses “pick lists” to facilitate report entry and improve data consistency, but it also offers ample opportunity to describe events. PEERs was developed with back-end reporting in mind, so that data could be used for reporting and analysis. The objective was to create information from gathered PEERs data to implement safer care processes.

The PEERs survey tool is divided into several sections with a series of followup questions that are linked directly to the event category that has been identified as the source of the problem. For example, if an incident is related to a patient fall, followup questions ask about the patient’s risk of falls and when the last fall-risk assessment was performed. If an event is related to medications, the followup questions ask about the type of order and the method of administration. Additional questions are applicable to any event category. Data are gathered about the type of event, the location of the event, contributing factors, injuries, and other factors. The reporter has the opportunity to describe the event and to provide feedback about cause and

prevention of the event. These sections of the report can provide the most valuable information as processes are redesigned.

Technical and Cultural Preparation

In order to implement PEERs, a hospital had to prepare for both the tool's technical and cultural impacts, the technical aspects being the easier of the two. PEERs is Web-based and resides on all hospital computers. Reporters wishing to create a PEERs report access the survey tool via an icon on the desktop of all hospital computers. In the first implementation, computer skills tended to be a factor for some clinical staff. However, that has been less of a problem over time, as more and more clinical functions have become computerized, and as the computer has become a tool routinely used by all hospital staff. Originally, inconsistencies in technical capabilities across hospitals and departments within a hospital were an issue, but these too have been mitigated over time, as Trinity Health has implemented standardized technical tools and processes across the system.

The cultural preparation posed, and continues to pose, the greatest challenges. Along with changes in policy, it was necessary to terminate the use of paper forms in order to implement the PEERs system. Abandoning the process associated with the old paper reports was frequently met with ambivalence.

Since no passwords were required to enter a report, anonymity was an option. The anonymous reporting feature was deemed critical to encourage the use of the PEERs system, since many employees still did not entirely trust the "just culture."⁷ Despite the perceived need for anonymous reporting, 70 percent of reporters identify themselves.

The tool is designed to capture identifying information, should the reporter choose to provide it. This allows for discrete followup by the risk manager/PEERs coordinator and helps provide additional information to study events.

At the outset, each site was required to implement a nonpunitive reporting policy and field a readiness survey. However, culture is not static and must be nurtured throughout the organization. An additional part of the preparation involved education. Although the survey tool is intuitive and easy to use, at the very least, staff had to be made aware of its existence. It has taken a major communication effort in larger hospitals to ensure that all staff in all departments know about the importance of completing PEERs reports.

The volume of reports is monitored monthly for each site, and an increase in the number of reports is celebrated and rewarded. A PEERs training site is available for use by each hospital to demonstrate the survey tool. Most of our PEERs hospitals introduce the tool to new employees as part of their orientation programs.

The Report Management Tool is used to manage event reports, analyze event classes and the cause of events, and identify mitigation strategies. It allows for more in-depth information to be added to a report subsequent to its creation as the report is further investigated. The Report Management Tool is more complex and requires advanced training. Risk managers and PEERs coordinators lead these efforts in our Ministry Organizations.

Legal Issues/Peer Review Protection

As PEERs was developed, Trinity Health worked to maintain the peer review protection afforded by State law. PEERs is designed to be used entirely for process improvement, and all staff involved in the PEERs report management process must be under the peer review umbrella of their particular hospital. Trinity Health legal staff guided the deployment of PEERs so that wherever PEERs is used, it complies with local and State law peer review protection requirements.

Replication and Redesign

Building the Base of PEERs Users

After using the PEERs tool for several months at the pilot site, it was ready for a broader audience. Using lessons learned from the pilot site, a deployment plan was developed that allowed for the rapid replication of the tool across the system. The implementation plan included both technical requirements to ensure the proper use of the tool and the more critical cultural issues.

The success of the PEERs system depends on reporters' trust. In part, trust is gained through communication. Staff need to feel that their contributions are valued and acted upon. They need to observe first-hand that reports are not being used to exact punishment. During the design phase and design upgrades, it remains a critical function to ensure that the questions in the survey tool, along with the possible answers available in the pick lists, are blame-neutral.

Naturally, dealing with many different hospitals, there are many different stages of readiness and many different cultures already in place. Trinity Health developed a nonpunitive error-reporting policy that was the keystone of the PEERs system. The goals of the policy are to:

- Support the values of respect, social justice, compassion, and care of the poor and underserved.
- Foster excellence, with direct error-prevention efforts aimed at the root cause of system and process weaknesses, not at individuals.
- Ensure there are no reprisals for reporting of errors and injuries, both actual occurrences and potential conditions ("near events").
- Develop a working culture in which communication flows freely, regardless of authority or position. The policy states the philosophy behind error reporting and outlines the exceptions, including criminal activity. It is assumed that employees are doing their best, and that errors are not the result of incompetence or misconduct.

One major lesson learned from the PEERs implementations is that culture does not remain static. It is not enough to merely have the policies in place at the outset. Work must continue daily to maintain and support a healthy culture. New employees regularly join the team, and seasoned employees need to be reminded that their input is valued and that senior leadership supports them. It is all too easy to slip back into old patterns. The PEERs Users Group must remain vigilant to keep blame and punishment out of the PEERs process.

PEERs is currently used by 32 different hospitals and four Trinity Health Home Care Agencies. Trinity Health has used the Agency for Healthcare Research and Quality (AHRQ) Culture of Safety Survey⁸ as an assessment of the culture across Trinity Health hospitals. Results show a strong correlation between the perception of a blame-free work environment and the number of PEERs reports received. The survey also found that there was work to be done, and that we had not completely achieved our goals.

Overcoming Acceptance Issues

One interesting aspect of an anonymous reporting system is the scope of issues that are reported. Staff see PEERs as an opportunity to share issues not related to patient safety. For example, some hospitals found that a greater volume of employee health issues was reported through PEERs than through normal channels.

Even though a number of reports have not been considered helpful from a risk-management perspective, they nevertheless add value in that they provide employees with a place to air concerns they might not feel comfortable doing otherwise. This contributes to the “culture of trust” required to keep PEERs functioning at its highest level.

As the number of hospitals using PEERs increased, a user support group was convened. This group meets monthly to discuss issues related to the tool, data issues, and information identified as a result of PEERs reports. This group has been instrumental in helping guide the growth of the PEERs tool through several iterations. Members of the group work together to develop enhancements to the tool. Formation of the group has led to increased acceptance of the tool and greater understanding of errors and their causes.

The use of PEERs by several Trinity Health home health care agencies and by a behavioral health hospital increases its complexity, since these entities require additional event categories and questions in order to meet their reporting needs.

Trinity Health is currently using PEERs version 5.1, so there have been five new and improved versions of PEERs since its original 2001 deployment. Since the original survey tool, report entry has evolved over time. A “facelift” has updated its appearance. Some new fields and event categories have been added to meet the needs of the PEERs Users’ Group. The biggest changes have been in streamlining the entry process, so a reporter could provide the maximum amount of information in a limited timeframe. It has been a struggle to balance the need for complete and accurate information while respecting a reporter’s time constraints.

Because a major difficulty with patient safety research into events and errors is the lack of an adequate denominator, one of the purposes of the PEERs system is to increase reporting. It is difficult to assess the scope of many problems, and the errors that are eventually reported represent only the “tip of the iceberg.”

Development of the Report Management Capability

To accommodate the needs of the risk manager/PEERs coordinator for more information, the Report Management Tool was developed for use in conjunction with the PEERs survey tool. When the reporter enters information into the survey tool and creates a report, the PEERs

coordinator is notified by e-mail that a report has been generated. To assist with prioritization of reports, the e-mail notification indicates whether the event resulted in any harm to a person. The report appears immediately in the Report Management Tool.

This tool allows the coordinator to assign the report to others involved in the peer review process for comments. Information can be corrected or clarified, although the original content of the report is saved for future reference. Recent enhancements allow the risk manager/PEERs coordinator to assign one report as the “parent” if multiple reports are filed on the same incident. This allows all versions of the event to be archived, but it prevents the system from double reporting when PEERs data are used to quantify events.

Using the Report Management Tool, the PEERs coordinator can “clarify” reports. The original report is never altered. Clarified reports are used for analytic purposes. Reports are clarified to correct information that might have been entered erroneously and add additional information that was not available at the time the report was created. The more thorough the clarification, the more useful the data generated by the reports. PEERs 5.1 allows the PEERs coordinator to upload pertinent documents so that they can be attached to the original PEERs report. This keeps all pertinent information electronic, negating the need for file drawers full of information.

PEERs reports are used for quality improvement within the Trinity Health facilities, and as such, they are protected under State laws that govern peer review protection. It is critical that all staff who use the PEERs system and are privy to the reports be under the umbrella of the hospitals’ peer review protection committee. As many reports contain sensitive information, the Report Management Tool has different levels of user access and requires authorization through user identities and passwords. Although communication about events drives increased reporting, there is a fine line that separates the types of information shared.

As highly complex organizations, HROs place a high value on expertise. For this reason, the role of “category administrator” was designed for the PEERs system. In larger hospitals, the risk manager/PEERs coordinator does not always have the time or the expertise to manage all varieties of PEERs reports. This is particularly true of medication events. In order to have the most useful information, the pharmacy safety officer has been brought into the loop of PEERs reports and has been given the role of “medication administrator,” providing support to the peer review committee as a medication therapy expert. This individual is able to view and manage all medication or adverse drug events reported in PEERs without action from the PEERs coordinator. This ensures that the information goes directly to the people who need it most and have the most knowledge of the event to complete the back-end information required for analyses. The pharmacist is able to assign the drug class for all medication events, so that potential problems can be uncovered related to a given type of drug. Combined with the severity of the event and the phase of the drug cycle implicated, these data have been extremely helpful to the pharmacy safety committee in prioritizing their improvement efforts. Other category administrators have been designed for events related to security and to employee health.

Using PEERs Data

PEERs Current Status

Trinity Health currently has over 200,000 reports in its PEERs database. Approximately 4,000 reports are logged each month, nearly half of which are filed by nursing staff: 60 percent are attributed to care problems/care processes, medications, or slip/falls. Upon review of each report, the risk manager/PEERs coordinator assigns it a severity index. This assists with prioritization by allowing data to be stratified based on levels of harm. However, because 90 percent of the reports were filed in the absence of significant harm to patients, the bulk of the data provide an opportunity to identify weaknesses proactively. These near events are the reports that really help achieve the tenets of the HRO by providing information on system weaknesses.

A “preoccupation with failure” requires analyses of these events in order to reduce complacency and increase attention. The preoccupation with failure is both about preventing an isolated failure and making the system as robust as possible so that it can respond quickly to operational hazards. The data are available at both the local level and the system level. Tools to use the data are provided with the system to allow data mining at the local hospital. These tools are easy to learn and to use. In addition, many standard reports are created monthly to assist with the patient safety efforts across the system.

PEERs Users Group

One of the key components of the PEERs system is the PEERs Users Group. The group consists of the risk manager/PEERs coordinator from each site and local administrators who are responsible for specific types of safety issues. The group meets monthly to discuss PEERs issues and to share success stories. Although these representatives are responsible for driving the technical aspects of the tool, this is not their most critical function. The main purpose for the group is to provide a forum that uses PEERs reports as the basis for discussing safety and process improvements.

Even though each hospital is unique, there is much common ground. This is especially true when it comes to faulty equipment. One hospital might experience only one or two instances of any given equipment failure. In HRO research, these are called “weak signals,” and they are frequently overlooked. Previously, one of the hospitals using the PEERs system noticed they had several reports that were attributed to the failure of a certain pump. They brought this issue to the group, and it became apparent that several other hospitals also had one or two events attributed to that same pump. This provided enough information to generate a warning to all Trinity Health staff using that particular pump. This alert allowed for a proactive response that prevented additional errors related to the discovered defect. It was only when data were studied across all hospitals that certain trends, that otherwise might have gone unnoticed, became observable.

Using PEERs Data for Process Improvements

De-identified PEERs data are also used by the pharmacy council to look for opportunities for improvement in medication administration across the system. This group routinely analyzes the types of medication errors that have occurred, the phases in the administration process where there are vulnerabilities, and the drug class most commonly associated with medication events. It

is not surprising that a high percentage of reports that document harm to patients are frequently attributed to high-risk medications, such as heparin, opiates, and electrolytes.⁹ This work has led to the development of a “heparin policy” that was recently shared with all hospitals at the Trinity Health Fall Conference.

PEERs data were also used to link the use of Computer Provider Order Entry (CPOE) to the decrease in medication events attributed to transcription error. This work provided the pharmacy council with hard data to convert reluctant technology adopters to make the leap to the available computer tools. Other medication-related improvements implemented because of PEERs data include barcoding technologies, smart pumps, and other improvements in the medication cycle.

In addition to the work related to medication errors, PEERs data also have been used to add urgency to the implementation of rapid response teams. The deployment of rapid response teams, one of the key safety recommendations of the Institute for Healthcare Improvement,¹⁰ was fully endorsed by Trinity Health. Data from PEERs made it easier to get a buy-in across the organization and to motivate teams.

PEERs data have also been instrumental in the development of programs for falls risk assessment and mitigation, pressure ulcer risk assessment and mitigation, and a suicide risk assessment, all of which have been hard-wired into our information system. The assessments, implemented in 14 organizations, require every nurse to assess each patient’s risk for falls, pressure ulcers, and suicide consistently across all 14 organizations. If a patient is found to be at risk, nurses are well-positioned to initiate order sets to mitigate that risk. These changes increase the reliability of the organization and prevent patients from falling through the cracks.

PEERs data reveal that many inpatient falls occur when patients get out of bed to use the bathroom. As a result, Trinity Health has implemented the practice of hourly rounding to meet these patient needs. This action has had the added advantage of increasing patient satisfaction with care because nursing staff are more visible. Using PEERs data is more about increasing resolve to deliver high-quality and defect-free care. The solutions implemented frequently have been thoroughly researched and well documented by experts. Making improvements requires resolve and follow-through, attributes that are encouraged in an HRO.

PEERs reports also have driven patient safety in the obstetrics department. Events related to obstetrics can have tragic consequences for patients, and this has resulted in high liability for a facility. A review of PEERs reports revealed that approximately 25 percent of all events could be attributed to failures in communication. This information has been used to develop simulation protocols and to encourage the use of such protocols by obstetric teams to improve teamwork and ensure that all staff can respond appropriately to emergent situations in the delivery room. Simulations for shoulder dystocia have been of particular importance because all team members must be prepared to move quickly to prevent such injury to the newborn.

It is very helpful to have data related to events, but to have real value, the data must result in actions and improvements. In addition to tracking events, the PEERs system also documents the results attributed to PEERs reports. During the past fiscal year, July 1, 2006 through June 30, 2007, eight policies were changed, 22 root cause analyses were completed, and an additional 22 policies have been initiated; 45 processes were changed, and 35 more are currently being revised,

all as a result of PEERs reports. In addition, nine changes to computer software, nine changes to the facility and 127 teachable moments for staff were implemented.

PEERs reports have been instrumental in increasing the amount of hospital-related safety communication. Reports are referred to applicable departments and leaders within the facility, ensuring that information is shared and that required action is taken. Many senior leaders are initially shocked at the volume of reports. In the previous paper world, many reports were filtered out as they rose up the chain of command until only those that resulted in harm actually reached the senior leaders within the organization.

Since Trinity Health engages in many different improvement efforts at any given time, it is difficult to attribute improvements solely to PEERs. However, Trinity Health facilities have demonstrated a 26 percent decrease in severity-adjusted mortality rates since January 2005. The current rate is 74 percent of the expected rate. Performance on Joint Commission core measures exceeds the norm for all measures and is above the top decile in five measures. There has been a 36 percent reduction in the pressure ulcer rate since July 2006. In addition, hospital professional liability costs have decreased by 46 percent, along with a 45 percent decline in the number of claims. PEERs has increased risk managers' awareness of a greater number of potentially compensable events in real time that could have been addressed while there was still a potential to improve or avoid serious, unintended consequences.

Striving for Zero Defects

Trinity Health's goal is to achieve zero defects. In most HROs, the cost of failure is extremely high; this is particularly true in health care. However, too many processes in health care still rely on human perfection to prevent error. As humans are imperfect, these systems are doomed to failure. The PEERs system attempts to measure how events are identified. Unfortunately, the majority of reported events are identified by individuals involved in the event rather than through these safety systems. Twenty-three percent of the reports were identified by human diligence, but only 3 percent were identified due to a built-in safety system; 4 percent were identified by a quality assurance process. The good news is that only 2 percent can be attributed to "good luck."

As we continue to strive for zero defects and work to more closely resemble an HRO, we look for an increase in the percentage of events identified by our improved processes. One complication of using PEERs reports for interventional analyses is the danger of having incomplete information. It is difficult to determine how many events should have been reported. Because potential events identified by built-in safety systems could be interpreted as successes rather than defects, they might have gone underreported.

Also, incident reports are not the best way to determine the success of a safety intervention. The number of reports could actually go up because of increased interest in reporting. As staff see their reports are having a positive effect, they might increase their vigilance. One major goal of the system is to increase reporting. That viewpoint makes increased reports a system success rather than a failure. However, it is not an effective way to judge the effectiveness of an intervention.

Conclusion

PEERs Has Made a Difference

The PEERs system has become part of the culture within Trinity Health and has been instrumental in helping Trinity Health achieve its quality and safety goals. It has helped drive common processes to deal with similar problems and events across the system and decrease variability. This leads to a common understanding and helps to foster a consistent culture within Trinity Health. PEERs data have been used by many different groups for their focused improvement work.

Data from falls are routinely collected and used in an ongoing effort to reduce the number of patient falls. The number of patient falls with injury per 1,000 inpatient days is one of the core clinical indicators used across Trinity Health to assess patient safety for the system. Because PEERs is an in-house tool, it has grown and developed to meet the needs of many different groups in hospitals across the system. In a number of cases, it has grown as the users determine new safety endeavors.

The newest version of PEERs includes an updated section to capture events specifically related to the laboratory. Several hospitals within the system plan to accelerate their focused improvement work around laboratory events, necessitating that specific questions be added to target key laboratory safety issues. PEERs is helping Trinity Health achieve its goal of becoming a high-reliability organization. It has been instrumental in both discovering and managing unexpected events and also in reducing unexpected events.

Next Steps

Trinity Health's experience with incident reporting will position the PEERs hospitals to respond quickly when patient safety organization reporting becomes a Federal requirement. Also, as Trinity Health moves forward with Genesis, our systemwide computer implementation, there are plans to link other clinical data to the data in the PEERs system. This will allow us to review incidents by clinical condition and to pull in full patient demographic information to add new depth to our data mining and reporting. The more information we can gather and use about our safety issues, the more opportunities we will have to improve our systems and to offer a safer hospital for our staff, our patients, and their families.

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References

1. Weick KE, Sutcliffe KM. Managing the unexpected: Assuring high performance in an age of complexity. San Francisco, CA: Jossey-Bass; 2001.
2. Institute of Medicine. To err is human: Building a safer health system. Washington, DC: National Academies Press; 1999.
3. Institute of Medicine: Crossing the quality chasm: A new health system for the 21st century. Washington, DC: National Academies Press; 2001.
4. Medical errors: The scope of the problem. AHRQ Pub. 00-P037. Rockville, MD: Agency for Healthcare Research and Quality; February 2000. Available at: www.ahrq.gov/qual/errback.htm. Accessed March 8, 2008.
5. Leape LL. Error in medicine. JAMA 1994; 272: 1851-1857.
6. Weeks WB, Bagian JP. Developing a culture of safety in the Veteran's Health Administration. Eff Clin Pract 2000; 3: 270-276.
7. Barach P, Small SD. Reporting and preventing medical mishaps: Lessons from non-medical near miss reporting systems. Br Med J 2002; 320: 759-763.
8. Patient safety culture surveys. Rockville, MD: Agency for Healthcare Research and Quality; 2004. Available at: www.ahrq.gov/qual/hospculture/. Accessed May 6, 2008.
9. Cohen MR, Kilo CM. High-alert medications: Safeguarding against errors. In: Cohen MR, ed, Medication errors. Washington, DC: American Pharmaceutical Association; 1999.
10. Deploy rapid response teams. Cambridge, MA: Institute for Healthcare Improvement; 2005. Available at: www.ihl.org/IHI/Programs/Campaign/RapidResponseTeams.htm. Accessed May 6, 2008.

Voluntary Adverse Event Reporting in Rural Hospitals

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Abstract

Since 2004, we have managed a voluntary Web-based medical adverse event (AE) reporting system with a special focus on small rural and critical access hospitals (CAHs). We monitor safety event reporting and provide concise, action-oriented feedback through quarterly composite reports, including peer group benchmarking. Hospital participation increased from 11 (5 CAH; 6 non-CAH) at the start of the project and peaked at 26 (15 CAH; 11 non-CAH). Reporting rates remained nearly constant over the nine quarters (52 ± 4 events/1,000 patient-days). Most AE categories were reported more frequently in CAHs and tended to increase over time. For example, the rate of reported wrong drug administration increased significantly among CAHs and declined 50 percent in others. Event rates in this passive surveillance system were substantially lower than have been reported in research settings. Despite this evidence of underreporting, participating hospitals have used the system as intended, discovering and remedying problems suggested by trends in the data.

Introduction

Public and professional concern over patient safety, adverse health care events, and medical error have been increasing since before the beginning of the new millennium. Lucian Leape, Don Berwick, and others pioneered research on these topics in the 1990s.^{1, 2, 3, 4} The landmark 1999 Institute of Medicine report, *To Err is Human*, advocated voluntary reporting systems for patient safety events to facilitate improvement through reporting of “near miss” events and those that result in no or minimal harm.⁵

Under a Transforming Healthcare Quality through Information Technology (THQIT) cooperative agreement with the Agency for Healthcare Research and Quality (AHRQ), the West Virginia Medical Institute (WVMI), in partnership with the State’s hospital association and office of rural health, Quantros, Inc., and Verizon, has been working to improve rural hospital patient safety in West Virginia. The overall goal of the cooperative agreement was the improvement of patient safety by implementation and use of a statewide voluntary patient safety reporting system.

One of the intended uses of the project’s data was to inform collaborating hospitals of opportunities for improvement, where performance in individual facilities or the collaborating hospitals collectively differed from that observed elsewhere in similar hospital settings. We approached this problem using the model of public health surveillance systems. According to the Centers for Disease Control and Prevention, public health surveillance is “...the ongoing,

systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health.”⁶

Ours is a passive surveillance system. The major limitation of such systems is underreporting, which can be substantial.^{7, 8, 9} One intervention early in this project showed that in one participating hospital, only about 4 percent of adverse drug events requiring rescue drugs had been reported to the voluntary system.¹⁰ We believed that systematic feedback would improve reporting rates if hospital staff and management found the information useful and relevant. We developed denominators and benchmarks appropriate to the different categories of events reported to allow comparison across hospitals (including rural critical access hospitals) and geographic boundaries.

We present the results of analysis of reported hospital safety events over the first nine quarters of reporting system operation. The goals of this project were to: (1) develop a consistent set of measures for comparing hospital adverse event (AE) reports, including denominators suitable for calculating event rates; (2) report these rates periodically to participating hospitals in an actionable format; and (3) evaluate patterns and trends in reported rates among hospitals and within groups of similar hospitals.

Methods

As a part of this project, we licensed a Web-based medical error reporting system (the Occurrence Report Management [ORM] system by Quantros, Inc., a reporting software vendor) and provided it free of cost to participating hospitals. We invited all of the State’s acute care hospitals in rural areas and critical access hospitals (CAHs) to participate in the voluntary patient safety event reporting system component of the project. Long-term care facilities associated with hospitals were also invited to participate.

Twenty-eight (16/18 CAHs and 12/32 other rural hospitals) hospitals accepted the invitation during the course of the project. CAHs are limited to 25 beds; the median bed size of the other rural hospitals was 71.5 (range 39-240). Seven CAHs and three other rural hospitals had associated long-term care facilities. In this report, we limited data to those reported from the acute care and CAHs because patient characteristics, risk exposure, and length of stay were substantially different in long-term care facilities. Statewide hospital counts are as of July 1, 2005, as determined from dates of Medicare acceptance and closing reported by the Centers for Medicare & Medicaid Services and do not include Veterans Affairs facilities. Numbers of participants varied over the course of the project due to sign-up dates, hospital closures, and conversion of hospitals from acute care hospitals to CAHs.

Reports concerning medical errors were available in real time to designated hospital administrators and to WVMI. Hospital staff could view and respond to details in individual reports and generate facility-level aggregate reports. WVMI produced statewide aggregated reports of numerator data (e.g., How many medication errors were reported?) and relative frequencies of events (e.g., What proportion of all reported errors were unobserved falls?).

We conducted a structured literature review using PubMed to identify appropriate denominators for comparing the numerator data across facilities and through time. By “denominators,” we mean measures of exposure to the risk of an AE. For example, if an AE is misidentification of a laboratory specimen, an appropriate measure of risk of exposure might be the number of laboratory specimens obtained within a specified time interval. We were interested in the denominators other investigators had chosen, in addition to their rationales. We expected to see different denominators in use for different kinds of AEs.

The literature review covered English language articles published between 1995 and 2004 that addressed medical errors in hospitals and provided statistics or numerical data. We looked within these articles for reports of rates, comparisons, or denominators. We refined search criteria as we identified potentially relevant articles by adding free text search terms that appeared in relevant articles and repeatedly searched until we stopped retrieving new articles. We used the following search terms: adverse events; calculat*; claims-based; compar*; denominator; falls; hospitals; hospitals/standards; measur*; medical errors; rate; report; safety; statistics and numerical data. In the list of terms, “*” was a “wildcard” denoting a word beginning with the characters listed.

A reference librarian scanned the abstracts of articles retrieved and identified those reporting counts or rates of medical error events in hospitals. Other articles were discarded. One author reviewed the abstracts and confirmed those that appeared to have specific information from which comparable event rates could be determined and calculated for different types of AEs in hospitals.

We examined the frequencies of AEs reported during the pilot phase of operation of the voluntary reporting system (June 30, 2002 to December 31, 2004). Using the Quantros system taxonomy, we grouped events into broader categories that represented appreciable proportions of the total. In that scheme, events were classified by affected party, occurrence type, and outcome. We created groups of similar events by occurrence type, such that each group would be expected to include 2 percent or more of reported events. Using the results of the systematic literature search, we chose appropriate denominators for comparing rates across hospitals and over time.

This process resulted in a set of indicators that we reported to participating hospitals quarterly, beginning in late 2005. We calculated percentile distributions of the indicators every quarter and examined indicator rates in individual hospitals, groups of similar hospitals, and statewide to assess trends. Where published data were available, we compared our results with these.

Results

Literature Review

Broad search terms such as “Benchmarking[MESH] AND Hospitals/standards[MESH] yielded large numbers of articles with little relevance to medical error rate calculation. Adding “Medical Error[MESH]” or the generic term “Error” to searches narrowed them considerably, but most articles reported numbers of errors, when they reported statistical information at all. When abstracts revealed studies calculating rates of error or AEs or presenting denominators, we selected terms that would have retrieved them. Using these more specific qualifiers, we screened

456 articles, identifying 60 as potentially relevant. Of these, 13 were found to be news items, numerator-only analyses, general reviews, or otherwise missing relevant information. The other 47 were included in the evidence table (available from the authors) summarized below.

A plurality (19/47) of the articles dealt with adverse drug events. The second largest group (16/47) presented results of studies on all AEs. Smaller numbers focused on infections, devices, laboratory errors, surgical errors, and falls. All but three articles provided results as rates. We examined each article to determine the denominator(s) used for comparing frequencies of events. Results are presented in Table 1, which shows denominators associated with particular kinds of AEs in at least one published study.

Table 1. Denominator measures used in 47 studies of various patient safety events

Type of adverse event (AE)	Denominator measures used				
	Discharge	Patient-day	Dose	Order	Procedure
General AE	X ^a	X			
Medication error		X	X	X	
Laboratory-related					X
Fall		X			
Surgical infection					X

a An "X" denotes one or more studies published between 1995 and 2004, using the stated measure as a denominator for computing rates of patient safety events in hospitals; e.g., AEs per 1,000 patient-days.

AE Frequencies

Analysis of AEs during the pilot and early operational phases of this project in 2002 to 2004, when eight hospitals had reported almost 9,000 events, showed the relative frequencies of events documented in Table 2. We limited consideration of categories for inclusion to those expected to account for at least 2 percent of reported events, based on observations early in implementation. In 2005, 13/19 reporting hospitals averaged fewer than 100 reported events per quarter. With such reporting rates, hospitals would be unlikely to observe events with expected frequency < 2 percent. The final list of event categories with definitions resulted from combination of similar event types in the reporting system and is presented in Table 3. Several of the final categories have relative frequencies less than 2 percent in the statewide system, but they were considered important enough to attempt to collect them anyway.

Table 2. Relative frequencies of AEs reported during pilot phase, West Virginia Patient Safety Project: June 30, 2002 to December 31, 2004

Event category/subcategory	Relative frequency ^a (%)
Other	10.0
Falls found on floor	7.1
Administrative discharge, left against medical advice	6.3
Administrative discharge, left without being seen	5.6
Medication/infusion omitted	5.2
Adverse clinical other/miscellaneous	5.1
Administrative patient/family dissatisfaction	4.9
Administrative other/miscellaneous	4.9
Adverse clinical work-related injury	3.2
Adverse clinical skin integrity	3.0
Medication/infusion other	2.7
Medication/infusion wrong dose	2.5
Administrative documentation/records	2.1
Administrative financial	2.1
Administrative HIPAA	2.1
Adverse clinical treatment/test issues (non-operative)	2.1

a Relative frequency = percent of all reported events during the pilot phase. Data from five hospitals reporting during all or part of the time interval. Event categories with <2 percent frequency are not shown.

Final Denominator Determination

None of the candidate denominator measures in Table 1, except number of discharges, are routinely available from administrative statistics. We surveyed participants to ascertain ability to supply counts of laboratory tests, employee work days, and drug doses ordered. For two quarters, we asked the hospitals to submit these counts. We computed ratios between these candidate event-specific denominator measures and the number of discharges within each hospital and observed very large quarter-to-quarter variation. On careful inquiry, we learned that these counts were not readily available within participating hospitals and ascertained that there had been significant misunderstanding of the definition of the denominators. We abandoned the attempt to use measure-specific denominators and settled on patient-days as a compromise denominator for all indicators.

Event Rates in Participating Hospitals

To date, we have captured over 40,000 events from hospitals and associated long-term care facilities in West Virginia. Table 4 shows event rates for a larger hospital and statewide in a single quarter and summarizes the definitions of the 11 indicators whose rates are calculated quarterly. Each hospital's event rates were compared with those in all other hospitals submitting data during the quarter, by showing the relative frequencies of events within the reporting hospital and statewide and by showing each hospital's event rate compared with the interquartile range statewide. The range informed hospital staff whether their observed rate was higher or lower than that of other hospitals and permitted a crude assessment of whether a hospital's event rate could be considered random fluctuation due to small numbers, or whether it was significantly different from its peers.

Table 4 presents total AE reporting for the first nine quarters of system operation, including AE rates and the number of hospitals reporting events. The latter was not necessarily the number of hospitals participating in the system. Technical problems occasionally delayed the start of reporting in hospitals that had joined the system. This was most often the case with the CAHs, due to a variety of reasons including lack of high-speed Internet service and inadequate or nonexistent computers. During the interval, the number of reporting hospitals and bed-days nearly doubled, but the AE rate remained between 45 and 60 per 1,000 bed-days, with little evidence of trend. Figure 1 shows statewide trends for each of the 11 indicators.

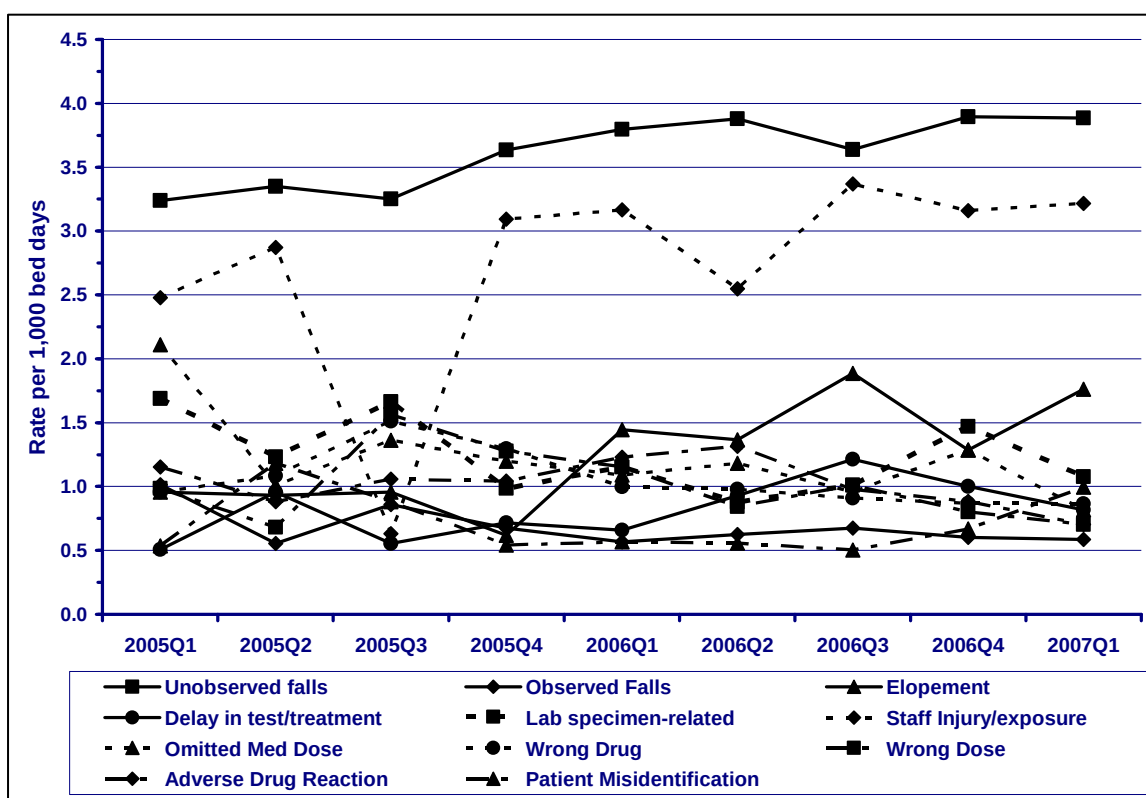


Figure 1. Statewide rates of reported events, by type and quarter: West Virginia Patient Safety Project, 2005-2007.

Table 3. Event reporting hospital comparison measures: October 1, 2005 – December 31, 2005**Sample quarterly hospital report: Acute care**

Indicator	Definition ^a		Your hospital			All participating hospitals	
	Occurrence type	Details	Number of events	Rate ^b	%	Range ^c	%
Unobserved falls	Fall/accident-related	The affected party was a patient, and the fall was not observed by hospital staff	26	2.96	3.81	1.40 – 4.48	6.96
Observed patient falls during ambulation, examination, or transfer	Fall/accident-related	The affected party was a patient, and the fall was observed by hospital staff and occurred during transfer or walking	10	1.14	1.47	0 – 0.99	1.29
Elopement	Environment of care	Patient is missing (AWOL)	22	2.50	3.23	0 – 0	1.18
Delay in test/treatment	Clinical diagnosis and general treatment-related	Delay in diagnosis, treatment, testing, or results	8	0.91	1.17	0 – 1.37	1.37
	Blood transfusion	Delay in administration					
	Treatment-related or surgery	Delay in treatment					
	Specimen	Labwork delay					
Laboratory specimen-related occurrences	Specimen	Any specimen-related occurrence, e.g., incorrect label or wrong test performed	21	2.39	3.08	0 – 2.30	1.89
Injury or exposure to hospital staff	Blood and body fluid exposure or needlestick and sharp injury or physical injury report	The affected party was employee or staff	7	0.80	1.03	2.68 – 6.87	5.92
Omitted medication dose	Medication error	Medication dose omitted	4	0.46	0.59	0 – 1.60	2.29

Table 3. Event reporting hospital comparison measures: October 1, 2005 – December 31, 2005 (continued)

Sample quarterly hospital report: Acute care

	Definition ^a		Your hospital			All participating hospitals	
Indicator	Occurrence type	Details	Number of events	Rate ^b	%	Range ^c	%
Wrong medication administered	Medication error	Wrong drug name	15	1.71	2.20	0 – 2.67	2.48
Wrong dose of drug	Medication error	Wrong dose	16	1.82	2.35	0 – 1.68	2.44
Adverse drug reaction	Adverse drug reaction	Any adverse drug reaction, e.g., skin rash, vomiting, or hypotension	36	4.1	5.28	0 – 0.57	2.00
Patient misidentification	Admission discharge transfer	Wrong patient, more than one ID, or incorrect ID bracelet	10	1.14	1.47	0 – 1.08	1.04
	Specimen	Wrong label or specimen obtained from wrong patient					
	Surgery invasive procedure	Wrong patient					
	Treatment	Wrong patient					
	Medication error	Order written, transcribed, dispensed, or administered to the wrong patient					
	Blood transfusion	Order written, transcribed, dispensed, or administered to the wrong patient					
Total number of events reported ^d			682			2,703	

a Definitions are based on ORM event-reporting system categories that were selected by the person reporting the event. See qxpert.quantros.com/orm/uqguide/tguide/DataEntryTraining.pdf for details.

b All rates are per 1,000 patient-days.

c 25th and 75th percentiles of values for all participating hospitals.

d Represents total number of events in the ORM system and will not be the sum of events in the report indicators.

For all events except adverse drug reactions, CAHs had consistently higher reporting rates. Typical values were approximately twice as high as those in non-CAHs (Figure 2). Over nine quarters, rates of unobserved falls increased significantly in CAHs (Chi-square for trend = 19.59, $P < 0.0001$) but not in non-CAHs. Reported rates of staff injury increased in all hospitals statewide. Reported rates of wrong drug administration increased significantly in CAHs but declined by about 50 percent in other hospitals during the same period. Elopements increased statewide; in CAHs to almost 4 per 1,000 bed-days in the most recent quarter, compared with 1 per 1,000 bed-days in non-CAHs.

Table 4. Quarterly number and rate of adverse event reports: West Virginia Patient Safety Project – 2005-2007

Period	Total adverse events	Bed-days	Rate*	No. of hospitals
2005Q1	1,751	35,513	49	11
2005Q2	2,097	39,718	53	14
2005Q3	2,398	39,658	60	19
2005Q4	2,703	51,736	52	24
2006Q1	2,958	65,079	45	25
2006Q2	3,154	59,286	53	26
2006Q3	3,154	59,361	53	26
2006Q4	3,117	59,848	52	24
2007Q1	3,162	61,257	52	23

* Rate of reported events per 1,000 bed-days.

Discussion

We have established a statewide voluntary patient safety event reporting system, targeting smaller rural hospitals and CAHs. This system achieved sustained reporting at consistent rates from most participating facilities. To allow comparison among hospitals and across time, we classified events by type into categories likely to have reasonable numbers of events reported, and we identified suitable denominators for producing rates that might be used for comparing hospitals of differing sizes.

Other investigators have reported total AE rates in hospitals. Using a cross-sectional chart review, Michel and colleagues found 9.8 to 15.4 percent of charts with one or more AEs.¹¹ Ignoring charts with more than one AE and converting to bed-days using current average length of stay (4.8 days) would yield an equivalent rate of 20 to 32 AEs per 1,000 bed-days.¹² Using active surveillance, Nettleman and Nelson counted 0.2 AEs per patient-day, or 200 per 1,000 bed-days.¹³ Thomas and colleagues conducted a structured chart review in Australia to identify AEs. Their observed AE rate of 10.6 percent of admissions cannot be directly converted to bed-days but would likely yield rates similar to those of Michel, et al. Unruh used hospital discharge data to estimate rates of specific AEs in Pennsylvania inpatients.¹⁴ None of these studies used comparable definitions of events, and none was a passive surveillance system.

Medication errors compared with doses dispensed or prescriptions written have generally been reported in the published literature.^{15, 16, 17, 18} One exception was the study by Kaushal and colleagues, which found a rate of 157/1,000 patient-days.¹⁹ It is questionable whether that rate is applicable to hospital patients of all ages. It is at least 30 times the rate we observed by

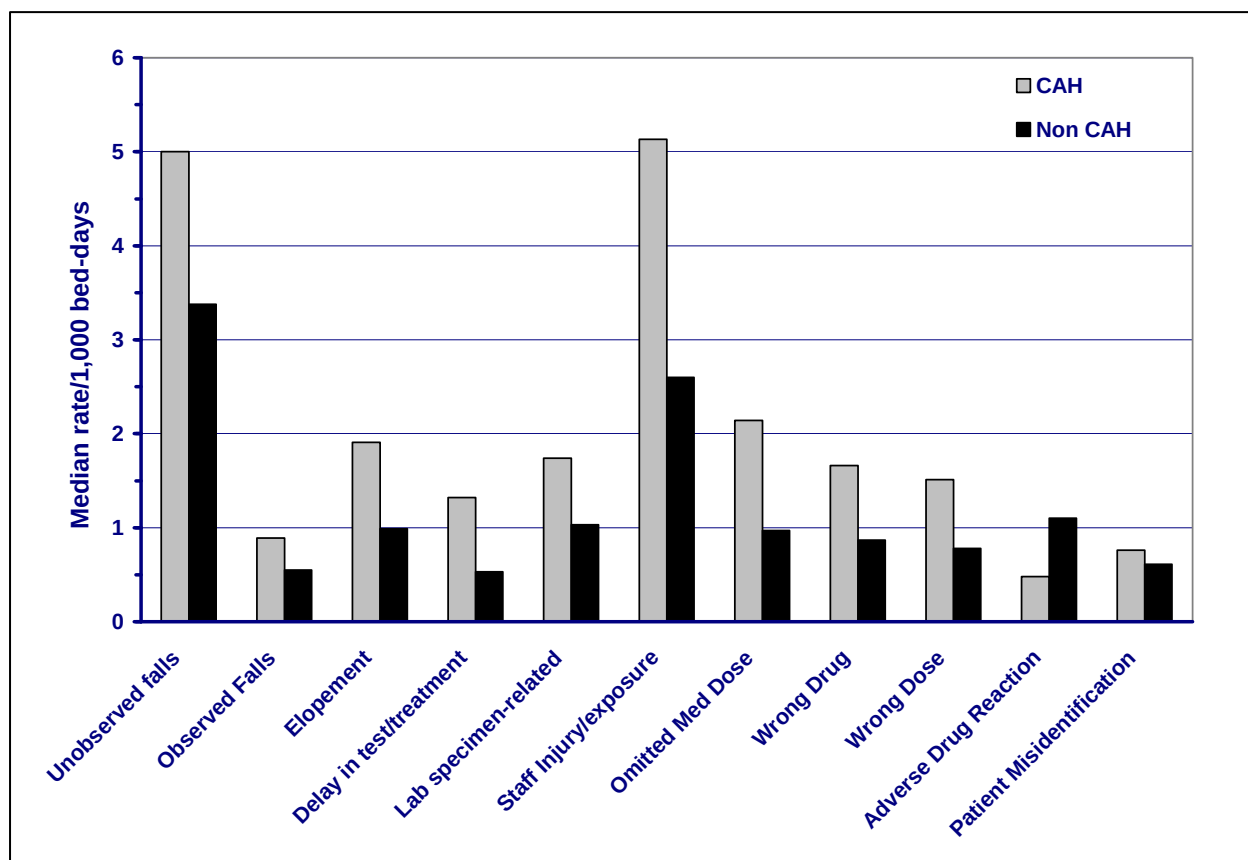


Figure 2. Median event rates over nine quarters, critical access and noncritical access hospitals; West Virginia Patient Safety Project 2005-2007

combining the four categories of medication AEs in our study (3.1 to 5.5); the large difference in rates is not surprising because Kaushal's team conducted active surveillance.¹⁹

The medical literature contains numerous studies of fall causation and prevention; however, relatively few reports focus on fall rates in institutions, and none are specific to small rural hospitals, including but not limited to CAHs. Morse observed a rate of 2.9/1,000 patient-days in acute care hospitals.²⁰ Hitcho and coworkers reported a rate of 6.1/1,000 patient-days in medicine and neurology wards.²¹

We speculate that our reported fall rates are consistent with published values because falls are very likely to generate reports in a hospital setting. A typical scenario involves a patient found on the floor by staff. Because this situation raises liability, treatment, and risk-mitigation questions, multiple channels exist for report generation. On the other hand, medication errors are grossly underreported in our surveillance system for two principal reasons: first, many are not recognized when they occur; and second, they are quite common and often have no detected harmful consequences. The large variation in rates of total AEs and the lack of a standardized definition makes comparison with our passive surveillance-based rates difficult. Of more interest is the wide variation in reported events among participating hospitals.

In general, CAHs have been reporting more events on a per-bed-day basis. Rates are typically twice as great in CAHs as they are in other hospitals. We doubt that CAHs are intrinsically less

safe than larger facilities. In some instances, the event rate difference is probably smaller than it should be because the denominator was not proportional to the risk of an event. For example, larger hospitals might well dispense more drugs and do more lab tests than smaller and critical access sites per bed day. The most likely explanation for differences is systematic reporting biases, with CAH staff generally more likely to report. The explanation for these differences must await further research into the risk of AEs and the likelihood of detecting and reporting them in different hospital settings.

Despite these problems related to accuracy, the reporting system has been useful to the hospitals involved. It has helped them recognize that falls are an increasing issue, as evidenced by their participation in a statewide falls-prevention collaborative. In addition, the utility of the reporting system to participating hospitals was specifically examined through a series of key informant interviews with CEOs, risk managers, and floor nurses, which will be the subject of a separate article under development.

A majority of risk managers interviewed reported undertaking a quality improvement (QI) project based on information from ORM. QI efforts focused on falls, patient flow through the emergency room, and medication errors. Floor nurses who were interviewed reported using the data to look at the environment surrounding an event (e.g., falls; and again, pre- and post- the QI intervention to monitor change). Floor nurses were almost unanimous in their positive assessment of ORM related to analysis and use of medication errors to implement change in their medication use process. Nurses said they were able to track particular weaknesses and focus on where the errors were occurring. By researching events, they report becoming more aware of the kinds of errors they were making. Unusual shifts in reporting rates have led to hospital-specific interventions, *“...we noticed an increase in falls, and after trending it, we implemented a hospitalwide falls program, plus education with staff – physical therapy, occupational therapy, and a few other people – and had everyone trained in transferring patients, lifting patients, walking patients. Right after that, we saw a decrease in falls.”* [Risk Manager]

Conclusion

A multihospital, voluntary, AE reporting system involving rural and CAHs generated event reports that were consistent with those appearing in the medical literature. The use of patient-days proved to be both a reasonable and feasible source of denominator data from small facilities with limited human resources; standardization of taxonomy and of denominator populations would increase comparability of reports. Aggregate event rate data have been useful to small hospitals in focusing their efforts to prevent and mitigate AEs.

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Supplementary Data

The full list of search criteria for the systematic review and detailed evidence table summarized in this report are available from the authors.

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References

1. Berwick DM, Leape LL. Reducing errors in medicine. *Br Med J* 1999; 319: 136-137.
2. Leape LL. Error in medicine. *JAMA* 1994; 272: 1851-1857.
3. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991; 324: 377-384.
4. Leape LL, Woods DD, Hatlie MJ, et al. Promoting patient safety by preventing medical error. *JAMA* 1998; 280:1444-1447.
5. Institute of Medicine, Committee on Health Care Quality in America. *To err is human: Building a safer health system*. Washington DC: National Academies Press; 2000.
6. Centers for Disease Control and Prevention. Updated guidelines for evaluating public health surveillance systems: Recommendations from the guidelines working group. *MMWR* 2001; 50(RR-13): 1-35.
7. Emori TG, Edwards JR, Culver DH, et al. Accuracy of reporting nosocomial infections in intensive care unit patients to the National Nosocomial Infections Surveillance System: A pilot study. *Infect Control Hosp Epidemiol* 1998; 19:308-316.
8. Rosenman KD, Kalush A, Reilly MJ, et al. How much work-related injury and illness is missed by the current national surveillance system? *J Occup Environ Med* 2006; 48: 357-365.
9. Stone PW, Horan TC, Shih HC, et al. Comparisons of health care-associated infections identification using two mechanisms for public reporting. *Am J Infect Control* 2007; 35: 145-149.
10. Schade CP, Hannah K, Ruddick P, et al. Improving self-reporting of adverse drug events in a West Virginia hospital. *Am J Med Qual* 2006; 21: 335-341.
11. Michel P, Quenon JL, de Sarasqueta AM, et al. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *Br Med J* 2004; 328: 199.
12. Health, United States 2006 with chartbook on trends in the health of Americans. Hyattsville, MD: National Center for Health Statistics; 2006.
13. Nettleman MD, Nelson AP. Adverse occurrences during hospitalization on a general medicine service. *Clin Perform Qual Health Care* 1994; 2: 67-72.
14. Unruh L. Trends in adverse events in hospitalized patients. *J Healthc Qual* 2002; 24: 4-10; quiz 10, 18.
15. Dean B, Schachter M, Vincent C, et al. Prescribing errors in hospital inpatients: Their incidence and clinical significance. *Qual Saf Health Care* 2002; 11: 340-344.

16. Fortescue EB, Kaushal R, Landrigan CP, et al. Prioritizing strategies for preventing medication errors and adverse drug events in pediatric inpatients. *Pediatrics* 2003; 111(4 Pt 1): 722-729.
17. Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA* 1997; 277: 312-317.
18. West DW, Levine S, Magram G, et al. Pediatric medication order error rates related to the mode of order transmission. *Arch Pediatr Adolesc Med* 1994; 148: 1322-1326.
19. Kaushal R, Bates DW, Landrigan C, et al. Medication errors and adverse drug events in pediatric inpatients. *JAMA* 2001; 285(16): 2114-2120.
20. Morse JM, Morse RM. Calculating fall rates: Methodological concerns. *QRB Qual Rev Bull* 1988; 14: 369-371.
21. Hitcho EB, Krauss MJ, Birge S, et al. Characteristics and circumstances of falls in a hospital setting: A prospective analysis. *J Gen Intern Med* 2004; 19: 732-739.

Improving Error Reporting in Ambulatory Pediatrics with a Team Approach

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Abstract

Objective: We aimed to determine the effectiveness of team-based reporting, systems analysis, and redesign to address medical errors in pediatric ambulatory care. **Methods:** Voluntary, anonymous, nonpunitive reporting, paired with a team-based system analysis and change implementation, was established in an outpatient pediatric department of an urban teaching hospital. **Results:** In the first year, 80 errors were reported, compared with only 5 errors reported during the prior year via a traditional incident reporting system. Reports originated from physicians (45 percent), nurses (41 percent), other staff (9 percent), and parents/patients (5 percent). Errors were classified as involving office administration (34 percent), medications and other treatment (24 percent), laboratory and diagnostic testing (19 percent), and communications (18 percent). To date, 65 percent of reports have resulted in completed interventions, and other changes are in progress. **Conclusion:** In an academic pediatric ambulatory practice, voluntary, nonpunitive reporting with team-based systems analysis and rapid redesign improved error reporting and resulted in changes to promote safety.

Introduction

The impact of medical errors as a cause of adverse patient outcomes has been described by the Institute of Medicine (IOM) in a series of reports since 1999.^{1, 2, 3} Traditional incident reporting systems are not sensitive to the majority of medical errors because they omit near misses and ignore many errors not directly related to health care personnel.^{4, 5} These systems are also perceived as punitive and primarily rely on administrative reporting, leaving the clinician out of the process. The IOM has called for a reporting system that includes both adverse events and near misses.

A systems approach—as advocated by the IOM—is a shift from a traditional blaming culture, which seeks to identify an individual person as the cause of each error. The identification of system flaws allows the development of preventive strategies to address most types of errors. Health care personnel have limited experience in identifying faulty systems, which are responsible for most errors in care. Clinician-based voluntary reporting has been effective in detecting errors in adult inpatient^{6, 7, 8} and outpatient⁴ settings. The new competency requirements in systems-based care from the Accreditation Council of Graduate Medical Education⁹ address the need for such understanding by resident physicians.

Limited information is available about the types of errors that occur in ambulatory care,^{4, 10, 11, 12, 13, 14, 15} particularly in pediatrics.^{16, 17, 18, 19} Early research suggests that adverse events and near misses are frequent occurrences, but little is known about types of errors, risk factors, or effective interventions. Since the vast majority of health care encounters with children occur on an outpatient basis, an understanding of the types and frequency of errors occurring in this setting is paramount.

We report on a voluntary, anonymous, nonpunitive, team-based reporting system, paired with team-based system analysis, “rapid redesign,” and monitoring of changes in the setting of a pediatric ambulatory department of an urban academic hospital. “Rapid redesign” is a focused, facilitated method of process improvement. Originating in manufacturing industries, rapid redesign brings together members of an improvement team to generate new processes or products over a short period of time.²⁰

Methods

This project was set in an academic ambulatory pediatric practice with 20 faculty physicians and 18 pediatric residents. Faculty included 9 general and 11 subspecialty providers. Annual visit volume during the study period was approximately 30,000 general pediatric and 6,000 pediatric subspecialty visits. Approximately 60 percent of patients were covered by Medicaid, with the remainder primarily covered by private health insurance plans. About half the patient population was of Hispanic ethnicity. During the course of this project, the practice used paper medical records.

At the onset of this initiative, a “pediatric safety champion team” was assembled, including representatives from all staff components: medical director, another physician, nurse manager, office manager, registered nurse, licensed practical nurse, nursing care technician, and patient service representative (registration and receptionist staff member). The responsibilities of the team members were to educate their coworkers about the project, encourage reporting of errors, meet monthly to review all error reports, conduct system-based root cause analyses, and design recommended interventions.

A voluntary, anonymous, nonpunitive, team-based reporting system was established. All practice staff were encouraged to report adverse events (AEs) and near misses of which they were aware. For 2 months prior to implementation, this process was discussed at various staff meetings. An error was defined as “any event in a patient’s medical care that did not go as intended and either harmed or could have harmed the patient.”⁴ All error reports were completed on standard forms¹⁸ and placed in receptacles located in several areas of the practice. The reports were reporter-anonymous and included a description of the event, identification of the patient, job classification of the reporter, and suggestions for prevention of such an event in the future.

All reports were reviewed monthly by the pediatric safety champion team, which conducted root-cause analyses. Further information was obtained by chart review. There was no patient contact in this process. The team reviewed each reported event to identify contributing factors and seek root causes. Errors were classified as office administration, medication or other treatment, laboratory or radiology, and communication processes.⁴ Although reporters of errors remained

anonymous, some error reports also fell under hospital guidelines for incident reporting and were also reported via this system.

To prevent error recurrences, the team decided by consensus on recommended interventions designed to address the root causes of the errors, using rapid redesign methodology.²⁰ Progress in implementation of recommendations was tracked in subsequent meetings. Summaries of all reported errors and recommended interventions were published and distributed to the practice staff in a monthly newsletter and discussed regularly in staff meetings. Participation of the practice's clinical and operational leadership on the safety team helped to facilitate the ability to implement interventions.

Results

During the first 12 months of the project, 80 medical errors were reported. This was a 16-fold increase compared with the 12-month period prior to the project, when only 5 errors were reported via the traditional incident reporting system (Figure 1). Reports originated from physicians (45 percent), nurses (41 percent), other staff (9 percent), and parents/patients (5 percent). Errors were classified by the safety team as primarily involving office administration (34 percent), medications and other treatment (30 percent), laboratory and diagnostic testing (19 percent), or communications (18 percent).

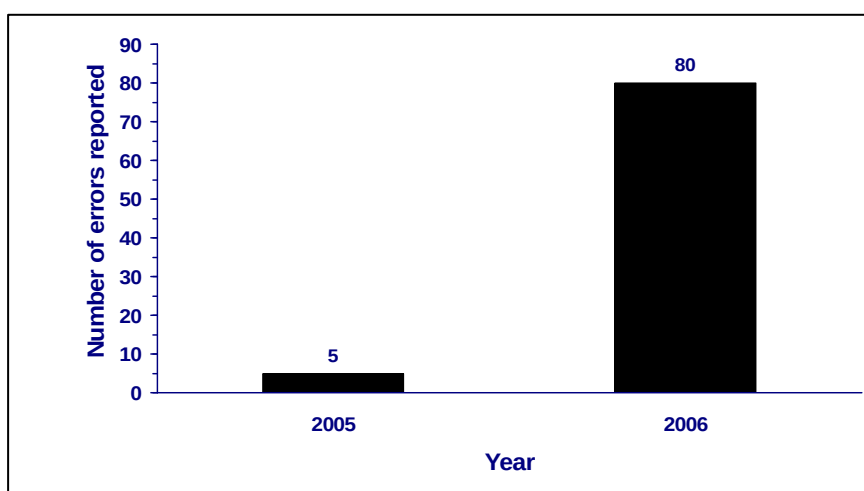


Figure 1. Medical error reports, 2005 and 2006.

Some examples of error reports in each of these categories are listed in Table 1. The most frequent office administration error reports included wrong demographic information or date of visit (seven reports), misfiled papers in chart (seven reports), and delays in processing patients due to misplaced registration forms (six reports).

The most frequent error reports attributed to medication and other treatment included miswritten vaccine and medication order near misses (five reports), wrong vaccine administered (four reports), wrong outside prescription dispensed (three reports), incomplete prescriptions returned by pharmacies (three reports), and patients revaccinated too early (three reports).

Among errors attributed to laboratory and diagnostic testing, the most common included missed specimen pickup (eight reports) and mislabeled specimens (three reports).

Table 1. Examples of error reports in pediatric ambulatory practice

Communications

Error: Child with varicella seated in waiting room for 30 minutes, exposing other children and adults.

Remedy: System established to alert reception desk to children with fever and rash and to communicate with nursing staff to isolate them.

Office administration

Error: Patients, caregivers, and staff often trip over scales in exam rooms.

Remedy: Scales relocated in exam rooms.

Laboratory or diagnostic tests

Error: Laboratory specimens not picked up by courier (several similar reports).

Remedy: Met with laboratory management to revise courier system.

Medications

Error: Wrong vaccine administered (several similar reports).

Remedies: Less interference with nurses preparing vaccines: Keep door closed.
Change physician order documentation to reduce misinterpretations.

The most frequent errors attributed to communication barriers included patients leaving the practice before ordered vaccines were administered (six reports).

The majority of reports (85 percent, N = 68) were of near misses rather than AEs (15 percent, N = 12). None of the AEs (e.g., wrong vaccine administered) resulted in significant harm to patients. To date, 65 percent of error reports have resulted in completed interventions, and other changes are in progress or pending. Interventions have included staff education, changes in systems, and equipment modifications. Some changes have involved collaboration with other departments, such as laboratory.

Discussion

In this urban, academic, hospital-based, pediatric ambulatory practice, voluntary nonpunitive reporting with team-based systems analysis and rapid redesign has increased error reporting, compared with a traditional incident reporting system. In many cases, interventions have been implemented to promote safety and prevent many types of errors. Most reports were near-misses. The 16-fold increase in error reporting compared with the prior traditional incident reporting system may be due to staff education, attempts to overcome the blaming culture in reporting errors, involvement of all staff categories in the team that encouraged and reviewed reports, and response of staff to feedback on reports and interventions.

Our project partially replicated a similar endeavor initiated in an internal medicine ambulatory practice. An academic internal medicine setting in Virginia reported a 20-fold increase in error reporting after implementing near miss/AE voluntary reporting coupled with systems analysis and redesign. As in our study, most of their reports were of near misses rather than AEs.⁴

Limited prior research has been done on the frequency and types of errors in ambulatory pediatric care, and many of these reports have centered on medication errors. In one study,²¹ 21 percent of outpatient prescriptions in a family medicine practice had at least one error. Other investigators found that medication samples were dispensed with inadequate documentation.²² High rates of medication documentation errors were found in another family medicine practice.²³ In a pediatric emergency department in Canada, 100 prescribing errors and 39 medication administration errors occurred per 1,000 patients.²⁴ In another pediatric emergency setting, 22 percent of acetaminophen dose orders were outside the recommendations.²⁵ In a sample of new prescriptions for 22 common medications in outpatient pediatric clinics, approximately 15 percent were dispensed with potential dosing errors.¹⁶

Some particular challenges that may augment the risk of medication errors in the pediatric outpatient setting include the need for rapid dose calculations with weight-based dosing, dilution of stock medications by pharmacists, clear communication with parents about administration, effective cooperative interaction between parents and children, and appropriate measuring devices.^{17, 18}

Our study had several limitations. We depended on voluntary reports from staff in a very busy practice, so that many errors went undetected or unreported. The 80 error reports during the study year represented 0.2 percent of patient encounters and most likely represent just the “tip of the iceberg,” given the size of the practice. Prior studies cited above suggest that medication errors alone may occur in 15 to 22 percent of outpatient encounters.^{11, 14, 16} Many medication errors by outside pharmacies may be difficult to detect and may go unreported. It is not clear whether the types of errors that were reported were representative of the totality of reported plus unreported errors.

The role of parents in reporting errors has been noted.¹⁸ More involvement of parents might have improved the process of error reporting, analysis, and interventions to improve safety in pediatric care. Despite these factors, we believe that our findings indicate a successful beginning in improving safety in ambulatory pediatrics.

Conclusion

A team-based, voluntary, nonpunitive medical error reporting project using systems analysis and rapid redesign effectively improved error reporting and the development of interventions to promote safety in an academic pediatric ambulatory practice. Resar²⁶ has noted that the goal of patient safety should be a focus on harm reduction rather than on simply tabulating errors. He suggests that humanly generated system flaws cannot be overcome simply by vigilance and hard work, but that system redesign is needed for a safer environment. We believe that this project has

helped us move in the direction of designing a safer system of health care delivery in ambulatory pediatrics.

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References

1. Kohn KT, Corrigan JM, Donaldson MS, eds. To err is human: Building a safer health system. Committee on Quality of Health Care in America, Institute of Medicine Washington, DC: National Academies Press; 2000.
2. Committee on Quality of Health Care in America, Institute of Medicine. Crossing the quality chasm: A new health system for the 21st century. Washington, DC: National Academies Press; 2001.
3. Aspden P, Wolcott JA, Bootman JL, et al. Preventing medication errors. Washington, DC: Committee on Identifying and Preventing Medication Errors, Institute of Medicine, National Academies Press; 2007.
4. Plews-Ogan ML, Nadkarni MM, Forren S, et al. Patient safety in the ambulatory setting: A clinician-based approach. *J Gen Intern Med* 2004 July; 19: 719-725.
5. Cullen CJ, Bates DW, Small SD, et al. The incident reporting system does not detect adverse drug events: A problem for quality improvement. *Jt Comm J Qual Improv* 1995; 12: 541-552.
6. Weingart S, Callanan L, Ship A, et al. A physician-based voluntary reporting system for adverse events and medical errors. *J Gen Intern Med* 2001; 16: 809-814.
7. Weingart SN, Ship AN, Aronson MD. Confidential clinician-reported surveillance of adverse events among medical inpatients. *J Gen Intern Med* 2000; 15: 470-477.
8. Chardhry S, Olfinboba K, Krumholz H. Detection of errors by attending physicians on a general medicine service. *J Gen Intern Med* 2003; 18: 595-600.
9. Accreditation Council for Graduate Medical Education. Program director guide to the common program requirements, 2007. Available at: www.acgme.org/acWebsite/navPages/nav_commonpr.asp. Accessed March 5, 2008.
10. Hammons T, Piland NF, Small SD, et al. Ambulatory patient safety. What we know and need to know. *J Ambul Care Manage* 2003; 26: 63-82.
11. Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA* 2003; 289: 1107-1116.
12. Gandhi R, Burstin HR, Cook EF, et al. Drug complications in outpatients. *J Gen Intern Med* 2000; 15: 149-54.
13. Dovey SM, Meyers DS, Phillips RL, et al. A preliminary taxonomy of medical errors in family practice. *Qual Saf Health Care*. 2002; 11: 233-238.
14. Gandhi T, Weingart S, Borus B, et al. Adverse drug events in primary care. *N Engl J Med*. 2003; 348: 1556-1564.
15. Foster A, Murff H, Peterson J, et al. The incidence and severity of adverse events affecting patients after discharge from the hospital. *Ann Intern Med* 2003; 138: 161-167.
16. McPhillips HA, Stille CJ, Smith D, et al. Potential medication dosing errors in outpatient pediatrics. *J Pediatr* 2005; 147: 761-767.

17. Kaushal R, Jaggi T, Walsh K, et al. Pediatric medication errors: What do we know? What gaps remain? *Ambul Pediatr* 2004; 4: 73-81.
18. Mohr JJ, Lannon CM, Thoma KA, et al. Learning from errors in ambulatory pediatrics. In: *Advances in Patient safety: From research to implementation*. Washington, DC; Agency for Healthcare Research and Quality, 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol1/Mohr.pdf. Accessed March 5, 2008.
19. Dovey S, Phillips R, Green L. Medical errors affecting vulnerable primary care patients in six countries: A report of the LINNAEUS Collaboration. Academy for Health Services Research and Health Policy Annual Research Meeting. Washington, DC: AHSRHP; 2002.
20. Fox LA, Thierry P. Process improvement: Tools and methodologies for the 21st century. *Advance online editions for health information professionals*, 2005 Oct 10. Available at: health-information.advanceweb.com/Editorial/Content/PrintFriendly.aspx?CC=60881. Accessed March 5, 2008.
21. Shaughnessy AF, Nickel RO. Prescription-writing patterns and errors in a family medicine residency program. *J Fam Pract* 1989; 29: 290-295.
22. Dill JL, Generali JA. Medication sample labeling practices. *Am J Health Syst Pharm* 2000; 57: 2087-2090.
23. Ernst ME, Brown GL, Klepser TB, et al. Medication discrepancies in an outpatient electronic medical record. *Am J Health Syst Pharm* 2001; 58: 2072-2075.
24. Kozar E, Scolnik D, Macpherson A, et al. Variables associated with medication errors in pediatric emergency medicine. *Pediatrics* 2002; 110: 737-742.
25. Losek JD. Acetaminophen dose accuracy and pediatric emergency care. *Pediatr Emerg Care* 2004; 20: 285-288.
26. Resar R. Will, ideas, and execution: Their role in reducing adverse medication events. *J Pediatr* 2005; 147: 727-728.

Relationship Between Patient Harm and Reported Medical Errors in Primary Care: A Report from the ASIPS Collaborative

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Abstract

Context: Harm associated with primary care medical errors is not well described. **Objective:** The objective of this project was to investigate the relationship between primary care medical errors and patient harm. **Main Outcome Measures:** The principal outcome measures for this study were: association between specific attributes of medical errors and levels of patient harm and frequency of harm classified hierarchically into five categories: (1) unknown or no known harm, (2) unstable or too early to tell if harm has occurred, (3) patient discomfort or inconvenience, (4) increased risk to patient or others, and (5) known clinical harm to the patient. **Results:** Clinical harm to the patient was reported in more than 10 percent of the 608 medical error reports. Prescription-related errors were most frequently associated with clinical harm (OR 5.25; 95 percent CI, 3.0-9.19; $P < 0.01$). **Conclusion:** Errors in certain processes and systems are associated with patient harm in primary care. These findings might help prioritize the key areas of clinical care that warrant further study and intervention to improve patient safety.

Introduction

Patient safety reporting systems (PSRS) are useful tools to understand the scope of errors that occur during medical care.^{1, 2, 3, 4} To date, research on errors in the primary care setting has focused principally on the types of errors that occur in primary care offices and less on the consequences of those errors.^{5, 6, 7, 8} Makeham, et al., described broad categories of errors that led to hospitalization or death, as reported to an international primary care error reporting system.¹ They found that errors involving clinical decisions (as opposed to system process errors) were more likely to lead to serious consequences. However, this and a second brief report by Dovey, et al.,⁹ did not describe whether and how harm relates to specific attributes of an error.

In this paper, we examine harm associated with the medical errors reported to the Applied Strategies for Improving Patient Safety (ASIPS) reporting system. The purpose of this study is to investigate the relationship between the attributes of medical errors in primary care settings and patient harm.

Methods

Study Population

The ASIPS project, a multi-institutional demonstration project, collected and analyzed medical errors in primary care ambulatory practice.¹⁰ The ASIPS Patient Safety Reporting System (ASIPS PSRS) collected error reports from clinicians and staff in two practice-based research networks: the Colorado Research Network (CaReNet) and the High Plains Research Network (HPRN). The participating practices are located in urban, suburban, rural, and frontier regions of Colorado and represent over 500 clinicians, who receive approximately 400,000 visits per year from a patient population diverse in terms of age, race, ethnicity, socioeconomic status, and medical problems. The ASIPS protocol was approved by the Colorado Multiple Institutional Review Board (COMIRB) and other applicable institutional review boards.

ASIPS Patient Safety Reporting System

The core of the ASIPS PSRS is a Web-based data collection and data management system, described in detail elsewhere.¹¹ Briefly, the system accepted both anonymous and confidential reports of “medical events you don’t wish to have happen again, that might represent a threat to patient safety.” This definition included near-miss events and events that led to varying degrees of patient harm. All clinicians and staff members of participating practices were encouraged to report errors. Through August 2003, 67 percent of reports were from clinicians; 24 percent were from other clinical staff; and 7 percent were from nonclinical staff;¹² 66 percent of the reports were submitted confidentially.¹⁰ Research personnel conducted telephone followup interviews with people who submitted confidential reports of interest to gather more detailed information about the report.

Error Coding and Classification

All error reports were reviewed and then coded by teams of at least three members, including one physician, using a multi-axial taxonomy, Dimensions of Medical Errors (DMO).¹³ The DMO taxonomy provides a detailed description of the processes and individuals involved in adverse events or adverse patient outcomes, including events with and without identified errors, across all locations of medical care. Whereas the DMO taxonomy includes 5 domains and 38 axes, the ASIPS project only used 4 domains and 10 axes. Within each axis are numerical codes that correspond to descriptions of process steps (including causation), associated diagnoses, associated tests, associated medications, participants, outcome(s), individual(s) who discovered the event, and the setting(s). These descriptions and labels are collectively referred to here as “error attributes.” Codes are arranged hierarchically within axes, ranging from 3-digit upper-level codes through 7-digit detailed, subordinate codes.¹⁴ Because we wanted to use all relevant taxonomic axes to describe each error, multiple attributes could be assigned to the same error.

Classification of Harm Level

In addition to identifying error attributes, we classified all errors hierarchically into one of five ordinal harm categories (Table 1). An earlier harm classification from the ASIPS Collaborative appeared in Fernald, et al.,¹⁰ with detailed descriptions in the online appendices. Errors with

Table 1. Harm classification

Harm category	Example
Known clinical harm to the patient	A positive herpes simplex culture of the eye, not handled over the weekend; by Monday the patient has severe eye pain and visual changes.
Increased risk to patient or others	A missed diagnosis of diabetes for several years; or an Rh-negative woman, who is sensitized due to failure to check a blood type during a spontaneous miscarriage.
Patient discomfort or inconvenience ^a	A patient who must undergo a second skin biopsy due to a lost specimen.
Unstable or too early to tell	A patient with atrial fibrillation and a missed low PT/INR that is reported prior to correcting the problem.
Unknown or no known harm	An unlabeled lab specimen for gonorrhea and <i>Chlamydia</i> PCR is discovered by the lab after the patient has been started on antibiotics.

a Used only if report specifically mentioned discomfort or convenience.

multiple harm outcomes (involving either more than one patient or multiple outcomes for a single patient) were assigned to the category that represented the highest level of harm. For example, errors that involve both known clinical harm and patient inconvenience were classified as “known clinical harm.”

Data Analysis

We calculated frequency distributions of error attributes for each harm category. We tested for bivariate associations between harm categories and each error attribute using chi-square tests. To measure the strength of the associations between “harm” and individual error attributes, crude odds ratios (ORs) and 95 percent confidence intervals (CI) were calculated with “no known harm/unknown” as the reference group. These analyses included only error attributes that were coded in at least 20 reports to reduce the possibility that someone could identify a particular event, provider, or practice because the attributes of that event were so unusual. Statistical analyses were performed using SPSS[®], Ver. 12.0 (SPSS, Inc., Chicago, IL).

Results

Of the 708 events reported to ASIPS, 608 reports were coded using the ASIPS refined version of the taxonomy^{13, 14} and analyzed for harm. (We determined that the remaining 100 reports did not describe medical errors.) Of the 608 errors, 405 (66.6 percent) were associated with no known harm; for 47 error reports (7.7 percent), it was too early to tell whether harm had occurred; 39 error reports (6.4 percent) were related to discomfort or inconvenience for the patient; and 55 error reports (9.0 percent) were related to increased risk to the patient or others; finally, 62 error reports (10.2 percent) were associated with clinical harm to the patient.

Types of Errors Associated with Harm

For purposes of the following analysis, we concentrated on the two highest levels of harm (“known clinical harm” and “future risk of clinical harm”), reasoning that these errors represent the greatest potential threat to patients’ welfare. We identified four main categories of errors significantly associated with one or both of these highest levels of harm: (1) prescription drug errors, (2) coordination of care errors (specifically errors involving communication), (3) errors in clinical activities (generally timing of these activities), and (4) errors related to cognition (Table 2). As previously stated, in describing the likelihood of clinical harm or future risk of clinical harm that we observed in each of these categories of error (Table 2), crude odds ratios (ORs) and 95 percent confidence intervals (CIs) were calculated with “no known harm/unknown” as the reference group.

Prescribing errors. Prescription-related errors, reported in 165 events (27.1 percent), were more than three times as likely to be associated with increased risk of future harm to patients and were more than five times as likely as other types of errors to be associated with clinical harm (the strongest association observed). Prescription errors included instances of (1) the wrong drug or device selected; (2) the incorrect administration, dosage, or timing of the correct drug; and (3) not prescribing a drug or device that was needed. Of those 165 events, in 99 (16.3 percent) the correct drug or device was prescribed, but there was an error in dosage, administration, or timing. This subset of errors was associated with increased risk of future harm (more than three times as likely than all other reported errors) and clinical harm (nearly six times as likely).

Coordination of care errors. Reported errors that were grouped under the heading “coordination of care” included (1) errors involving participants outside of the office, (2) problems with communication from another office, and (3) errors related to disclosure, explanation, or followup with a patient.

Errors involving participants outside the office were reported in 137 events (22.5 percent) and were nearly three times as likely to be associated with clinical harm. Errors involving communication from other offices were reported in 73 events (12.0 percent) and were also nearly three times as likely to be associated with clinical harm. Errors involving disclosure, explanation, or followup with patients were reported in 55 events (9.9 percent) and were approximately four times as likely to be associated with increased risk to the patient or others and with clinical harm.

Errors in clinical activities. Clinical activity errors included mistimed procedures, examination errors, diagnostic errors, and delays in therapy. Errors involving mistimed procedures were reported in 244 events (40.1 percent) and were more than twice as likely to be associated with clinical harm. Examination errors were reported in 38 events (6.3 percent) and were more than three times as likely to be associated with clinical harm.

Diagnostic errors were reported in 74 events (12.2 percent) and were more than twice as likely to be associated with increased risk to the patient or others. Delays in therapy were reported in 81 events (13.3 percent), were nearly five times as likely to be associated with increased risk to patient or others, and were more than five times as likely to be associated with clinical harm.

Errors related to cognition or systems. Errors classified as having been related to judgment and knowledge or to systems issues were included within the cognition and systems grouping.

Judgment and knowledge errors were reported in 129 events (21.2 percent) and were three times as likely to be associated with clinical harm. Errors appearing to have been caused by either the failure or lack of a good system were reported in 72 events (11.8 percent) and were more than twice as likely to be associated with clinical harm.

When coding errors, the ASIPS team considered many repetitive office activities as “systems,” even if the office staff did not at times recognize the system construct. If an office indicated it had a formal process for handling a specific activity and if training was provided to new employees in the area, the process was considered a “system.” Likewise, repetitive activities for which an office did not have a systematic or standardized process were considered “system absences.” Therefore, system-related harm would include reported failures to follow up on missing laboratory or imaging results, either because the office did not track this information (lack of a system), the office system was used intermittently (inadequate system), or the system output was ignored by the staff (system overridden or ignored).

Participants in Errors Associated with Harm

People in certain roles were more often involved in reported errors. The clinician of record was reported to be involved in 267 events (43.9 percent), compared with licensed staff within the office (118 events, 19.4 percent); patients or individuals associated with the patient (65 events, 10.7 percent); and providers of patient care outside the office (137 events, 22.5 percent). Patients were included as participants only if their conscious action or inaction was related to the error (e.g., knowing about a drug allergy but not reporting it to the clinician).

Multiple roles could be involved in any single error event. Errors involving the physician of record were nearly twice as likely to be associated with increased risk of harm to the patient or others and were more than twice as likely to be associated with clinical harm than were errors not involving the clinician of record (Table 2).

Discussion

These results indicate what many have long suspected¹⁵ and what smaller studies⁹ have suggested: errors that occur in primary care can result in harm to patients and others. The types of errors for which we found harm were similar to previous reports concerning ambulatory medical errors.^{15, 16}

The strongest associations with clinical harm involved reported prescription-related errors. The high prevalence of errors involving prescription medications makes this finding a particular concern. Gandhi and colleagues’ survey and chart review of primary care patients identified 162 adverse drug events, 13 percent of which were serious.⁶ The analysis by Zhan, et al., of National Ambulatory Medical Survey (NAMCS) data on outpatient visits by elderly patients found that 2.58 percent (95 percent CI = 2.44 - 2.72) of visits that included prescription medications had one or more inappropriate drug-disease combinations.¹⁷

The results of the present study suggest that certain types of errors might be good candidates for the development of systems, such as those that can facilitate reliable communication within and between offices, as well as with other external organizations (e.g., labs and pharmacies). As part of the ASIPS project, our research team designed interventions to improve systems in primary

Table 2. Attributes of errors related to harm (N = 608)

Error type	Error attributes [N (%)]	Future risk of harm to patient or others [Frequency (%)]	Known clinical harm to patient [Frequency (%)]
		OR (95% CI) (N = 55)	OR (95% CI) (N = 62)
Prescription error	Any prescription drug or device error 165 (27.1)	26 (47.3) 3.18 (1.78 - 5.68) ^b	37 (59.7) 5.25 (3.00 - 9.19) ^b
	Correct drug selected, but other prescribing error 99 (16.3)	17 (30.9) 3.41 (1.78 - 5.61) ^b	27 (43.5) 5.88 (3.27-10.57) ^b
Coordination of care error	Error participants outside of the office 137(22.5)	NS	25 (40.3) 2.88 (1.64 - 5.06) ^b
	Problems with communication from another office 73 (12.0)	NS	15 (24.2) 2.91 (1.50 - 5.67) ^b
	Errors relating to disclosure to, explanation to, or followup with a patient 55 (9.9)	11 (20) 3.80 (1.75 - 8.25) ^b	13 (21) 4.03 (1.94 - 8.40) ^b
	Mistimed procedures 244 (40.1)	NS	33 (53.2) 2.18 (1.27 - 3.73) ^b
Errors in clinical activities	Examination errors 38 (6.3)	NS	8 (12.9) 3.60 (1.47 - 8.82) ^a
	Diagnostic errors 74 (12.2)	10 (18.2) 2.35 (1.09-5.06) ^b	NS
	Delays in therapy 81 (13.3)	17 (30.9) 4.88 (2.50 - 9.55) ^b	20 (32.3) 5.20 (2.75 - 9.83) ^b
	Judgment and knowledge 129 (21.2)	NS	26 (41.9) 3.40 (1.93 -5.98) ^b
Errors related to cognition	Systems issue 72 (11.8)	NS	11 (17.7) 2.08 (1.00 - 4.33) ^a
	Clinician of record 267(43.9)	31 (56.4) 1.84 (1.04 - 3.25) ^a	39 (62.9) 2.42 (1.39 - 4.20) ^a

a $P < 0.05$.b $P < 0.01$ in chi-square test.

care offices, such as automated tracking of orders for diagnostic tests to ensure receipt of results and electronic prescribing to reduce errors in the prescribing process.¹⁸ However, further research is required to learn if these efforts can reduce the medical errors that result in clinical harm.

Our findings about the harm associated with communication problems are consistent with a recent analysis of error cascades (one error leading to another) by Woolf, et al.¹⁹ and also one of the first studies of primary care errors by Bhasale, et al.²⁰ The cascade analysis found that 80 percent of the errors that set off cascades involved informational or personal miscommunication, and two of three errors in treatment or diagnosis were actually set in motion by errors in communication.¹⁹ The earlier study found that one of the most common factors contributing to incidents of potential or actual harm was poor communication between patients and health care professionals (23 per 100 incidents).²⁰ While improving interpersonal communication appears to be a useful goal, systematic intervention may be necessary. Smith et al. reported that clinical information was unavailable in 13.6 percent of primary care visits and that this missing information was at least somewhat likely to adversely affect patients 44 percent of the time.²¹ We found that communication with other offices appears to be especially problematic, particularly for clinicians attempting to fulfill what the Institute of Medicine and others consider the defining task of primary care, coordinating comprehensive care across the health care system.^{22, 23, 24}

We also found errors associated with patient harm that might be less amenable to systematic intervention, namely, the errors in judgment and knowledge. Woolf et al., found that over three-quarters of errors reported by family physicians to a primary care error reporting system were mistakes in treatment or diagnosis;¹⁹ Bhasale and colleagues reported that errors in judgment were common factors contributing to poor outcomes.²⁰ Our results show that errors in judgment and knowledge were more than three times as likely to result in clinical harm to patients as errors not involving this lapse. Educational interventions that address the way physicians in training frame clinical hypotheses and confront inconsistencies with their hypotheses, such as those proposed by Borell-Carrió and Epstein,²⁵ might address some of the diagnostic and other clinical errors that lead to harm. In the meantime, very specific, effective interventions to address cognitive errors (e.g., decision support) are needed.

We acknowledge that there are a number of limitations associated with our research, including the fact that the error data collected and analyzed were self-reported by clinicians and office staff. Reports of the errors themselves and any clinical harm (or lack of harm) associated with each error could not be independently verified. In addition, the frequency—and thus the number—of reported errors resulting in harm was also a limiting factor in our analysis. Large-scale studies with more reported events would allow for the development of a fuller understanding of the relationships of specific categories of errors to overall harm and to one another. Finally, the ASIPS data, which were reported to a voluntary reporting system, might not be representative of all errors that occur in primary care or the harm associated with those errors, and they likely underestimate the occurrence of medical errors.²⁶ Until we can create a culture that embraces learning from our mistakes, including implementing comprehensive error reporting, we will understand only a fraction of all medical errors and their associated harm.

Despite these limitations, this study is among the first primary care studies to document the potential patient harm of ambulatory primary care medical errors. Better understanding of what distinguishes errors that are associated with patient harm from those that are not is essential in our attempts to improve patient safety. Additional, efficient methods of identifying and studying medical errors in primary care are necessary. Detailed mapping of specific processes within primary care settings that correspond to those areas most associated with patient harm is

necessary for the development and evaluation of specific interventions designed to reduce the harm caused by medical errors.

Conclusion

Across inpatient and outpatient care settings, the utility of medical error reporting systems is being recognized. However, the resultant data can present researchers and practitioners alike with large data sets containing hundreds or even thousands of carefully analyzed and coded errors. The challenge is to determine how to best use these data to improve patient safety. The ASIPS project team developed one such approach using a mixed methods strategy,²⁷ but certainly other approaches exist.

Our efforts have shown that it is possible, using reporting systems and coding methods designed to capture the presence of patient harm, to isolate the attributes of certain reported medical errors that are most frequently associated with harm. We posit that this is a step in the critical path toward identifying and isolating those clinical processes that warrant our closest attention. By incorporating these data into a clinical quality improvement framework, quality and safety improvement efforts can focus on isolating the root causes of the most dangerous medical errors and identifying the critical control points or workflows that could be changed to reduce or eliminate future hazards.

The areas of clinical harm and risk of future harm identified by our analysis might not come as a surprise to experienced clinicians or researchers who have long been concerned about the harm associated with prescribing errors and those errors related to communication with entities outside the physician's office. By increasing our ability to capture information about patient harm in medical error reports and by assessing the association of harm with specific types of errors, we believe our efforts to become better "detectives" to identify the problems within our clinical processes will be enhanced, and our interventions will become more targeted, more appropriately evaluated, and thus, more effective in the future.

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References

1. Makeham MA, Dovey SM, County M, et al. An international taxonomy for errors in general practice: A pilot study. *Med J Aust* 2002; 177: 68-72.
2. Motschman TL, Moore SB. Error detection and reduction in blood banking. *Clin Lab Med* 1996; 16: 961-973.
3. Evans RS, Pestotnik SL, Classen DC. A computer-assisted management program for antibiotics and other anti-infective agents. *N Engl J Med* 1997; 338: 232-238.
4. Frey B, Kehrler B, Losa M, et al. Comprehensive critical incident monitoring in a neonatal-pediatric intensive care unit: Experience with the system approach. *Intensive Care Med* 2000; 26: 69-74.
5. Wilf-Miron R, Lewenhoff I, Benyamini Z, et al. From aviation to medicine: Applying concepts of aviation safety to risk management in ambulatory care. *Qual Saf Health Care* 2003; 12: 35-39.
6. Gandhi TK, Weingart SN, Borus J, et al. Adverse drug events in ambulatory care. *N Engl J Med* 2003; 348: 1556-1564.
7. Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA* 2003; 289: 1107-1116.
8. Elder NC, Dovey SM. Classification of medical errors and preventable adverse events in primary care: A synthesis of the literature. *J Fam Pract* 2002; 51: 927-932.
9. Dovey SM, Meyers DS, Phillips RL Jr, et al. A preliminary taxonomy of medical errors in family practice. *Qual Saf Health Care* 2002; 11: 233-238.
10. Fernald DH, Pace WD, Harris DM, et al. Event reporting to a primary care patient safety reporting system: A report from the ASIPS Collaborative. *Ann Fam Med* 2004; 2: 327-332.
11. Pace WD, Staton EW, Higgins GS, et al. Database design to ensure anonymous study of medical errors: A report from the ASIPS Collaborative. *J Am Informat Assoc* 2003; 10: 531-540.
12. Harris D, Pace WD, Fernald DH. A comparison of medical error reports submitted to a voluntary patient safety reporting system by different classes of reporters: A report from the ASIPS Collaborative. Academy Health Annual Research Meeting; 2004 June 6; San Diego, CA. Available at: academyhealth.org/2004/harris.pdf. Accessed March 31, 2008.
13. Dimensions of medical outcome. ASIPS-Victoroff dimensions of medical outcome. Medical error taxonomies. A research forum; 2003. Available at: www.errorsinmedicine.net/taxonomy/asips/default.aspx. Accessed March 31, 2008.
14. Pace WD, Fernald DH, Harris D, et al. Developing a taxonomy for coding ambulatory medical errors: A report from the ASIPS Collaborative. Advances in patient safety: From research to implementation. Vol. 2, Concepts and methodology. AHRQ Pub. 05-0021-2. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol2/Pace.pdf. Accessed March 31, 2008.
15. Phillips DP, Christenfeld N, Glynn LM. Increase in U.S. medication-error deaths between 1983 and 1993. *Lancet* 1998; 351:643-644.
16. Fischer G, Feters MD, Munro AP, et al. Adverse events in primary care identified from a risk-management database. *J Fam Pract* 1997; 45: 40-46.
17. Zhan C, Correa-de-Araujo R, Bierman AS, et al. Suboptimal prescribing in elderly outpatients: Potentially harmful drug-drug and drug-disease combinations. *J Am Geriatr Soc* 2005; 53: 262-267.
18. West D, Westfall JM, Araya-Guerra R, et al. Using reported primary care errors to develop and implement patient safety interventions: A report from the ASIPS Collaborative. Advances in patient safety: From research to implementation. Vol. 3, Implementation issues. AHRQ Pub. 05-0021-3. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol3/West.pdf. Accessed March 31, 2008.
19. Woolf SH, Kuzel AJ, Dovey SM, et al. A string of mistakes: The importance of cascade analysis in describing, counting, and preventing medical errors. *Ann Fam Med* 2004; 2: 317-326.

20. Bhasale AL, Miller GC, Reid SE, et al. Analysing potential harm in Australian general practice: An incident-monitoring study. *Med J Aust* 1998; 169: 73-76.
21. Smith PC, Araya-Guerra R, Bublitz C, et al. Missing clinical information during primary care visits. A report from SNOCAP and the ASIPS Collaborative. *JAMA* 2005; 293: 565.
22. Future of Family Medicine Project Leadership Committee. The future of family medicine: A collaborative project of the family medicine community. *Ann Fam Med* 2004; 2(suppl 1): S3-S32.
23. Donaldson MS, Yordy KD, Lohr KN, et al, eds. Primary care: America's health in a new era. Washington, DC: National Academies Press; 1996.
24. Aspden P, Corrigan JM, Wolcott J, et al, eds. Patient safety: Achieving a new standard for care. Washington, DC: National Academies Press; 2004.
25. Borrell-Carrió F, Epstein RM. Preventing errors in clinical practice: A call for self-awareness. *Ann Fam Med* 2004; 2: 310-316.
26. Tuttle D, Holloway R, Baird T, et al. Electronic reporting to improve patient safety. *Qual Saf Health Care* 2004; 13: 281-286.
27. Harris DM, Westfall JM, Fernald DH, et al. Mixed methods analysis of medical error event reports: a report from the ASIPS Collaborative. *Advances in patient safety: From research to implementation*. Vol. 2, Concepts and methodology. AHRQ Pub. 05-0021-2. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol2/Harris.pdf. Accessed March 31, 2008.

Structure and Features of a Care Enhancement Model Implementing the Patient Safety and Quality Improvement Act

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Abstract

The Patient Safety and Quality Improvement Act, passed in 2005, has been heralded as an important advance in patient safety. Numerous questions have been raised regarding details of the implementation of the legislation. Recent concern has been expressed that progress in implementing the legislation has been slow, and important issues have not been addressed to transform the legislative intent into a viable patient safety system. To date, no model has yet been offered on how the information exchange between the Patient Safety Organization (PSO) contemplated by the Act and client health care organizations can be completed and acted upon. In this article, we propose a Care Enhancement Model, based on our experience in aviation and health care safety, which describes how information can be prioritized, acted upon, and used for improvement. We present the thematic tenets of the “Care Enhancement Model” as a blueprint to connect the PSO with a provider setting and a national Network of Patient Safety Databases (NPSD) as created by the Act. We then provide detailed roles and responsibilities of each of these components that might provide guidance for an effective tripartite safety system.

Introduction

The Patient Safety and Quality Improvement Act of 2005 (the Act) has been heralded as an important advance in patient safety. Several reviews of the Act outline its main features.^{1, 2, 3, 4} The Act reflects the need for voluntary reporting of error and system weakness information for organizational and industry learning. The Act provides for legal privilege for reports and information regarding safety between any health care provider and a Patient Safety Organization (PSO). Furthermore, the Act provides for a national Network of Patient Safety Databases (NPSD) of voluntary incident reports submitted by PSOs and others for broad dissemination and learning. Therefore, the Act has the potential to create an event reporting system that provides feedback for developing safer practices associated with preventing, identifying, and mitigating harm to patients associated with the processes of care.⁵

Due to the complexity of the regulatory process,⁶ the limited guidance available for providers, and the uncertainty about the role PSOs should play, progress in implementing the Act has been slow.^{7, 8, 9, 10} Moreover, it is recognized that the detection, by itself, of an event or error is not sufficient to improve patient safety.¹¹ Detecting and reporting of harm and near misses as they occur in health care settings are essential, but they are only part of the full complement of

components of patient safety improvement and error management programs.¹² Clearly, the control of safe operations is a continual process.

No model has yet been offered that describes how the information exchange between the PSO and client health care organization can be completed and acted upon. This article presents a model to describe how voluntarily reported information can be prioritized, acted upon, and used for improvement among providers and PSOs. Specifically, we propose a “Care Enhancement Model” as a blueprint that connects the PSO and health care organization in the context of the national database network. We then discuss the roles and responsibilities of each part of the triumvirate of health care organization, PSO, and national database network. In this description, we outline the manner by which health care organizations would interface with the PSO and the national NPSD to improve safety.

In addition to the ability to respond rapidly and effectively to changes in the safety realm, the prerequisites for adequate safety control require a sensitive multichannel feedback system.¹³ While a more proactive approach to risk assessment is desirable,¹⁰ no construct has yet provided guidance as to how providers and PSOs can and should work together to effectively improve safety.

Care Enhancement Model

The Act provides a basic framework for the structure and function of the PSO and how it relates to health care organizations that are the source of error reporting.^{4, 5} There are three main components in a national voluntary reporting system: the PSO, the client health care provider organization, and the national database network. The Act suggests specific roles for each of these three components: (1) the PSO provides a defined list of services that are legislatively described; (2) the health care provider organization is a client to the PSO and uses its services to improve patient safety within the service setting; and (3) the national NPSD acts as an archive and resource for safety information. Figure 1 shows the three components of the Care Enhancement Model for the national voluntary reporting system and how they can relate to each other.

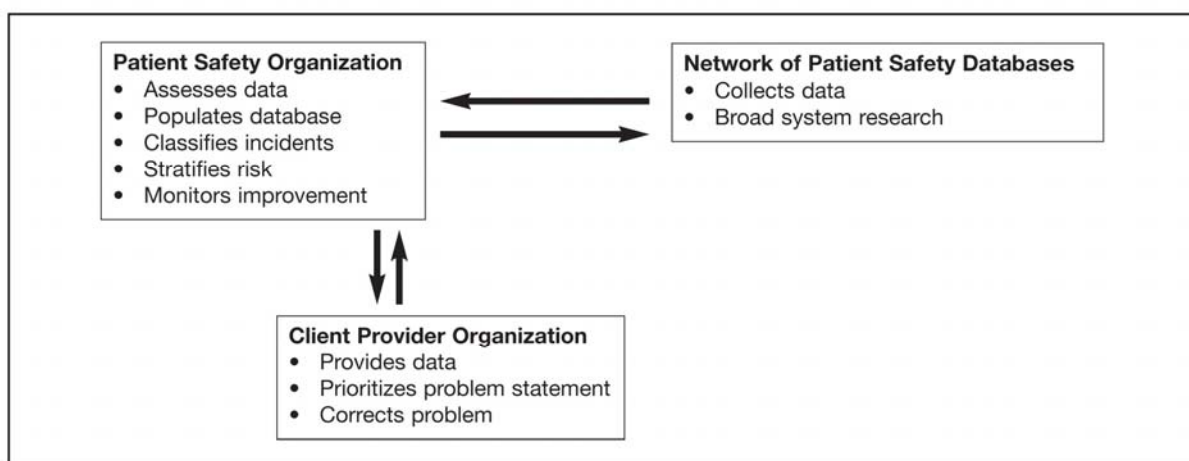


Figure 1. Three components of a national Care Enhancement Model for a voluntary patient reporting system.

The broad relationships noted in the Care Enhancement Model are thematic. Hence, some details with respect to the roles and responsibilities of these three components may be helpful to guide implementation by each entity to maximize safety improvement in the health care delivery system. Through this model, reports are analyzed for local purposes, used for national assessments, and archived for future use. They are provided internally to the provider organization and externally for global application and alerts. This circular flow of information provides a continually improving safety effort while consistently adding data to allow for additional work for care enhancement in ways not contemplated at the time they are reported or analyzed.

The Health Care Organization

The central focus in the voluntary reporting system is the health care organization, which serves as both the source of error reporting and the location where safety management and improvement programs provide feedback meant to improve care. As such, the health care organization must participate in error reporting for its own benefit and to benefit the industry as well. The health care provider organization also represents the “sharp end,” and hence, is responsible for in-depth event investigation to assess associated event or incident causal factors. Tight coupling of this information with appropriate system change and redesign,¹⁴—through use of Problem Statements to focus efforts—will help to improve system functionality and safety.

Problem Statements describe and quantify identified risks the institution faces. The health care organization transmits the Problem Statement to the PSO and concretely defines the core performance issue to be addressed. The health care organization is responsible in the Care Enhancement Model to assign priority for Problem Statements and to implement corrective measures. Figure 2 illustrates the application of the patient safety information received from the PSO and describes how the Problem Statements are used for improvement. This structure is patterned after the air carrier risk-management model and positions the health care organization



Figure 2. Use of problem statements in health care organizations.

as both the source of near miss reporting and user of the products from the PSO to improve its systems and safety practices.

We identify four distinct components inside the health care organization. First, the Patient Safety Department (PSD) serves as the interface between the PSO and the organization. The data are reduced to the format agreed upon by the PSO and transmitted to the PSO. The key questions asked of each Problem Statement are:

- What is the frequency of occurrence?
- Was this a one-time event or a point on a trend line?
- What are the ramifications of the Problem Statement's recurrence?

The second component in this model is senior management, which holds ultimate accountability for the Problem Statements. Senior management must take several critical steps for care enhancement including:

- Determine priorities for correction, as reflected by allocation of resources to problem correction.
- Assign responsibility to appropriate line departments to design and implement corrective strategies.
- Create a timeline for process improvement.

Managing the Problem Statement involves management's determination of priorities and resources to be committed to correction; assignment of responsibility for correction; and development of processes to track the accomplishment of corrective measures and changes in system performance.

The Problem Statements would be presented to senior medical center management in regularly scheduled periodic meetings. In conference with PSD staff, this leadership group receives the information contained in the Problem Statements, the assessed risk of which has been determined by PSD staff. As appropriate, leadership directs further inquiry and then deliberates on the implications of the information. Senior leadership then assigns priority for corrective measures, including budgetary and policy alignments, as necessary, based on a management determination of the best interests of the institution. In making these decisions, the senior leadership could ask the following questions to assist in prioritizing the Problem Statements:

- Could the Problem Statement issue directly cause a medical accident?
- Could the Problem Statement issue result in death or serious injuries to individuals?
- Does the Problem Statement issue have a significant impact on patient care?
- Does the Problem Statement issue have a serious impact on cost, reliability, or compliance?

The third component in this model is the Clinical Unit Leadership (CUL). Once senior management has prioritized the Problem Statements, it must identify the accountable line department responsible for corrective action. Unresolved Problem Statements then become Prioritized Problem Statements and are assigned to the CUL. The accountable department within the institution that is responsible for corrective action receives the statement as a directive to develop relevant and effective solutions. The CUL should be able to draw on other resources

within the organization—such as engineering, patient safety, and quality improvement departments—as needed. For example, if senior management has prioritized a Problem Statement for surgical care, the perioperative division would be the accountable department within the institution that is responsible for corrective action and would receive support from other departments. Key to this system is the fact that, rather than having a support department assume the primary responsibility, management of the operational department is itself accountable for the correction with the assistance of a support department.

The accountable department that is responsible for corrective action receives the Problem Statement as a directive to develop an intervention or solution in conjunction with PSD staff and whatever additional resources are required. The solutions are crafted by the line organization designated responsible by senior management. Both the accountable department and senior management should look to external support to implement appropriate changes. The PSO, as well as other sources of guidance, should be available to the accountable department to create positive changes that address the Problem Statement. In this manner, all available resources are utilized to engage the process of system safety improvement.

The health care organization cannot simply stop at accepting a Problem Statement and assigning it to an accountable group. Organizational management is also responsible for monitoring the progress of potential corrective actions. As measures are implemented responding to the various Problem Statements of the organization, senior management should receive routine updates to chart the organization's performance and any issues created by the safety interventions. Should an intended improvement not produce the expected results, that fact should be identified and the cycle repeated. In this manner, proactive interventions are developed, and the embedded regularly scheduled reviews by senior management assure continual understanding of the organization's performance improvement and mitigation of risk. This methodology helps enhance the culture of safety and provides a real-time understanding of system function, both critical goals of the Act and in the safety improvement enterprise.

The fourth component in our model is the Safety Dashboard (SD), a graphic depiction similar to a Gantt chart on which PSD staff record the progress of corrective actions accomplished by the responsible organization. The chart depicts timelines for implementing the various corrective measures, and assignments are color-coded, tracked, and displayed to give a rapid overview of the progress of all prioritized Problem Statements. The Safety Dashboard is the core means to communicate the Problem Statement and risk assignment, the organization unit accountable for the Problem Statement, the interventions, and the timeline for completion.

The Safety Dashboard is reviewed at the regular PSD meetings with senior management to assure that remedial measures are being implemented as agreed, thereby assuring that senior management has complete information to meet its accountability obligations. In addition, once the interventions have been applied, the SD serves as a link to the safety databases to monitor performance improvement. As corrective measures are implemented, the PSD continues to chart the organization's performance. If an improvement does not produce better results, that fact would be identified and the process begun again.

Three points are important to emphasize. First, the PSD is a staff organization that supports both senior management in its requirement to account for the organization's performance and the

CUL for practical and technical assistance in meeting the responsibilities assigned to them. At no time does the PSD assume an active role as designer or implementer of corrections. This separation is essential for assuring that the PSD remains unbiased in its assessments of performance. By virtue of its position outside daily operations, the PSD is able to serve an objective measurement and reporting function.

Second, management of the Problem Statement includes management's determination of priorities for correction, as reflected by allocation of resources to problem correction. Management simultaneously assigns responsibility to appropriate line departments to design and implement corrective strategies.

Third, the near misses encountered by practitioners in the workplace can be reported in the health care organization without fear of punishment or retribution. Personnel within the organization are the sources of the reports, which are transferred through the PSO to the organizational entity's administration. The entity's administration can then provide the reports to the PSO using its patient safety evaluation system as defined by the Act.

The PSO

The second component of the model in Figure 1, the PSO, creates and populates the performance database from various data sources, identifies trends and stratifies risk, and develops Problem Statements. The PSO receives information from two sources: the client organizations and the Network of Patient Safety Databases. The PSO assesses the information from these sources and feeds back lessons learned to those health care organizations with whom it has contracted, as well as to the broader health care industry. In addition, the PSO is responsible for tracking corrective measures and measuring summative changes in system performance.

The PSO classifies, analyzes, and warehouses the reported data and returns a Problem Statement to the PSD. The PSO applies hierarchical linear modeling, determines best methods to analyze data that reside at multiple levels of analysis, analyzes trends, reduces data, and assigns the report to existing Problem Statements or creates a new Problem Statement. The risk assessment assignment of the Problem Statement is a statistical calculation that considers the probability the hazard will be encountered and the severity and ramifications of a hazard encounter.

Note that the PSO can be a freestanding organization, or it can be associated with an existing organization. In the latter case, this "component organization" would be required to have sufficient protections to isolate the PSO functions from the other operating functions of the larger organizations.¹⁵ However, this should not affect its ability to function effectively within the Care Enhancement Model. The PSO will receive reports from client organizations and assess these data. Using these reports and lessons learned, the PSO will populate its own database, as well as a national network of databases.

On a local level, the PSO will classify and stratify risk on the basis of reports and analysis, provide avenues and pathways for potential improvement, and monitor whether improvement has in fact been accomplished. As noted above, one of its most important roles is to prepare and disseminate Problem Statements to client provider organizations and perform a clearinghouse function for the associated potential benefits from this activity on the local and national levels.

Reports distributed by the PSO would include not merely adverse events, but also information derived from the several sources. These include near miss and hazard reports, *in situ* simulations, sentinel events, security reports, and any other lens through which reliable insights into the organization can be obtained. This PSO role is essential for health care organizations to benefit from a near-miss reporting and analysis system.

The aviation experience with the Aviation Safety Reporting System (ASRS) suggests a near-miss reporting and analysis system can provide: (1) modeling, to gain insight into near misses that can become an adverse event; (2) trending, to gain insight into the distribution of failure and recovery factors; and (3) mindfulness, to maintain a level of alertness in the work environment.¹⁶

A key underlying assumption of the Act is that voluntary reporting of near misses will improve patient safety. This assumption is based on the success of the voluntary reporting system developed in commercial aviation, which has shown that analysis of near-miss data provides an opportunity to design systems that can prevent catastrophic events. The ASRS system—as it has matured into the Aviation Safety Action Program (ASAP)—is an effective model for health care hazard/near-miss reporting. Similar to aviation, the PSO will require an effective patient safety taxonomy (classification) system to gather, classify, analyze, and retrieve information about near misses, hazards, and adverse events. Following this pattern, a PSO will direct the development of a taxonomy by which system deficiencies are classified for entry into a secure database. The near miss/hazard reports will become a uniquely rich source of system intelligence.

A standardized taxonomy is needed because many organizations and agencies collect safety data, yet there are few common frameworks to classify such data.¹⁴ The Patient Safety Event Taxonomy (PSET), developed by the Joint Commission, is a standardized terminology and patient classification scheme for near misses and adverse events.¹⁷ The PSET taxonomy is a key prototype for a PSO system because it can link to other patient safety taxonomies and to local reporting systems and specific areas of clinical care.¹⁸ Appropriately qualified personnel will continually evaluate these data for improvement opportunities. Developed information will be transmitted regularly and systematically to accountable management in provider organizations that participate with the PSO.

The structure of these reports may vary, depending on the health care organization and the PSO assisting the organization due to differences within the local environment. For example, acute care hospitals in urban environments will require different data reporting formats from those needed by outpatient surgical centers in rural settings. The PSO within the Care Enhancement Model would assign data to taxonomies, determine best methods for analyzing specific data at multiple levels, perform trend analysis and data reduction, and identify issues as they relate to existing Problem Statements or create new Problem Statements for the health care organization.

PSO Problem Statements can be developed and articulated based on the answers to several key questions derived from errors or incidents. These include:

- What is the frequency of occurrence?
- Was this a one-time event or a point on a trend line?

- What is the risk assessment of hazards associated with the event and potential severity of a negative outcome?
- What are the ramifications of the Problem Statement issue recurrence?

The answers to these questions are a function of the particular events or incidents, the locale of care, the providers and management involved, and other factors reflecting the fact that all health care is local. This is an important benefit of creating these Problem Statements and a reason why they are of primary importance in the Care Enhancement Model presented here. The Problem Statements developed by the PSO are transmitted to the health care organization and acted upon based on prioritization by management in the client facility. To complete the feedback loop, the health care organization should also submit periodic reports to the PSO. In this way, improvements can be monitored and shared with other organizations, the health care system generally, and the national database network.

The airline industry has shown that analysis of near-miss data provides an opportunity to design systems that can prevent adverse events. However, near-miss data for the health care domain require more extensive analysis than is currently done and must be acted upon at the level where system weaknesses are found.¹⁴

The incident causation model developed by Van der Schaaf¹⁹ has four components: (1) initial failure, (2) dangerous situation, (3) inadequate defenses, and (4) recovery. In this incident causation model, near misses are precursors to possible adverse events. Examining near misses provides two types of information relevant for patient safety: weaknesses of the health care organization processes (errors, failures, and inadequate system defenses) and strengths of the organization—such as unplanned recovery—which compensate for those weaknesses. These informal recovery systems are characteristic strengths of high-reliability organizations.²⁰

National Database Network

The third component, the national Network of Patient Safety Databases (NPSD), will collect data from PSOs and other information. However, it is clear that the national database network is not a “national PSO.”¹⁵ The Act directs that the national NPSD be authorized to accumulate and analyze voluntarily reported, nonidentifiable patient safety data; develop common reporting formats for the reporting to and among the network’s patient safety databases; and analyze national and regional statistics, including patterns of health care errors.² We propose that the NPSD be patterned after the ASRS,²¹ which allows for voluntary reports regarding safety issues across the aviation system for broad research and learning purposes.

The Patient Safety and Quality Improvement Act calls for a national, voluntary patient safety reporting system based on a network of regional PSOs that contract with local health care organizations.⁴ One primary responsibility of the national NPSD is to collect data from PSOs throughout the country. However, it is very important that the network make such information easily available for providers and researchers in health care system safety. We emphasize that the full benefits of such a database can be realized only by making the information accessible.

In addition, like the ASRS,²² the network database should be used by government researchers and agencies—such as the Centers for Medicare & Medicaid Services—to ensure that care is

being enhanced. Incentives such as reporting to PSOs, whose reports are certified as being placed with the network, might be the basis of hospital and other provider reimbursement increases. This is currently the procedure used in the Physician Quality Reporting Initiative and the Reporting Hospital Quality Data initiative.^{23, 24} Also, like the ASRS, newsletters and other means of disseminating NPSD findings should be a fundamental part of the national database network's scope of responsibility. This would allow the NPSD to maximize its potential for safety promotion.

Conclusion

In this article, we have described a Care Enhancement Model to implement the components of the Patient Safety and Quality Improvement Act. We have drawn upon principles garnered from the aviation and health care safety systems to create what we believe is a practical approach with the capability to fulfill the potential of the Act. To be useful as a management tool, patient safety data must be voluntarily reported and reduced to meaningful information. The risk management process—accomplished through the Problem Statement, Prioritized Problem Statement, and Safety Dashboard methodologies—creates a transparent sequence to ensure that the organization is aware of the risks and challenges it faces. Proactive interventions are developed, and regularly scheduled reviews by senior management assure continual understanding of the organization's performance improvement and mitigation of risk.

Using the Care Enhancement Model approach, which is patterned after the air carrier risk management model,²¹ the PSO can create and populate the performance database from these and other data sources in order to develop trends and risk stratification for the health care organization's experience. This structure can also provide health care managers with an important safety tool based on learning from the commercial aviation industry: concrete Problem Statements that describe and quantify identified risks confronting the institution.

Using Problem Statements, the health care organization, the PSO, and the national database network are integrated. They provide the health care manager with a focus on the areas of safety and system weakness that are important to improve care, reflecting the local nature of all health care system performance. The Problem Statement also allows the PSO to focus on assisting and engaging health care providers with information and lessons learned from safety experience within and outside local health care organizations' geographic and professional locales. Moreover, lessons from efforts focused on the Problem Statement can then be fed to other health care entities and used to populate the national database network.

As we have emphasized throughout this article, all health care is local. An effective voluntary reporting system can only be developed by extensive accountability at the provider organization that acts on near miss and incident reporting data. These data are not currently available and will not be available without a national system as is contemplated by the Patient Safety and Quality Improvement Act. By building on the basic infrastructure represented by the three components of a national voluntary reporting system (the health care organization, the PSO, and the national database network), the Care Enhancement Model should be adaptable and flexible enough to address system issues across a wide spectrum of health care delivery settings.

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References

1. Fassett WE. Patient safety and quality improvement act of 2005. *Ann Pharmacother* 2006; 40: 917-24.
2. Jeffords J. S. 544 [109th]: Patient Safety and Quality Improvement Act of 2005. Available at: www.govtrack.us/congress/bill.xpd?bill=s109-544. Accessed April 4, 2008.
3. Gaul G. Plan would compile, analyze medical errors. *Washington Post* 2005 July 9; p. A06.
4. Liang BA, Riley W, Hamman W, et al. The patient safety and quality improvement act of 2005: Provisions and potential. *Am J Med Qual* 2007; 22: 8-12.
5. Riley W, Liang BA, Hamman W, et al. The patient safety and quality improvement act of 2005: Developing an error reporting system to promote patient safety. *J Patient Saf* 2008; 4: 13-17.
6. Hansen D. Medical error reporting system still a year off. Several agencies must review the rules that will govern the patient safety organizations to which physicians will report. *amednews.com* 2007 Aug 20; Available at: www.ama-assn.org/amednews/2007/08/20/gvsc0820.htm. Accessed April 4, 2008.
7. Provider-PSO relationships, contacts and disclosures. [public hearing] Rockville, MD: Agency for Healthcare Research and Quality; 2006 Mar 8.
8. Operation of a component PSO. [public hearing] Rockville, MD: Agency for Healthcare Research and Quality; 2006 Mar 13.
9. Security and confidentiality issues. [public hearing] Rockville, MD: Agency for Healthcare Research and Quality; 2006 Mar 16.
10. Sloane T. One delay we can live with. *Modern Healthcare* 2006 Jul 24; 36(29): 23.
11. Battles JB, Lilford RJ. Organizing patient safety research to identify risks and hazards. *Qual Saf Health Care* 2003; 12: ii2-ii7.
12. Reason J. Managing the risks of organizational accidents. Aldershot, UK: Ashgate Publishing Limited; 1997.
13. Reason J. Human error. Cambridge, UK: Cambridge University Press; 1990.
14. Institute of Medicine. Patient safety: Achieving a new standard for care. Washington, DC: The National Academy of Sciences; 2004.
15. Munier W. Security and confidentiality issues. [public hearing] Rockville, MD: Agency for Healthcare Research and Quality; 2006 March 16.
16. Battles JB, Kaplan HS, Van der Schaaf TW, et al. The attributes of medical event reporting systems: Experience with a prototype medical event reporting system for transfusion medicine. *Arch Pathol Lab Med* 1998; 122: 231-238.

17. Chang A, Schyve PM, Croteau RJ, et al. The JCAHO patient safety event taxonomy: A standardized terminology and classification schema for near misses and adverse events. *J Qual Health Care* 2005; 17: 95-105.
18. Standardizing a patient safety taxonomy. Washington, DC: National Quality Forum; 2006. Available at: www.qualityforum.org/projects/completed/taxonomy.asp. Accessed April 5, 2008.
19. Van der Schaaf T. Near miss reporting in the chemical process industry. Eindhoven, Netherlands: Technische Universiteit Eindhoven; 1992.
20. Roberts KH, Madsen P, Desai V, et al. A case of the birth and death of a high reliability healthcare organisation. *Qual Saf Health Care* 2005; 14: 216-220.
21. Hamman WR. The complexity of team training. What we have learned from aviation and its applications to medicine. *Qual Saf Health Care* 2004; 13: 72-79.
22. FAA. Aviation safety reporting program (ASRP). Advisory Circular 00-46. May 9, 1975.
23. 2007 Physician Quality Reporting Initiative (PQRI) general information. Baltimore, MD: Center for Medicare & Medicaid Services. Available at: www.cms.hhs.gov/PQRI/33_2007_General_Info.asp#TopOfPage. Accessed April 6, 2008.
24. Reporting hospital quality data for annual payment update. Baltimore, MD: Center for Medicare & Medicaid Services. Available at: www.cms.hhs.gov/HospitalQualityInits/20_HospitalRHQDAPU.asp. Accessed April 4, 2008.

Taxonomies and Measurement

Development of a Comprehensive Medical Error Ontology

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Abstract

A critical step towards reducing errors in health care is the collection and assessment of medical error data so that potential harms to patients can be identified and steps taken to prevent or mitigate them. However, no standardized framework for classifying and evaluating such data currently exists. This paper describes our efforts in developing a comprehensive medical error ontology to serve as a standard representation for medical error concepts from various existing published taxonomies. Eight candidate taxonomies were selected from the published literature and merged to create a reference ontology consisting of 12 multidimensional axes that encompass all the aspects of a medical error event. The ultimate goal of the project is to use the medical error ontology to identify strategies for preventing future adverse events in health care.

Introduction

The study and reduction of medical errors has become a major concern in health care today. In its report, *To Err Is Human: Building a Safer Health System*, the Institute of Medicine (IOM) estimated that between 44,000 and 98,000 Americans die each year because of preventable medical errors, making hospital errors between the fifth and eighth leading causes of death.¹ In order to identify medical errors and develop strategies to prevent or mitigate them, it is essential to develop reporting systems for the collection, analysis, interpretation, and sharing of medical error data.

A number of proprietary reporting systems are currently available or under development to collect and evaluate medical error data.^{2, 3, 4, 5, 6, 7, 8, 9, 10} However, no current single standardized nomenclature or universal classification system is broad enough in coverage yet sufficiently detailed to encode medical error data from all health care delivery settings and application areas.^{11, 12} While most of the existing classification schemes may be well suited to the particular clinical setting or safety applications for which they were developed (e.g., medication error reporting,¹⁰ primary care error taxonomy⁸), such application-specific and often organization-specific representations limit the reuse of medical error data.¹¹ It is seldom possible to map terminologies of the different classification systems to each other because of differences in granularity (e.g., the NCC-MERP Taxonomy of Medication Errors has a very detailed classification of product labeling issues as a cause of error that is not matched by the codes in DoctorQuality Inc.'s RPM system) or asymmetries in classification (i.e., assigning terms under different categories in different terminologies). Additionally, many of the existing terminologies

have been developed using ad hoc approaches. More complex semantic relations among terms often are lacking. Finally, such ad hoc development can also lead to incomplete, inconsistent, and/or redundant terminological representations.¹¹ It is clear that the lack of a framework and agreement about how to define and classify adverse patient safety events, medical errors, and systems failures is a major barrier to understanding where, how, and why problems occur. A major goal of this project was to find a standard, generalizable mechanism to bring consistency to the published literature addressing medical errors and near-miss accounts.

An ontology of medical errors is one approach to solving the problem. An ontology can be defined as a specification of a conceptualization.¹³ An ontology defines a common and controlled vocabulary that enables knowledge sharing and reuse of information.¹⁴ Many disciplines now develop standardized ontologies so that domain experts can share and annotate information in their fields. Medicine, for example, has produced SNOMED¹⁵ and UMLS.¹⁶ In the context of medical errors, a medical error ontology can provide formal definitions and coverage of various concepts relevant to the domain of medical errors; enable building a knowledge base through unification of information from data across various organizations, practice domains, and applications; and offer sufficient detail to be of practical use.

As part of a larger research project designed to develop a cognitive framework of medical errors, we have begun to develop a comprehensive medical error ontology to serve as a standard representation of medical error-related concepts and relations. The first goal is to create the ontology for a standardized mechanism for coding the published literature on medical errors and near-miss accounts. We believe that the ontology would also be useful in error reporting systems and medical error and near-miss classification systems. However, the original goal is focused on the codification of the published literature. Once the ontology development is complete, it will be used in a parent project for enabling collection, aggregation, comparison, and analysis of medical error events across varied health care settings and medical error domains. The ultimate goal of the project is to identify strategies for improvement to prevent future adverse events.

This paper reports the initial progress in developing the medical error ontology. In the sections that follow, the paper presents: (1) the scope and requirements for the ontology, (2) the development approach, (3) the steps in the development process we have completed, and (4) plans for future work. In particular, we focus on the integration-based development approach we adopted, which involves reusing knowledge from existing relevant taxonomies in published literature by merging individual taxonomies to create a reference ontology, followed by mapping the reference ontology with the original taxonomies to produce the end product, a shared medical error ontology.

For the purpose of this paper, our discussions are restricted to the steps addressing the creation of the reference ontology. Other aspects of the project will be described in future articles. This will include the relations among the merged taxonomies, extensions to the ontology as it is adapted for other purposes, and the use of the ontology for a real-time medical error reporting system.

Ontology Scope and Requirements

The scope and requirements for the medical error reference ontology resulted from a series of discussions among the project members and the goals of the greater project. The first goal of the ontology was to code and represent the reported literature of medical errors and near-miss

events. In order to be useful for data analysis and for learning from errors and to promote development of interventions for patient safety, it was determined that the ontology should have the following attributes:

- Cover the full range of settings in which health care can take place (e.g., not limited to hospital care).
- Capture the richness of the domain of errors and adverse events.
- Enable the capture of data from all sources (including event reports and sources, such as drug use data).
- Permit identification and analysis of medical error events.
- Enable analyses that support identification of strategies for improvement by all users (including health care providers, policymakers, and others).

Apart from the above requirements, the project team agreed that our ontology should incorporate the following suggestions from Cimino's desiderata for controlled medical vocabularies:¹⁷

1. **Concept orientation.** Each concept in the ontology should have a single coherent meaning; i.e., avoid redundancy, ambiguity, and vagueness in a concept.
2. **Formal definition of concepts in the ontology.** Expressed as a collection of relations to other concepts.
3. **Polyhierarchy.** A concept can belong to more than one location in the hierarchy.
4. **Multiple granularities of concepts.** Expression of concepts at different levels of detail.
5. **Graceful evolution.** To enable integration of new concepts from other, independently developed ontologies of medical errors.

Development Approach

A primary decision was that this ontology should “reuse” knowledge from existing, published medical error classifications. Reuse of independently developed, heterogeneous taxonomies together in a single system requires an integration-based ontology development approach. There are three main approaches for ontology integration:

1. **Single ontology approach.** Merging existing ontologies to create a single coherent ontology.^{18, 19, 20} Often, the original ontologies cover similar or overlapping domains.
2. **Multiple ontologies approach.** Aligning existing ontologies and establishing links (mappings) amongst them for exchange of information, while preserving their original states.^{18, 19, 20}
3. **Hybrid approach.**²¹ Incorporating features of both the above approaches. Like the single ontology approach, a single, common, standard ontology is created. It is then used as a basis for reconciling the original ontologies through mappings to each individual ontology.²² Like the multiple ontologies approach, the individual ontologies are left unchanged, but mappings among them are indirect; i.e., to map information and knowledge from one individual ontology (O1) to another individual ontology (O2), two steps are required: first, map from O1 to the common ontology, then from the common ontology to O2.

While the single ontology approach makes alignment of the ontologies easier, the resulting ontology is often too rigid and does not scale well.²¹ On the other hand, while the multiple

ontologies approach preserves the integrity of the source ontologies, it is much harder to align them, and it necessitates many sets of mappings when many ontologies need to be reconciled ($O(n^2)$ sets of bidirectional mappings for n individual ontologies).²²

The methodology we chose for developing the medical error ontology was the hybrid approach—i.e., merge independently developed medical error-related ontologies to build a reference meta-model ontology first, and then use the vocabulary, definitions, relationships, and constraints specified in the reference ontology to implement actual mappings to the source ontologies (Figure 1).

We chose this approach because it incorporates advantages of both other approaches.²² New ontologies can easily be added without the need of modification in the mappings, thus encouraging scalability and evolution of the medical error ontology. The use of a reference ontology makes the source ontologies comparable, but at the same time, avoids the disadvantages of multiple ontology approaches, since it cuts down the number of sets of mappings to just n (bidirectional) mappings for n ontologies.

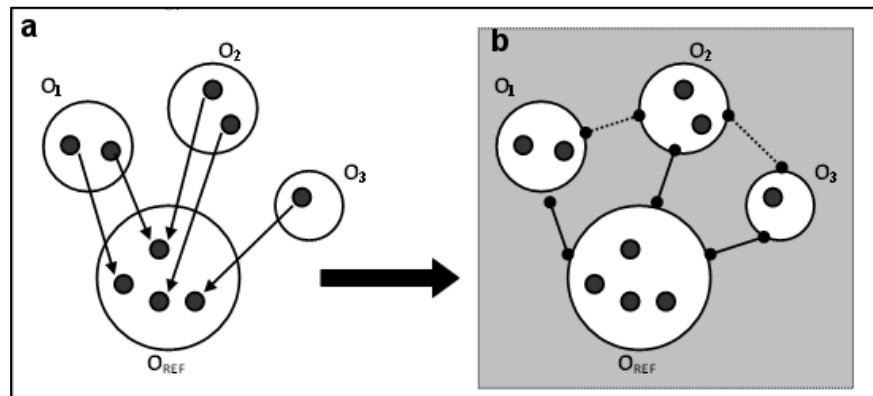


Figure 1. Medical error ontology development approach. (a) The source ontologies (O_1 , O_2 , O_3) are merged to create a single reference ontology (O_{REF}). Arrows indicate incorporation of concepts from each ontology in the reference ontology. See text for the detailed merging process. (b) The mapped ontologies. Solid links indicate direct mappings; dotted links indicate mappings that did not exist before the merging of the ontologies. They are derived from the mapping process and show the value of the integrated ontology approach.

Ontology Development Process

Our development process was divided into seven major steps:

1. **Identify source ontologies.** Literature search and identification of candidate ontologies.
2. **Align source ontologies (ontology comparison).** Resolve semantic heterogeneities among the individual ontologies to bring them to mutual agreement.
3. **Merge source ontologies (reference ontology).** Merge and rationalize concepts from the aligned ontologies into a reference ontology.
4. **Validate and refine reference ontology.** Test (and refine based on feedback) the ontology for logical consistency, programmatic accuracy, and completeness.
5. **Map source ontologies.** Map original ontologies via linkages between reference ontology and each individual ontology to create a shared medical error ontology.
6. **Validate medical error ontology.** Repeat step 4 to verify and extend defined mappings in order to detect inconsistencies and implied mappings.

7. **Build knowledge base.** Instantiate the ontology with medical error data from various data sources.

Our research is currently at the end of step 4. Therefore, for the rest of this section, we devote our discussions to steps 1 through 4.

Identifying Source Ontologies

Identification of source ontologies started with a literature review using MEDLINE and other Web resources, to search for relevant articles containing medical error taxonomies. We used terms such as taxonomy, categorization, classification, and documentation in conjunction with terms, such as medical error and adverse event. The criterion was to include any taxonomy that would assist us in describing medical errors in one or more clinical domains and/or settings of care and had the potential to be made open source. The taxonomies obtained from the literature review were evaluated for model coverage, utility, and validity in an ad hoc fashion. At the end, the following eight taxonomies were selected for supplying the sum of domains and semantic relations needed for building the reference medical error ontology: NCC MERP Taxonomy of Medication Errors¹⁰ (NCCMERP); Joint Commission Patient Safety Event Taxonomy⁷ (PSET); Joint Commission Sentinel Events Reporting⁹ (JSER); Taxonomy of Nursing Errors⁶ (TNE); A Preliminary Taxonomy of Medical Errors in Family Practice³ (PTFP); Cognitive Taxonomy of Medical Errors²³ (COG); Taxonomy of Medical Errors for Neonatal Intensive Care²⁴ (NIC); and MedWatch Index²⁵ (MEDWATCH). Table 1 shows the high level concepts in the selected taxonomies.

All of these taxonomies were structured as hierarchical taxonomies. We are not aware of and could not find any medical error taxonomies that have been implemented as formal ontologies. In order to integrate these classifications, it was necessary to create an ontology corresponding to each source taxonomy first. While time consuming, this also guaranteed that all the taxonomies and the reference ontology were represented in the same language, thus avoiding the problem of language-level heterogeneity described in the next section.

The source ontologies were implemented in OWL-DL using the Protégé OWL Plugin²⁶ (protege.stanford.edu/plugins/owl/index.html). OWL-DL is based on description logics DL, dl.kr.org/) that make it possible for concepts to be defined and described. Complex concepts can therefore be built up in definitions out of simpler concepts. Furthermore, the logical model allows the use of DL reasoners that can help build and maintain sharable ontologies by revealing inconsistencies, hidden discrepancies, redundancies, and misclassifications.

Table 1. Top level concepts in the selected eight taxonomies

NCC MERP Taxonomy of Medication Errors ¹⁰ (NCCMERP)	Preliminary Taxonomy of Medical Errors in Family Practice ³ (PTFP)	Joint Commission Sentinel Events Reporting ⁹ (JSER)	Joint Commission Patient Safety Event Taxonomy ⁷ (PSET)
• Patient information • The event • Patient outcome • Product information • Type • Causes • Contributing factors	• Process errors • Knowledge and skill errors	• Type • Settings • Cause • Outcomes • Sources for identification • Method of response	• Impact • Type • Domain • Cause • Prevention and mitigation
Taxonomy of Errors for Neonatal Intensive Care ²⁴ (NIC)	Taxonomy of Cognitive Errors ²³ (COG)	Taxonomy of Nursing Errors ⁶ (TNE)	MedWatch Index ²⁵ (MEDWATCH)
• Actual or potential harm • Patient location • Time since event • Categories of error • Contributing factors	• Cognitive error • Cognitive mechanism • Potential solution	• Lack of attentiveness • Lack of agency/ fiduciary concern • Inappropriate judgment • Medication errors • Lack of intervention on the patient's behalf • Lack of prevention • Missed or mistaken MD/health care provider's orders • Documentation errors	• Patient information • Adverse event or product problem • Suspect medication(s) • Suspect medical device • Reporter • Routes of administration

Aligning Source Ontologies (Ontology Comparison)

In order to successfully merge or map individual ontologies, it is necessary to first align them to bring them to mutual agreement. Several semi-automatic and automatic ontology comparison and integration methods and tools are available.^{19, 27, 28, 29} After reviewing several of them, the project team decided that none completely met the needs for this reference ontology. However, using insights gained from these methods, a manual approach for aligning the ontologies by identifying and resolving mismatches between them was adopted.

Two types of mismatches between ontologies have been reported to occur:^{19, 29, 30}

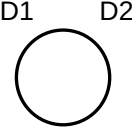
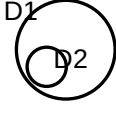
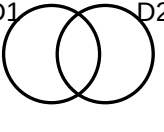
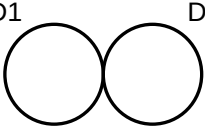
1. **Language-level heterogeneity.** Includes differences in syntax, logical representation, language expressivity, etc., and is a result of different representational languages used for defining classes and relations. As mentioned earlier, since we were creating source and

reference ontologies in the same language, we were able to avoid having to translate between different representational languages.

2. **Ontology-level (semantic) heterogeneity.** Includes differences in conceptualization and explication of the same real world entities and may be caused by differences in scope, model coverage, granularity, concept description, and terminology mismatches (synonyms and homonyms).

Differences in model coverage and granularity do not induce conflicting views of the same concept and therefore do not obstruct the integration process. On the other hand, semantic differences due to differences in conceptualizations can be identified by means of semantic relations between terms and definitions in the individual ontologies.^{19, 29, 30, 31} If we assume that the conceptualization of a real-world entity consists of a term T and a definition D (e.g., natural language definition), then a concept C is represented by $C = (T, D)$.²⁹ Different combinations of these two elements result in a set of possible semantic relations between similar concepts as shown in Table 2.

Table 2. Semantic relations between similar concepts resulting from different combinations of term (T) and definition (D) cases

	 D1 = D2	 D1 > D2	 D1 * D2	 D1 ≠ D2
T1 = T2	Equivalency	Additional	Overlap	Homonymy
T1 ≠ T2	Synonymy	Is-A	Overlap	Disjoint

Using these similarity relations, the project team completed the task of aligning the source ontologies manually by finding places where the ontologies were equivalent, disjoint, overlapped, or filled gaps.

Merging Source Ontologies (Reference Ontology)

Once aligned, the source ontologies were merged into the reference ontology, resulting in the creation of the following 12 multidimensional axes in the reference ontology model:

1. Practitioners involved.
2. Patient profile.
3. Health care service.
4. Error location.
5. Contributing factors.
6. Professional activity.
7. Time of error.
8. System factors.

9. Patient outcome.
10. Human factors.
11. Interface design factors.
12. Medical product involved.

The creation of the axes was the equivalent of a metastructure, representing the sum of domains from the source ontologies. While they do not necessarily represent all the individual concepts available in the source ontologies, they represent an aggregation of the existing concepts and their relationships. The ontology was designed in such a way that a given medical error event could be represented as an intersection of the above-mentioned multidimensional axes.

Below are a few examples of how concepts from source ontologies were incorporated into the reference ontology:

- If two concepts had similar definitions (equivalency, synonyms), the result of merging was a single conceptual definition, to be referred to by both original terms during mapping. For example, “Personnel Involved” (NCCMERP) and “Staff” (PSET) are both defined as the health care personnel involved in a medical error event. In the reference ontology, we have created the “Practitioners Involved” class corresponding to both terms.
- If the definition of one concept specialized the definition of another concept—i.e., the latter implied the former—they were in an additional relationship. The result of merging in this case was two concepts related through a concept-subconcept relationship (i.e., every instance of the subconcept also belongs to the parent concept). For example, “Documentation Error” (NIC) was added as a subconcept of “Process Error” (PTFP).
- In some cases, concepts overlapped with each other or existed under a single category in a force-flattened, redundant structure (i.e., an instance of one concept may or may not be an instance of the other). Such ambiguities were resolved by separating out the different concepts (i.e., unflattening the structure) and then declaring an additional new concept or relationship as the intersection (with appropriate constraints specified). For example, NCCMERP includes health care settings (locations) and health care services within the same category of “Setting.” Although health care service and clinical location may seem similar, they are different. For example, an error in oncology (the health care service area) could be committed either in the ICU, the operating room, or the rehabilitation center (the location). This ambiguity was resolved by creating two separate concepts, “Health Care Service” and “Error Location.” The intersection of these two concepts represents the “Setting” in which an error can occur.
- Occasionally, concepts that existed as separate categories in the source ontologies were merged into a single concept. For example, “Contributing Factors” and/or “Cause” (leading to a medical error) are included as top-level categories in many of our source ontologies (NCCMERP, PSET, JSER, TNE).
- In some cases, concepts that were present in lower layers of classification in the source ontologies were elevated to higher levels, and vice versa, based on decisions made by the project team about the degree of significance and applicability of these concepts to the purpose of the ontology.

During the process of developing the ontology, once the concept was clarified, its location on an axis had to be assigned. To the extent possible, we took direction from the existing taxonomies as to where concepts were placed in their hierarchical arrangement. Using the Contributing Factors Axis, concepts were aligned into Action Domains and Action Types using the following structure:

Contributing factors

Action domain

Communication

Communication with nonphysician colleagues

Communication with physician colleagues

Communication with patients

Investigation

Diagnosis imaging

Laboratory

Other

Office administration

Appointments

Chart completeness

Filing system

Message handling

Patient flow

Action type

Documenting

Followup

Implementing

Ordering

Receiving

Reporting

Responding to a correct action

Responding to an incorrect action

The Contributing Factor Axis covers actions that were taken, not taken, or should have been taken. It does not reflect the person or people who were involved with the action. Personnel are addressed in the Practitioners Involved Axis. At first, it seems counterintuitive to separate actions from the personnel. However, in reviewing the published literature, we found many instances where the personnel were listed but not the actions that were contributing factors to a

medical error or near miss report. Likewise, we found reports where the actions were listed, but the personnel were either not explicitly stated or had to be inferred. Since the goal of this ontology was to index the published literature, we felt it was critical that the ontology not force the user to index information that was not explicitly stated in the article. Yet, because the information exists on the two axes, it is quite easy to link the information when both are reported in a given article. The published literature was the consistent gold standard for decisions about how to separate or relate concepts and when to join concepts in order to represent the medical errors and near-miss events.

Reference Ontology Implementation

Implementation of the reference ontology was done using Protégé-OWL. Concepts and subconcepts within each multidimensional axis were defined as classes and subclasses by using the “necessary conditions.” At the top of the ontology was the class *MedicalErrorEvent*, which represented the point of linkage between all the axes. Attributes for each class were defined as properties (functional, transitive, or symmetric). In OWL-DL, properties are binary relations,²⁶ linking individuals (instances) of two classes (e.g., the expression, “*MedicalErrorEvent hasContributingFactor ContributingFactors*” indicates that an individual belonging to the class *MedicalErrorEvent* has the property *hasContributingFactor* relating it to another individual from the class *ContributingFactors*). Properties were also used to create restrictions on a class (e.g., quantifier restrictions, cardinality restrictions), specified within the necessary conditions for that class (e.g., to specify that a medical error event must have at least one contributing factor associated with it, we represented it as, “*hasContributingFactor owl:minCardinality 1*”). Figure 2 shows a graphic representation of some of the high-level concepts and relationships in the reference ontology.

Apart from directly creating named classes, new classes were also created as logical combinations of source classes using OWL expressions, such as *unionOf*, *intersectionOf*, *complementOf*, and others. For example, the concept of “Setting” mentioned earlier was defined as the logical combination of *HealthcareService* and *ErrorLocation* through *owl:intersectionOf*. The resulting anonymous class was then related to class *MedicalErrorEvent* by specifying the relationship within *MedicalErrorEvent*’s necessary conditions list as: “*occurredinSetting (HealthcareService owl:unionOf ErrorLocation)*.”

Following the above manner, the *MedicalErrorEvent* class was related, through its properties and restrictions, to every top-level class corresponding to each of the multidimensional axes (e.g., *involvedPatient PatientInvolved*; *wasInitiatedBy PractitionersInvolved*; *wasDiscoveredBy PractitionersInvolved*; *involvedMedicalProduct [MedicalDevice owl:unionOf MedicationProdu]*; *ledToPatientOutcome PatientOutcome*; etc.), thus bringing all the axes together at the time of instantiation of this class (an example is provided in the next section).

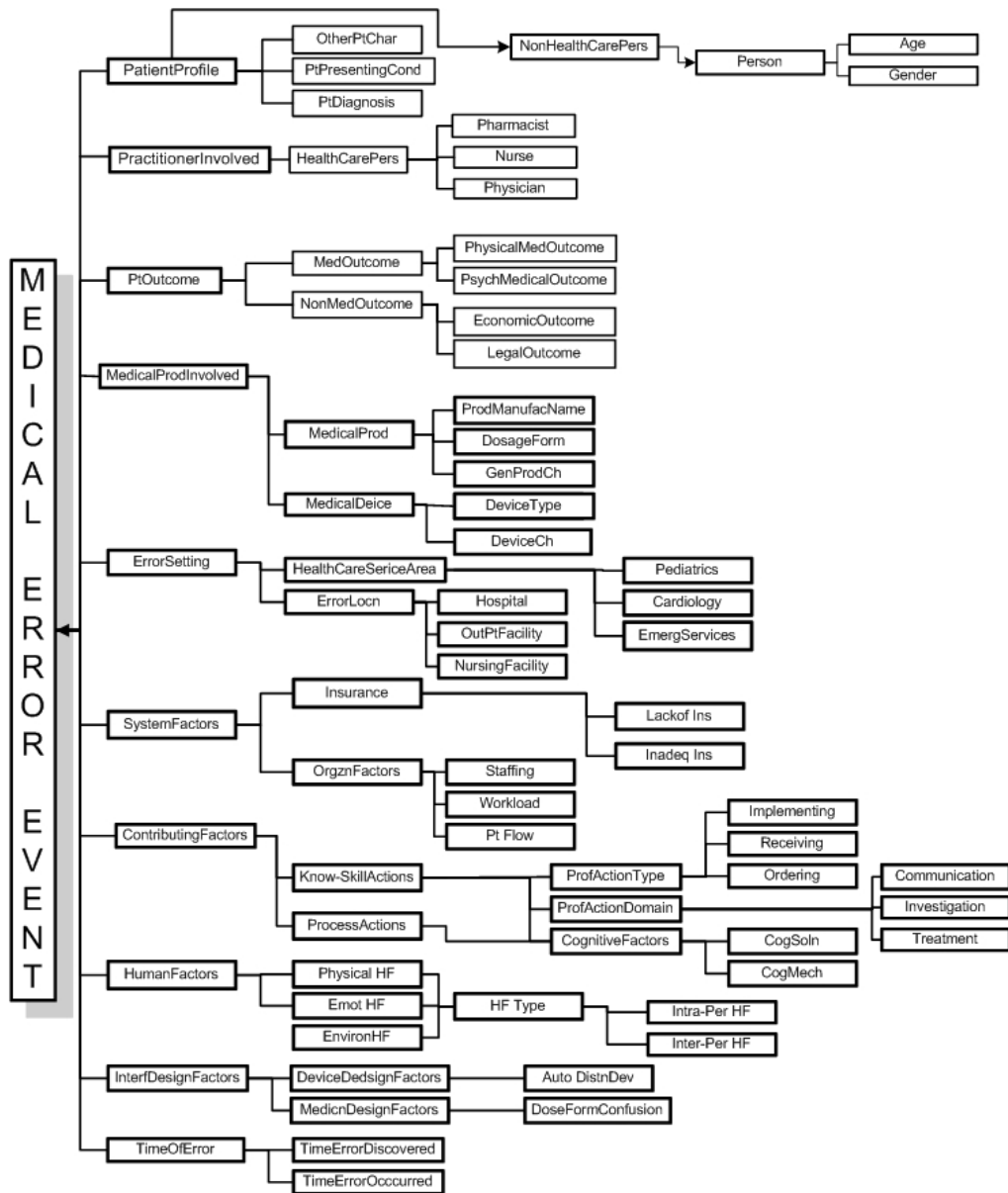


Figure 2. Graphic representation of some high level concepts and relationships in the reference ontology. This reference ontology integrates the various concepts from the source ontology and serves as an integrated ontology.

Validating the Reference Ontology

Since the task of aligning and merging the ontologies was done on an ad hoc basis, such an approach bears the risk of inconsistency and incompleteness. Therefore, once the merger process was complete, an iterative process of validating followed by refining the ontology ensued. As mentioned earlier, DL reasoners can help detect inconsistencies and discrepancies in ontologies.²⁶ Racer,³² the DL reasoner to which Protégé-OWL provides access, was used for verifying the logical consistency of the reference ontology. Based on the description (conditions) of a class, Racer can check whether it is possible for the class to have any instances. A class is

deemed inconsistent if it cannot possibly have any instances (e.g., a class with two superclasses, where the superclasses are disjoint from each other). Besides consistency checking, Racer also enables automatic computation of the classification hierarchy by determining whether one class is a subclass of another class (multiple inheritance). This helped to keep the ontology structure simple and maintainable, while also minimizing human errors that are inherent in maintaining a multiple inheritance hierarchy.²⁶ In addition, to ensure best design practices, we performed tests on the ontology on a periodic basis using Protégé-OWL's test framework that provides a standard set of ontology tests (e.g., checking that a property's characteristics correspond correctly with its inverse property's characteristics).

Finally, the ontology was tested for its utility and completeness by instantiating a number of medical error cases selected from the published literature. The cases helped the researchers verify that all the characteristics of a given error case were adequately represented in the reference ontology and provided feedback on further modifications to the ontology. For example, below is a brief description of a medical error case from the Agency for Healthcare Research and Quality Morbidity and Mortality rounds (AHRQ Web M&M) case archive:³³

A patient was admitted to the intensive care unit (ICU) with septic shock, and required vasopressors. He appeared to have suffered from a myocardial infarction (MI) in the course of his treatment. It was determined that the cause of the MI was related to a wrong dosage of the drug, Vasopressin (the patient had been receiving 0.4 units/min of vasopressin, rather than the intended dose of 0.04 units/min). The error was discovered the next day, and the patient recovered. Other factors that appeared to have contributed to the case included, (i) a verbal direction was given by the ICU fellow to the resident to order vasopressin; (ii) the resident directly entered the wrong dosage for vasopressin into the computerized physician order entry (CPOE) system, which had a menu of several possible doses of vasopressin; (iii) the error persisted through the next day's multidisciplinary team rounds; and (iv) the error was discovered when one of the ICU nurses was discussing the medication dosing with nursing students, and the incorrect dose was overheard by the ICU fellow and the error recognized.

The various details of this case were first coded in the reference ontology as individuals (instances) of classes and subclasses within the different axes. For example, details about the patient were entered as individuals of classes, PatientAge, PatientGender, PatientPresentingConditions, PatientCo-existingConditions, PatientDiagnosis, etc, which were then related, through properties, to "Pt-1," an individual created for class PatientProfile (corresponding to the "Patient Profile" axis).

Figure 3(a) shows a visualization of Pt-1, using Protégé-OWL's Ontoviz³⁴ tool (properties listed on the left and individuals of the related classes listed on the right). Similarly, information on the contributing factors leading to the error; personnel involved in initiating, perpetuating, and discovering the error; patient outcome; interface design issues involved in the error; and system factors, etc., were entered as individuals of the corresponding classes.

In the final step, an individual (“Case-1”) was created for the class, *MedicalErrorEvent*, which took in the above individuals as its properties, thus bringing all the multidimensional axes together in a single instance. Figure 3(b) shows the Ontoviz visualization of “Case-1.”

Since the original goal for the ontology was to codify the published literature of medical errors and near-miss events, we continue to use published error reports to test the completeness and organization of the ontology. As we enter the individual published articles, we are slowly building a searchable knowledge base of published medical errors and near-miss events.

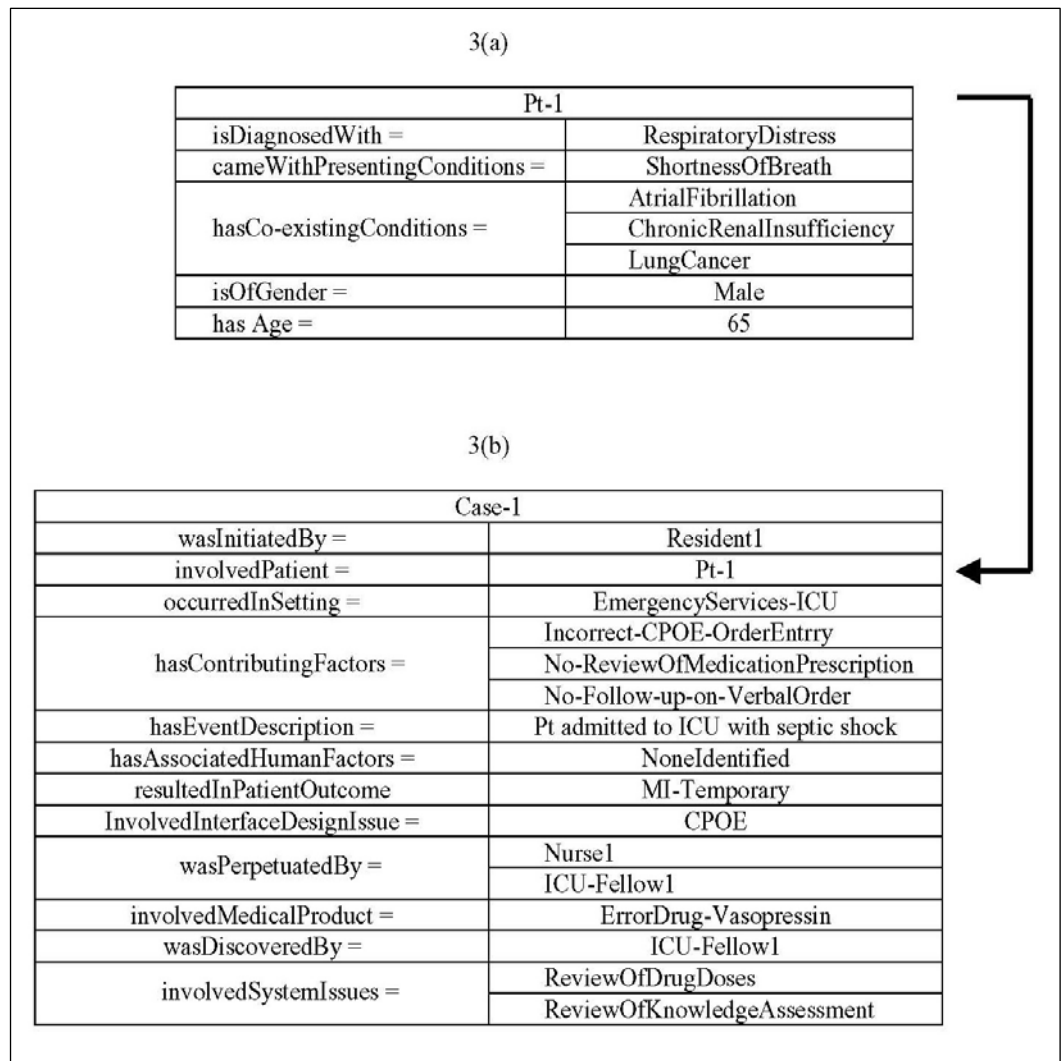


Figure 3. (a) Ontoviz visualization of “Pt-1,” an instance of *PatientProfile* class; (b) Ontoviz visualization of “Case-1,” an instance of *MedicalErrorEvent* class. (Ontoviz is a visualization plug-in in Protégé). The left boxes in each figure are the relations, and the right boxes are the values of the relations.

Conclusions and Future Work

A critical step in the direction of reducing errors and adverse events in health care is the collection, aggregation, and assessment of medical error data, so that potential harm to patients can be identified and steps taken to prevent or mitigate harm. Despite the efforts now devoted to reporting and collecting medical error data, no standardized framework for classifying and evaluating such data is currently available. This paper describes our experience with developing a comprehensive medical error ontology to serve as a standard representation for medical error concepts gleaned from various existing published taxonomies, with the ultimate goal of preventing errors and improving patient safety.

Following a literature review of existing and published taxonomies related to medical errors, we selected eight candidate taxonomies to supply the sum of domains for our ontology. The taxonomies were modeled as ontologies in Protégé-OWL and then aligned with one another through identification of semantic relations between concepts contained in the source ontologies. Once aligned, the source ontologies were merged to produce a single reference ontology with 12 multidimensional axes, the intersection of which characterizes a medical error event. The classes and relationships in the reference ontology were implemented using Protégé-OWL.

The next step in our project will be to create mappings among the source ontologies via the reference ontology. Once mapped, the source ontologies will form the integrated medical error ontology that combines the domains of the source ontologies, while preserving their integrity. The mechanism for mapping will involve defining equivalencies between classes and properties—i.e., specifying that a particular class or property in one ontology is equivalent to a class or property in a second ontology. Protégé-OWL provides built-in mapping support³⁵ for defining such equivalence classes using “necessary & sufficient” conditions.

The medical error ontology will continue to evolve as we map additional relevant ontologies to the reference ontology as they become available. Candidate ontologies for consideration will include those that have potential to be made open source and are designed to encompass one or more clinical domains and/or settings of care. For example, Stetson, et al., are developing an ontology that models medical errors as an intersection of three domains: human/system errors, information needs, and communication space.³⁶ Once developed and published, the concepts defined in this ontology will help enrich and extend the representation of these three domains in our integrated medical error ontology.

We have seen how combined use of ontologies can be hindered by language-level and ontology-level (semantic) heterogeneities. While language-level heterogeneities did not pose a problem for us, since all the source ontologies were coded using OWL-DL, they might pose a problem when integrating new ontologies represented in other languages. However, one of the major benefits of using Protégé-OWL for our medical error ontology is that its underlying knowledge model is designed to be compatible with Open Knowledge Base Connectivity (OKBC),¹⁹ which provides reasonable support for language-level interoperability. Semantic heterogeneities during the integration process will be identified in the manner described in the ontology alignment section. The merger of new ontologies into the reference ontology will entail using a set of change operations that may affect the present ontology structure. Our choice for a change model will be based on experiences and ideas of other researchers^{37, 38, 39} and our own ideas.

The final step in the project involves using the shared medical error ontology to build a knowledge base of medical error events from various published data sources, using the *Forms* and *Individuals* tab provided by Protégé-OWL. Once the knowledge base is built, medical error events can be analyzed, interpreted, and understood. The “Queries tab” provided by Protégé-OWL enables running simple queries on the ontology knowledge base at an instance level, while more complex queries can be built using a more powerful query language such as RDQL (www.w3.org/Submission/2004/SUBM-RDQL-20040109/). For example, one could obtain all the instances of medical error events that were initiated in a particular health care setting (e.g., ICU) and involved a particular interface design issue (e.g., in the computerized physician order

entry system). Such querying techniques would help in identifying potential targets for which patient safety interventions could be developed to prevent future adverse events.

Finally, although the shared medical error ontology itself is not a reporting system, it is designed to support integration of data across varied reporting systems and can provide systematic, principled methods for the design of improved medical error reporting systems in the future.

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References

1. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human. Washington, DC: National Academies Press; 1999.
2. FDA. MEDWATCH - The FDA Safety Information and Adverse Event Reporting Program. Available at: www.accessdata.fda.gov/scripts/medwatch/. Accessed April 18, 2008.
3. Dovey SM, Meyers DS, Phillips RL Jr, et al. A preliminary taxonomy of medical errors in family practice. *Qual Saf Health Care* 2002; 11: 233-238.
4. Battles JB, Shea CE. A system of analyzing medical errors to improve GME curricula and programs. *Acad Med* 2001; 76: 125-133.
5. Runciman WB, Helps SC, Sexton EJ, et al. A classification for incidents and accidents in the health care system. *J Qual Clin Pract* 1998; 18: 199-211.
6. Benner P, Sheets V, Uris P, et al. Individual, practice, and system causes of errors in nursing: A taxonomy. *J Nurs Adm* 2002; 32: 509-523.
7. Chang A, Schyve PM, Croteau RJ, et al. The JCAHO patient safety event taxonomy: A standardized terminology and classification schema for near misses and adverse events. *Int J Qual Health Care* 2005; 17: 95-105.
8. Elder NC, Dovey SM. Classification of medical errors and preventable adverse events in primary care: A synthesis of the literature. *J Fam Pract* 2002; 51: 927-932.
9. Joint Commission. Sentinel event statistics. 2005 Mar 31. Available at: <http://www.jcaho.org/accredited+organizations/sentinel+event/sentinel+event+statistics.htm>. Accessed April 28, 2005.

10. National Coordinating Council on Medication Error Reporting and Prevention. Taxonomy of medication errors. Available at: www.nccmerp.org/pdf/taxo2001-07-31.pdf. Accessed April 18, 2008.
11. Boxwala AA, Dierks M, Keenan M, et al. Organization and representation of patient safety data: Current status and issues around generalizability and scalability. *J Am Med Inform Assoc* 2004; 11: 468-478.
12. Quality Interagency Coordination Task Force. Doing what counts for patient safety: Federal actions to reduce medical errors and their impact. Report of the Quality Interagency Coordination Task Force (QuIC) to the President. Available at: <http://www.quic.gov/report/toc.htm>. Accessed April 18, 2008.
13. Gruber TR. A translational approach to portable ontologies. *Knowl Acquis* 1993; 5: 199-220.
14. Noy NF, McGuinness DL. Ontology development 101: A guide to creating your first ontology. Stanford Knowledge Systems Laboratory Technical Report KSL-01-05 and Stanford Medical Informatics Technical Report SMI-2001-0880. Stanford, CA: Knowledge Systems Laboratory, Stanford University; 2001.
15. Stearns MQ, Price C, Spackman KA, et al. SNOMED clinical terms: Overview of the development process and project status. *AMIA Annu Symp Proc* 2001; 662-666.
16. Humphreys BL, Lindberg DA. The UMLS project: Making the conceptual connection between users and the information they need. *Bull Med Libr Assoc* 1993; 81: 170-177.
17. Cimino JJ. Desiderata for controlled medical vocabularies in the twenty-first century. *Methods Inf Med* 1998; 37: 394-403.
18. Noy NF, Musen MA. An algorithm for merging and aligning ontologies: Automation and tool support. Sixteenth National Conference on Artificial Intelligence (AAAI99), Workshop on Ontology Management; July 18-22, 1999; Orlando, FL.
19. Klein M. Combining and relating ontologies: Problems and solutions. *IJCAI workshop on ontologies*; 2001 Aug 4; Seattle, WA.
20. Pinto HS, Martins JP. A methodology for ontology integration. Proceedings of the First International Conference on Knowledge Capture (K-CAP); 2001 Oct 21-23; Victoria, BC.
21. Su X. A text categorization perspective for ontology mapping. Norway: Department of Computer and Information Science, Norwegian University of Science and Technology; 2002.
22. Hameed A, Preece AD, Sleeman DH. Ontology reconciliation. In: Staab S, Studer R, eds. *Handbook on ontologies. International handbook on information systems*. New York: Springer; 2004. p. 231-250.
23. Zhang J, Patel VL, Johnson TR, et al. Toward an action-based taxonomy of human errors in medicine. In: Gray W, Schunn C, eds. *Proceedings of the Twenty-Fourth Annual Conference of the Cognitive Science Society*. Mahwah, NJ: Lawrence Erlbaum Associates; 2002. p. 970-975.
24. Suresh G, Horbar JD, Plsek P, et al. Voluntary anonymous reporting of medical errors for neonatal intensive care. *Pediatrics* 2004; 113: 1609-1618.
25. Meadows M. MedWatch: Managing risks at the FDA. *FDA Consum* 2003; 37: 10-11.
26. Knublauch H, Fergerson RW, Noy NF, et al. The Protégé OWL plugin: An open development environment for semantic web applications. Third International Semantic Web Conference - An architectural overview for developers and decision-makers. Hiroshima, Japan: ISWC; 2004.
27. Noy NF, Musen MA. PROMPT: Algorithm and tool for automated ontology merging and alignment. Proceedings of the 17th National Conference on Artificial Intelligence (AAAI-2000). Austin, TX: AAAI/MIT Press; 2000.
28. McGuinness DL, Fikes R, Rice J, et al. An environment for merging and testing large ontologies. In: Cohn AG, Giunchiglia F, Selman B, eds. *KR2000: Principles of knowledge representation and reasoning*. San Francisco: Morgan Kaufmann; 2000. p. 483-493.
29. Kavouras M. A unified ontological framework for semantic integration. Proceedings of the International Workshop on Next Generation Geospatial Information; Boston, MA; 2003 Oct 19-21.
30. Hakimpour F, Geppert A. Resolving semantic heterogeneity in schema integration. Proceedings of the international conference on formal ontology in information systems; 2001 Oct 17-19. Ogunquit, ME. p. 297-308.
31. Hammer J, McLeod D. An approach to resolving semantic heterogeneity in a federation of autonomous, heterogeneous database systems. *Int J Intel Coop Inform Syst* 1993; 2: 51-83.
32. Liebig T, Pfeifer H, Henke FW. Reasoning services for an OWL authoring tool: An experience report. In: Haarslev V, Möller R, eds. *Proceedings of the 2004 International Workshop on Description Logics (DL2004)*. CEUR Workshop; 2004 June 6-8; Whistler, BC: CEUR-WS.org; 2004.

33. Flanders SA, Saint S. Getting to the root of the matter. AHRQ Web M&M. Available at: www.webmm.ahrq.gov/case.aspx?caseID=98. Accessed April 18, 2008.
34. Storey M, Lintern R, Ernst N, Perrin D. Visualization and Protégé. Victoria, BC, Canada: University of Victoria;. Available at: <http://www.smi.stanford.edu/projects/protége/conference/2004/abstracts/Storey.pdf>. Accessed June 16, 2008.
35. Knublauch H, Musen MA, Noy NF. Tutorial: Creating semantic Web (OWL) ontologies with Protégé. 2nd International Semantic Web Conference (ISWC2003); 2003 Oct 20-23; Sanibel Island, FL.
36. Stetson PD, McKnight LK, Bakken S, et al. Development of an ontology to model medical errors, information needs, and the clinical communication space. AMIA Annu Symp Proc 2001: 672-676.
37. Cimino JJ. Formal descriptions and adaptive mechanisms for changes in controlled medical vocabularies. *Methods Inf Med* 1996; 35: 202-210.
38. Oliver DE, Shahar Y. Development of a change model for a controlled medical vocabulary. *Proc AMIA Annu Fall Symp* 1997: 605-609.
39. Bernauer J. Subsumption principles underlying medical concept systems and their formal reconstruction. *Proc Annu Symp Comput Appl Med Care* 1994: 140-144.

Mapping a Large Patient Safety Database to the 2005 Patient Safety Event Taxonomy

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Abstract

Objective: To evaluate the Patient Safety Event Taxonomy (PSET) using a large existing database with near-miss reports. **Methods:** Analysts from the Pennsylvania Patient Safety Reporting System (PA-PSRS) mapped 420 reports from PA-PSRS into PSET. **Results:** We evaluated 34 PSET classifications accepting values. For five classifications, data could be translated directly from PA-PSRS for at least 95 percent of reports. For 11 PSET classifications, PA-PSRS data fields were not available for at least 95 percent of reports. Data were predominately unavailable in PA-PSRS data fields for two classifications. For 16 PSET classifications, translation required analysts' reviews of multiple PA-PSRS fields and free-text narratives. Useful data in seven PA-PSRS fields could not be transferred to PSET. **Conclusion:** Mapping an existing patient safety database to PSET would require analysts' interpretation and/or considerable realignment of the existing database. With a large flow of near-miss reports, either effort would require considerable resources.

Introduction

The Federal Patient Safety and Quality Improvement Act of 2005, signed on July 29, 2005, states that the Secretary of Health and Human Services may set standards for the definitions, data elements, and interface for a national network of patient safety databases.¹

On August 3, 2005, the National Quality Forum (NQF) endorsed a National Voluntary Consensus Standard for the Joint Commission's Patient Safety Event Taxonomy (PSET), in addition to definitions of patient safety terms, data elements for patient safety reporting systems, principles for improving the taxonomy, and recommendations for integrating the taxonomy into the health care information technology infrastructure.² PSET (or a modification of PSET) may become the basis for any national network of patient safety databases. The consensus standard stated that the standards were not intended to replace the taxonomy, definitions, or elements of reporting systems already in use, but that existing systems should be mapped to the standards in an evolutionary way.

The NQF standard definitions include:

- “A threat to patient safety,” defined as “any event that has harmed patients or could lead to patient harm.”
- “A hazard,” defined as “anything that can cause harm.”

From these definitions, we infer that the NQF-endorsed PSET is intended to be used for reports of near-miss events as well as for the sentinel events for which it was originally designed. We became interested in whether a large existing database with near-miss reports could be mapped to PSET, how difficult it would be to provide information for the PSET classifications, and whether useful information would be left behind.

Under the Pennsylvania Medical Care Availability and Reduction of Error (MCARE) Act of 2002,³ acute health care facilities in the State are required to report near-miss events (called “incidents” by the Act), as well as serious events involving unanticipated injury, to the Pennsylvania Patient Safety Authority, an independent State agency. The Pennsylvania Patient Safety Authority developed the Pennsylvania Patient Safety Reporting System (PA-PSRS) in order to receive these reports.

PA-PSRS is a Web-based electronic reporting system based on a taxonomy and data fields developed by the University HealthSystem Consortium (UHC) Patient Safety Net (PSN)⁴ and modified to meet the requirements of the MCARE Act. The taxonomy, which we will refer to as the PA-PSRS taxonomy, includes information to analyze the reported patient safety events. The main descriptive element is what others might call the “incident type,” but which we call the “event type” – given the very specific definition for “incident” in the MCARE law, as noted above.

Table 1. PA-PSRS event types, primary categories

- | |
|---|
| A. Medication error |
| B. Adverse drug reaction (not a medication error) |
| C. Equipment, supplies, and/or devices |
| D. Fall |
| E. Error related to procedure, treatment, and/or test |
| F. Complication of procedure, treatment, and/or test |
| G. Transfusion |
| H. Skin integrity |
| I. Other and/or miscellaneous |

Nine primary categories of event types (Table 1) are modified by multiple secondary and tertiary subcategories, resulting in 195 distinct clinical event types, classified by the three levels of descriptors (e.g., F, complication; 1, procedure; g, retained foreign body). One of the primary categories is “Other,” and 20 of the subcategories within primary categories are described as “other” (e.g., A, medication error; 9, other). These event types drive the collection of information germane to a specific event. The UHC PSN is comparable.

At the end of the first 2 years of data collection (June 2004 - June 2006), PA-PSRS contained 380,000 reports, 96 percent of which were reports of near misses. The total number of reports in the UHC PSN database was of the same order of magnitude.

We mapped event reports in the existing PA-PSRS to PSET. We wanted to determine how much information in the PSET classifications could be mapped directly from our electronic system, how much could be mapped at all, and how much effort would be involved to achieve full mapping. We wanted to understand the potential implications of mapping our system, with its large volume of near-miss reports, to any future national network of patient safety databases. We also wanted to determine if any PSET classifications were perceived as essential components of a patient safety database that would add value to PA-PSRS, and whether any PA-PSRS data fields that provided useful information had been missed by the currently endorsed version of PSET.

Methods

We listed the most recent PA-PSRS reports that met the following criteria:

1. The reports were initially entered more than 90 days previously, thus, beyond the time limit for further revisions.
2. The free-text narratives of the event contained more than 200 characters. This threshold was set a priori by the analysts to exclude reports likely to contain inadequate information in free text.

In order to capture an assortment of reports that were not unduly biased by the particular taxonomy of PA-PSRS, but were broadly representative of a variety of event types, we selected reports from that list using the following four strategies (in sequence). Altogether, 420 reports were reviewed. (Whenever applicable, facilities were selected based on which ones submitted the most recent reports.)

1. In order to get a “consecutive sample” without being biased by a select group of large-volume reporters, we selected the most recent report from 100 different facilities.
2. In order to get a “representative sample” of clinical event types, we selected the most recent report from each of the 195 specific event types, excluding the “other” categories.
3. In order to capture events that might not be well described by PA-PSRS, we selected the most recent reports from five different facilities for each of the 20 “other” event-type subcategories.
4. For the same reason as described in number 3, we selected the most recent reports from 25 different facilities for the primary event type called “Other.”

If an analyst had previously reviewed a report in depth, that analyst did the mapping. If not, the analyst normally assigned to review reports of that event type did the mapping. Prior to mapping the values from PA-PSRS fields into the PSET classifications, a mapping diagram was agreed upon by consensus meetings of all the analysts, linking PA-PSRS fields with appropriate PSET classifications. For each PSET classification, a value was entered to indicate whether:

- The value for that PSET classification could be translated directly from the value for a field in PA-PSRS (direct mapping).

- The value for that PSET classification could be filled in by an analyst from information in PA-PSRS (analyst interpretation).
- The value for that PSET classification could not be entered because there was no information in the comparable field in PA-PSRS (unknown value).
- The value for that PSET classification could not be entered because there was no comparable field and no comparable source for information in PA-PSRS (field absent).

If the value for an individual report did not follow the mapping diagram convention for that PSET classification, the expected value was changed to the appropriate value for that particular report. For instance, if the “age” field, which can be translated from PA-PSRS, had no entry in an individual report, the value assigned to PSET’s “age” field would be changed from the expected “direct mapping” to “unknown value.” If the place where the report originated was the intensive care unit, but the free-text narrative indicated that the event had occurred in the operating room, the value assigned to PSET’s “place” field would be changed from the expected “direct mapping” to “analyst interpretation.” If the analyst could find the patient’s diagnosis, which had no field in PA-PSRS, in the free-text narrative of the event, the value assigned to PSET’s patient “diagnosis” field would be changed from the expected “field absent” to “analyst interpretation.”

Errors in coding PA-PSRS fields were not an issue because of numerous error-checking mechanisms in the data entry interface of the electronic reporting system.

Considering the report in its entirety, each analyst then made two further subjective assessments:

1. What information included in the PSET classifications, but not available from PA-PSRS data fields, might have contributed to the understanding of the reported event had it been available?
2. What information in the PA-PSRS report that was useful to the understanding of the reported event would not be captured by the PSET classifications?

Although there was no direct measure of inter-rater reliability, in addition to the consensus meetings of all the analysts to create a uniform mapping diagram, the analysts presented selected reports for group discussion during weekly group analyses.

Results

Of the 420 reports mapped into 34 PSET classifications, 79 percent were reports of incidents or near misses. Table 2 shows the results of our efforts to map information from PA-PSRS reports into the 34 PSET classifications.

Five PSET classifications could have values directly and accurately translated from PA-PSRS data fields for more than 95 percent of the reports. Another nine classifications could have values directly and accurately translated from PA-PSRS data fields for between 30 and 44 percent of reports. However, for between 10 and 49 percent of the reports, this would require that patient safety analysts extract values, translate values for the PSET classification, or modify the directly translated values for better accuracy, after a complete review of the report. The result was an

accurate transfer of the value for between 43 and 87 percent of reports. For an additional seven classifications, values could be entered following extraction of the information from a complete review of the report by the patient safety analyst for between 10 and 56 percent of reports, despite the absence of a comparable data field or other consistent source of information in PA-PSRS. The analysts were able to find the information by linking information residing in different data and/or text fields.

Two classifications could not have values recorded because the value typically was not available in PA-PSRS, even though a comparable data field was present. Eleven classifications could not have values recorded in over 95 percent of the PA-PSRS reports due to the absence of data fields and any other sources of information in the PA-PSRS reports.

Each review took an average of 5 minutes for an analyst to extract and check values to be mapped into the PSET classifications.

Each analyst indicated information in the PSET classifications that was not present in PA-PSRS but might have contributed to the understanding of the reported event. The PSET domain classifications of staff, patient diagnosis, and coexisting conditions were cited commonly, in about three-quarters of the reviews (Table 3). Four other PSET “type” classifications were cited only rarely.

Each analyst also indicated, for each report, information in the PA-PSRS report that was useful to the understanding of the reported event but could not be mapped to the PSET classifications. The free-text narrative description of the event was most commonly noted as providing useful information not captured in PSET classifications (Table 4). Other data fields commonly cited as useful, but not in the PSET classifications, were identification of the event as a near-miss or “serious event”; the clinical event type according to the PA-PSRS taxonomy used in PA-PSRS; the procedure involved; how the event was discovered; the disposition of the event; and the date of initial contact prior to the event (i.e., a “new” patient vs. a long-standing consumer of care in the venue). Information specific to the clinical event type was occasionally identified as potentially useful.

Discussion

The results of the actual mappings show no anticipated difficulties mapping from the PA-PSRS system (which includes near-miss reports and uses a modified UHC taxonomy) for date, time, patient age and sex, and setting. All five of these PSET classifications, except possibly the last, should be able to be mapped from any robust reporting system.

Currently, 16 of the 34 PSET classifications would sometimes benefit from a review of the report by an analyst with manual entry of missing information or correction of information entered automatically from specific data fields. With regard to the 9 of these 16 classifications currently needing analysts’ reviews for mapping from near-miss and “serious event” PA-PSRS reports, the analysts believe that reviews of every report will continue to be necessary to sometimes clarify the values for physical impact. It will also be necessary to critique these values for the types of

communication and patient management and for the organizational, technical, patient, and practitioner causes for any error, plus the indicated prevention.

Table 2. Mapping from PA-PSRS fields to PSET classifications^a

PSET classifications for which values could be translated directly from the value for a field in PA-PSRS (%)			
Domain: Date	100.0		
Domain: Time	100.0		
Domain: Patient – Age	100.0		
Domain: Patient – Gender	99.8		
Domain: Setting	98.6		
PSET classifications for which values were sometimes extracted, translated, or clarified from PA-PSRS data fields by a patient safety analyst's review of the complete PA-PSRS report			
A. PSET classifications with comparable sources for information in PA-PSRS (%)			
	Directly	By Analyst	Total
Impact: Physical	41.0	46.2	87.2
Type: Patient management	30.5	48.8	79.3
Impact: Economic	44.0	30.2	74.2
Cause: Practitioner	38.3	21.0	59.3
Type: Communication	36.2	21.7	57.9
Cause: Organizational	43.3	10.5	53.8
Prevention: Indicated	41.4	10.0	51.4
Cause: Patient (contribution)	33.1	13.1	46.2
Cause: Technical	31.0	12.4	43.4
B. PSET classifications without comparable data fields or other consistent sources for information in PA-PSRS (%)			
Type: Intervention	56.4		
Domain: Staff	50.5		
Type: Post-intervention	38.1		
Domain: Target	36.0		
Type: Pre-intervention	29.8		
Domain: Patient – Diagnosis	23.3		
Domain: Patient – Co-existing Condition	10.5		
PSET classifications for which values could not be entered because there was rarely information in existing comparable data fields or other consistent sources for comparable information in PA-PSRS (see text) (%)			
Prevention: Selective	8.3		
Prevention: Universal	7.6		

Table 2. Mapping from PA-PSRS fields to PSET classifications (continued)

PSET classifications whose values could almost never be entered because there were no comparable data fields or other consistent sources for comparable information in PA-PSRS (range 3.6% – 0.0%)

Cause: External
Cause: Negligence
Cause: Recklessness
Domain: Patient – Duration Disease
Domain: Patient – Education
Domain: Patient – Other Information
Domain: Patient – Socio-Economic Class
Impact: Psychological
Impact: Legal
Impact: Social
Impact: Satisfaction

a Full descriptions of the PSET classifications can be found in the NQF report: *Standardizing a Patient Safety Taxonomy*.²

Table 3. Percent of PSET classifications, not present in PA-PSRS data fields, identified as potentially useful during the reviews of individual reports

Domain: Patient diagnosis	76.9
Domain: Patient coexisting condition	76.9
Domain: Staff	75.5
For few reports:	
Type: Patient management	1.0
Type: Preintervention	1.0
Type: Intervention	0.5
Type: Postintervention	0.5

Note: Full descriptions of the PSET classifications can be found in the NQF report: *Standardizing a Patient Safety Taxonomy*.²

Table 4. Percent of PA-PSRS data fields, not present in the PSET classifications, identified as potentially useful during the reviews of individual reports

Narrative free-text description of event	75.5
Date of admission	37.9
Type (near-miss or serious event)	37.6
How was event discovered	37.6
Event type (modified UHC taxonomy)	37.6
Disposition of event	37.6
Procedure error: Procedure	30.0
Fall: Type-specific information	7.6
Skin integrity: Type-specific information	5.0
Equipment: Type-specific information	4.0
Medication error: Type-specific information	0.2

For the remaining seven PSET classifications, the mapping could be better automated by adding PSET data elements to PA-PSRS. In the analysts' opinion, dedicating data fields to patient diagnosis, coexisting conditions, staff, and target or reason for care could provide consistently useful information. The analysts believe staff classifications would be helpful in identifying groups for interventions, such as team training and education.

For some of the PSET classifications in which information was unavailable in the existing comparable PA-PSRS data fields, the information may not have been entered by the reporter, either because it was anticipated to be included in the narrative field and was not; it was considered unimportant; or it was not required to be entered.

Virtually no information would currently be mapped from PA-PSRS for socioeconomic group and education; psychological, legal, or social impact; patient satisfaction, duration of disease, or "other" patient information; or causes due to recklessness, negligence, or external causes related to human failures beyond the control and responsibility of the facility. Of these 11 PSET classifications, recklessness, negligence, and external causes are excluded uniquely from PA-PSRS by the MCARE Act.³ The analysts believe that socioeconomic class and education would rarely be recorded, even if relevant. In their opinion, the information about duration of disease present in PSET may be better than the PA-PSRS surrogate, "date of admission." Distinguishing acute from chronic conditions—diagnoses with a single opportunity for error vs. diagnoses with multiple opportunities for error—can be useful.

Adding valuable PSET data elements that are currently not in PA-PSRS, although desirable, would require a significant effort that must be approached as a comprehensive system upgrade. Adding data fields to the reporting system involves adding the fields to the database, changing the data-entry interface, and changing the reports. It would also require facilities that interface their legacy systems with PA-PSRS to change their interface systems. Facilities that collect information internally on paper would need to change their data collection forms as well.

We already spend time critiquing causes and prevention during discussions in weekly group analyses of important reports. We estimate that the additional time to process an individual report to include mapping to PSET with quality control would be approximately 5 minutes. With our current annual load of about 200,000 near-miss and serious-event reports for an estimated population of 12 million people, the additional time to review the mapping of every report would total more than 16,000 hours per year, requiring an additional eight full-time analysts. Even with major improvements in efficiency, extra personnel would be needed. Other patient safety reporting systems capturing large volumes of near-miss reports, such as the UHC PSN system, the Veterans Health Administration National Center for Patient Safety's reporting system, and (internationally) the United Kingdom's National Patient Safety Agency's reporting system, might have similar requirements for additional personnel if they were to map to an American or world patient safety database.

Cost-effective alternatives to having patient safety analysts do manual reviews of all reports and assign or critique values to PSET classifications by hand include the following:

- Radically change the PA-PSRS data fields to mimic essentially all the PSET data elements. This option would require a wholesale system overhaul of the current reporting system to make it into an electronic front-end entry system for a PSET database. This presumes no universal quality control. This solution would also make future data incompatible with the 380,000 reports already collected in PA-PSRS and a comparable number collected by UHC PSN.
- Automate the mapping done by the analysts, who bring together multiple data fields and free-text narrative fields. PA-PSRS currently prioritizes and distributes reports for analysts' queues using Bayesian classification predictors of importance and type of problem. PSET mapping could theoretically be done using more Bayesian classification predictors and, optimally, natural language processing. The inevitable rate of misclassification using automation might be offset by better consistency compared with human review. Resources, ideally in the form of research funding, would be needed to develop appropriate Bayesian classification programs, have them learn classifications from the analysts, and perform validation studies.
- Use a risk assessment index or other criterion to select a subset of important reports for mapping to PSET. This strategy would transmit salient information but would preclude epidemiologic studies based on complete sampling.
- Map only key indexing fields, such as “setting,” “physical impact,” “patient diagnosis,” and “coexisting conditions,” and organizational, practitioner, and technical causes.

Either radically changing an existing reporting system or accurately mapping reports would require a significant expenditure of resources. Any decision to do so would have to be justified by its value in providing significantly more information. For small-volume reporting systems with limited extra workloads and synergy from participating in an aggregated network of databases, the extra work may be worthwhile. For large-volume systems that can generate their own metrics, the significant extra work may not be justified.

If the difference in value of fully integrating a large, existing near-miss patient safety reporting system, such as PA-PSRS, with PSET is not perceived as adding enough information to justify the expenditure of resources, one or more partial solutions may be possible:

- Use a “free” unspecified field to link disparate patient safety database systems with a single joint index field. The usual index field for linked, or relational, databases—identifiable information in the report—may not be appropriate because of confidentiality concerns. We feel that a field describing the provider-reported descriptive event type (or incident type as understood by others) would be most appropriate because, in our opinion, it drives the most search strategies.
- Continue to improve the current PSET as existing reporting systems evolve toward PSET standards.

There are some general similarities between PSET and PA-PSRS. Most notably, both divide data elements into two levels: (1) those that are entered initially after an event occurs and (2) those that are entered after followup and analysis. This division is particularly valuable when near-miss reports are added to sentinel event reports, since the former do not always have followup and analysis, although information of similar value may be present in the recovery action.

There also are some differences:

- PSET has five primary parts to the classification of an event: one, the type of failure; two, the domain (setting, providers, and patient characteristics); three, the cause; four, the impact; and five, prevention or mitigation. Each primary classification is subdivided into subclassifications, with up to four designated levels: primary, secondary, tertiary, and quaternary. The type of failure has three secondary classifications, with a total of 21 possible data entries.
- PA-PSRS uses a modification of the UHC taxonomy of event types, which classifies the failure into one of nine primary event types (Table) with subtypes up to a total of three levels, including 20 embedded “other” categories, resulting in 195 distinct clinical event types at the terminal secondary or tertiary level, plus the 21 “other” categories. General information about domain, cause, and impact is collected by separate data elements.
- Whereas the PA-PSRS event types are mutually exclusive (either/or), the PSET classifications and subclassifications are mostly all yes/no (and/or), with possible entries in 115 different data fields in 34 primary, secondary, and tertiary classes and subclasses overall, most of which would be in the default “no.”
- The PSET classification of the type of event is based on an assessment of the cause; the PSET “type” classification within its taxonomy does not describe the cause, which is a separate part of the event. However, it requires an evaluation of the event to document the possibility of specific communication failures, specific problems with patient management, and the correctness of the patient’s diagnosis.

Alternatively, the event type (or incident type as understood by others) used by PA-PSRS is a description of the observed process error or adverse outcome devoid of analysis. Instead of being an evaluation of the event, it is the “chief complaint”—the problem as perceived by the provider or others involved with the event. As such, it requires no assessment to be accurately recorded. Furthermore, this “chief complaint” of a patient safety event then drives the electronic reporting system interface to ask more detailed type-specific questions as part of the examination of the problem.

Of the standard initial data elements for PSET, most of the basic “who, what, when, where, and how” can be found in PA-PSRS, but the following have no comparable data fields in PA-PSRS: who was involved (i.e., those involved in the event, described by role), diagnoses, and coexisting conditions. Of note to States or patient safety organizations planning to develop patient safety databases, procedures are not found in PSET, nor are they found in PA-PSRS, except within the primary event type “Error Related to Procedure.”

Also of possible interest to States or patient safety organizations planning to develop patient safety databases, PA-PSRS records whether a reported event was a near-miss or “serious event,” how the event was discovered, and its disposition, all of which are considered useful by the PA-PSRS analysts but are not found in PSET. PA-PSRS also includes a narrative field, which the analysts regard as the most valuable of all.

Qualitatively, the PA-PSRS analysts also perceived some weaknesses in the current PSET that could be improved:

- The PSET event-type classification presumes prior evaluation. We believe a descriptive event type, or incident type, based on process of care or clinical outcome would be more successful in initiating the evaluation process. This is especially true for data fields for which values do not just sit in a database but are used during the data entry process to drive coherent electronic collection of specific relevant data for that event through the data entry interface.
- Despite the Institute of Medicine's emphasis on errors of commission and omission,⁵ errors of timing and technique,⁶ such classifications are not available in PSET. PSET also focuses the assessment of clinical performance on the diagnosis rather than on the process of care, which, along with the context in which it is given, relates to the outcome. The PA-PSRS analysts find the reports most helpful when the processes and outcomes are specific, so that the clinical story can be reconstructed: e.g., diagnosis Q in a patient with comorbidity R, treated with process S by a provider type A in environment B, complicated by process error type T, corrected with action U by provider type C in environment D, gets (or is prevented from getting) complication X.
- Despite emphasis in the patient safety community on the components of a high-reliability organization⁷ with a system for providing reliable care through standardization and teamwork, important elements of such variables are not collected. For example, institutional and personal factors are captured, but team factors are not.
- The recovery and mitigation responses, which result in events being "near misses" when successful, could be improved to lead to discoveries about how systems can change to prevent errors from harming patients.

Why did some reports in this mapping exercise, but not others, have comparable PA-PSRS data fields for mapping values to the PSET classifications? The PA-PSRS data entry interface is interactive; different details are requested depending on the PA-PSRS event type. For instance, a procedure data field is only available for the event type of "error related to procedure."

With specific reference to the study methodology, the following are emphasized:

- Not all of the 458 acute health care facilities, or even 238 hospitals, reporting to PA-PSRS were included.
- The sample was not random or a sample of consecutive reports. Instead, it was an assorted sample of the variations possible across facilities and event types, with special emphasis on reports of event types not specifically classified by the taxonomy used in PA-PSRS. We attempted to minimize the multiple biases of selecting consecutive reports (over-representing large-volume reporters and common event types) and reports that fit into our existing taxonomy.
- The reports were intentionally a distribution of "near misses" and what PA-PSRS calls "serious events." The difference between the percentage of near-miss reports in this study (79 percent) and PA-PSRS as a whole (96 percent) is due to the intentional sampling of a set number of reports from each event type, some of which (e.g., adverse drug reactions and complications) always presume harm.

- The analysts may have had a bias, based on familiarity with PA-PSRS, in favor of the usefulness of PA-PSRS data fields for understanding reported events. Others may be encouraged to map their patient safety systems to the current version or future iterations of PSET.

Conclusion

Different reporting systems and taxonomies have different conceptual premises that make mapping between them not just a programming exercise. There are some data elements in PSET that were identified in the mapping exercise and were considered worth adding to our existing patient safety reporting system. However, adding these data elements is not trivial. Mapping all reports without total alignment of the reporting system to PSET could double the workload of a large volume near-miss reporting system.

The value of changing existing reporting systems, laborious mapping of all reports, or developing sophisticated software to map them automatically would have to be justified by the net value added by doing so. In our opinion, PSET has weaknesses and strengths, compared with other established patient safety reporting systems. PSET may be most appropriate for new patient safety reporting systems or small systems for which changes or mapping would not be a burden.

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Any opinions in this manuscript are those of the authors and not the institutions with which they are affiliated.

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References

1. Liang BA, Riley W, Rutherford W, et al. The Patient Safety and Quality Improvement Act of 2005: Provisions and potential opportunities. *Am J Med Qual* 2007; 22: 8-12.
2. National Quality Forum. Standardizing a patient safety taxonomy. Washington, DC: National Quality Forum; 2006.
3. Medical Care Availability and Reduction of Error (MCARE) Act. Available at: www.psa.state.pa.us/psa/lib/psa/act_13/act_13.pdf. Accessed January 25, 2008.
4. Poniatowski L, Stanley S, Youngberg B. Using information to empower nurse managers to become champions for patient safety. *Nurs Adm Q* 2005; 29: 72-77.
5. Aspden P, Corrigan JM, Wolcott J, et al, editors. Patient safety: Achieving a new standard of care. Washington, DC: National Academies Press; 2004. p. 31.
6. Clarke JR, Spejewski B, Gertner AS, et al. An objective analysis of process errors in trauma resuscitations. *Acad Emerg Med* 2000; 7: 1303-1310.
7. Roberts KH, Yu K, Van Stralen D. Patient safety as an organizational systems issue: Lessons from a variety of industries. In Youngberg BJ, Hatlie MJ, editors. *The patient safety handbook*. Sudbury MA: Jones & Bartlett; 2004. p. 169-186.

A System to Describe and Reduce Medical Errors in Primary Care

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Abstract

Although much attention has been focused on finding ways to identify medical errors and thereby reduce harm in hospital settings, few efforts have been directed at these issues in ambulatory settings. Duke University's Department of Community and Family Medicine has developed and implemented a practical, voluntary reporting system with classification and tracking of types of errors. Initially created in the Family Medicine Center, this system is now used in all of the department's wide variety of clinical operations. By reporting errors, analyzing error patterns, and addressing them, the clinical practices have become better able to identify faulty systems and error-prone areas and to change processes to prevent future errors.

Introduction

Efforts to increase patient safety within hospital settings are numerous and have resulted in many organizational, cultural, and systemic environmental changes that have reduced harm.^{1, 2, 3, 4, 5, 6,}
⁷ However, less attention has been paid to outpatient settings. This limited research scope risks missing the everyday errors that occur where the largest proportion of care is delivered—in primary care. Understanding and reducing errors in primary care practices could potentially have a wide range of positive effects, including better clinical outcomes, decreased hospitalizations, improved patient-physician trust, reduced costs, and lower malpractice claims.

Few research studies have examined errors in primary care, and even fewer have addressed how relevant data can be collected in a real-life clinical setting and used to reduce errors and build a culture of safety. This paper describes how the Duke University Medical Center Department of Community and Family Medicine (CFM) developed a customized error reporting and classification system for its outpatient clinics and changed its culture to encourage reporting and quality improvement.

Previous studies have shown that frequencies of error types recorded vary between countries and regions. Some of these differences may be real, while others may simply be due to different reporting routines and classification systems. The top five types of errors reported by U.S. family physicians are:

1. Errors in prescribing medication.
2. Errors in getting the right laboratory tests done for the right patient at the right time.
3. Errors related to filing systems.
4. Errors in dispensing medications.
5. Errors in responding to abnormal laboratory test results.⁸

Studies have found that most errors in primary care practice are preventable. In 1998, Bhasale, et al.,⁹ found that of 805 incidents reported in general practice settings in Australia, 76 percent were preventable. Fischer, et al.,¹⁰ reviewed incident reports from eight primary care clinics affiliated with an academic medical center in the Midwestern United States and found that 83 percent of the events were preventable.

Of particular importance in studying errors in primary care is the question of how small- and medium-sized practices can develop patient safety systems within the time and cost constraints under which they function. Elder, et al.,¹¹ suggested that barriers to establishing systems in family medicine offices include the burden associated with the effort to report, a lack of clarity regarding the information requested in an error report, the perceived benefit (and risk) to the reporter, and the properties of the error (e.g., severity, responsibility). Although the same study found less agreement in identifying motivating factors, the most commonly cited factor in encouraging reporting was perceived benefit, particularly the idea that reporting will improve the overall process.

Overcoming these barriers requires a reporting system that involves minimum time and effort and a process that emphasizes that information gathered is directly used to improve the practice environment. It is also important to recognize that the close interactions between staff in a small office will discourage reporting if the system is perceived as designed to “punish” individuals.

Development of the Duke CFM Quality Improvement System

Initial quality improvement (QI) efforts in the Department of Community and Family Medicine focused on the Family Medicine Center. This practice currently has a volume of approximately 40,000 visits per year and a patient population that closely mirrors the racial and ethnic composition of its surrounding community: 46 percent African American, 41 percent white, 6 percent Latino, and 7 percent other. Management of chronic disease is a major focus. One-third of patients have Medicare or Medicaid coverage, 40 percent are Duke employees covered under a Duke health insurance plan, and the remainder are covered by a mix of other private payers. At any given time, there are approximately 10 full-time providers—including physicians and mid-level practitioners—supported by an interdisciplinary staff of nurses, pharmacists, social workers, dietitians, psychologists, and laboratory, radiology, and clerical staff.

This academic practice serves as the primary continuity site for family medicine residents, as well as other “providers in training,” such as medical/physician assistants and pharmacy students. The clinic’s population, volume, staffing mix, and funding sources were roughly the same a decade ago, when the QI efforts were begun. The only structural change is that the practice is now an outpatient facility of Duke Hospital.

The State of North Carolina has no mandatory reporting laws for primary care providers, and other than the standard requirement by The Joint Commission to report sentinel events, there have never been mandatory reporting requirements outside of those a medical center sets for itself. As part of the hospital peer review system, the Duke Family Medicine Center had a well established voluntary reporting system by the late 1980s. The quality efforts at that time centered on individual error and correction in a traditional “quality assurance” approach, in which the focus was on meeting preset criteria.

In 1996, in conjunction with an institutional movement to QI, patient safety efforts refocused on systems analysis, process improvement, and care improvement. With the understanding that humans are imperfect and will make errors, attention was directed to systems that would support health professionals in care delivery and could help identify errors before they affected patients. The departmental voluntary reporting system was redesigned and expanded beyond the hospital requirements. All members of the practice were encouraged to report problems and near misses of all types within a confidential, protected peer-review system.

It is notable that those reporting were not asked to determine that an error had occurred—only that there was concern about a possible error. All significant adverse events (e.g., unexpected deaths and hospitalizations) were to be reported for peer review to help determine if the event might have been prevented. Also of note, the system was not anonymous; no attempt was made to blind reviewers to the identities of reporters or involved providers.

To make the reporting system simple and yet thorough, a one-page form was created that asked the reporter to identify the issue and actions taken, if any. The form included patient identification information, the concern, and a description of any actions taken so far, along with clear labeling for confidentiality and instructions against copying or distribution. Reporters were asked to describe in free text the concern or incident and any actions taken. Attachments could be included with the sheet if available.

Refinements to the form were made based on user and reviewer requests. A severity assessment was added, in which reporters circled one of five outcomes ranging from “no adverse outcome” to “death.” As technology changed and to encourage the widest possible reporting, reports were accepted in other forms if these were more convenient at the time. For example, a provider could send a brief e-mail, or a staff member could forward a copy of a patient complaint letter.

All reports were logged into a secure, confidential database and forwarded by a staff coordinator for case review. Initial reviews were done by a nurse practitioner or physician assistant on the QI team or were requested from involved providers in order to get their perspective. All cases were routed in clearly marked confidential packets, tracked closely, and hand delivered to maintain peer review protection. Reviewers filled out a peer review sheet to indicate their opinion as to whether standard of care had been met, as well as their recommendations. Specific questions on the review form asked whether the error was an individual provider issue, a systems issue, or indicated a pattern or trend. Reviewers could identify cases for committee discussion, QI projects, and/or divisional morbidity and mortality (M & M) conferences. No case was closed until action had been taken to rectify all issues identified. Systems were developed as needed to prevent recurrences.

M & M conferences, held roughly monthly in the Family Medicine Center as part of the peer-review program, were converted in 1996 into dialogues about how systems of care could be improved. These conferences included all Family Medicine Center providers, as well as interested staff. The traditional inquisition to identify a scapegoat who might have made a mistake was eliminated.

As the practice group realized that investigations resulted in systems improvements, and that human error was not punished or ridiculed, rates of reporting increased. The rapid volume growth—from 15 reported concerns in 1996 to 113 in 2003—made it difficult to keep track of the types of problems observed (Figure 1). In 2003, to enable better tracking and analysis of error patterns, we sought a coherent and comprehensive coding system by which to classify the cases.

A search of the existing literature revealed two potentially applicable taxonomies for medical errors. Pace, et al.,¹² with the Applied Strategies for Improving Patient Safety (ASIPS) Collaborative in Colorado, had created a comprehensive and thoroughly researched coding system. We found many good ideas in the system, but realized that, in a busy practice setting of our size, it would be too cumbersome and require too much time for efficient usage. Dovey, et al.,¹³ had published a taxonomy based on work in family medicine offices in the United States. Although this taxonomy was much more usable in a clinical environment, initial attempts at application were problematic. In particular, Dovey's division of knowledge and process errors was found to be difficult to apply. In practice, many incidents included aspects of both, and the distinction was difficult to make based on medical records.

Building on this previous research and our reported cases, we developed a simplified taxonomy around seven main error clusters: (1) communication, (2) studies, (3) diagnosis, (4) medication, (5) other treatment or followup, (6) records, and (7) administration. Each category included several subcategories. For example, communication errors were divided into problems in communication with patients or families and between providers and/or staff. See the Appendix for a full listing. Subsequently, as adoption of the system and form progressed, we identified the need for an eighth category: (8) no error (e.g., adverse

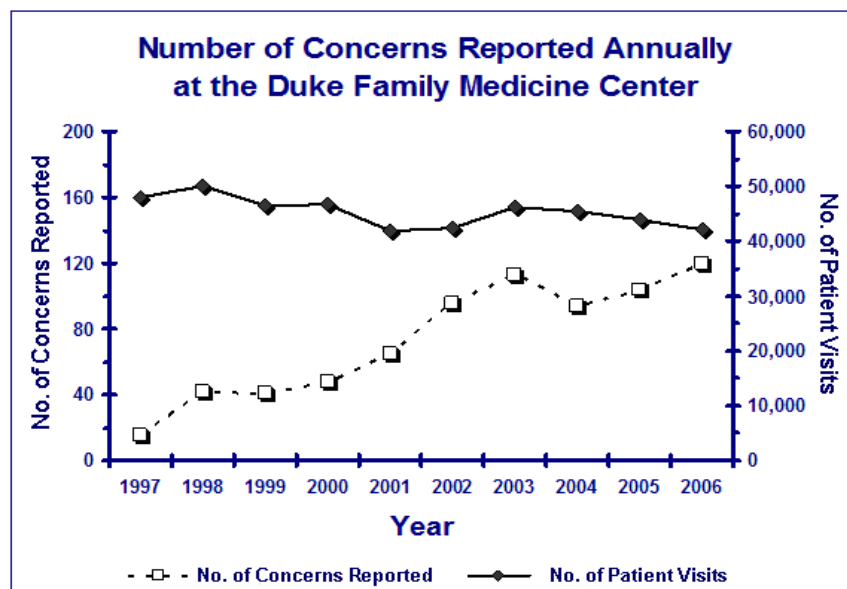


Figure 1. Number of reported concerns and patient visits per year (Duke Family Medicine Center).

outcome despite appropriate care, unhappy patient). Since all unexpected deaths and quality-related patient complaints were reviewed, this category was needed for those cases in which no error was identified.

After each incident had been analyzed and peer review completed, the QI director assigned a primary error code. All reported errors were coded, regardless of whether they reached or harmed a patient (e.g., a “near miss” of a dosing error that was caught by a pharmacist and corrected was coded as a dosing error). The draft taxonomy was revised and refined based on experience with the cases of 2002 and 2003. To assess for agreement among multiple raters, a sample of cases was independently coded by three senior faculty members. Substantial variability was found in the assignment of subcategories, but agreement on assignment of each case into a major cluster was better.

In 2005, the confidential QI Concern Report form was revised to ask reporters to indicate their impression of the type of error according to the new classification, in addition to describing the concern or incident and corrective actions taken (see Appendix^a). This initial code assignment was for consideration by the reviewers as they completed further investigation. In practice, reporters have been much less likely to complete this step (30/133 in 2006). Cases and final codes assigned are registered and tracked in a password-protected, peer review database with access strictly limited to the QI director and QI staff only.

Beginning in 2004, the system developed for the Family Medicine Center was rolled out and adapted for all clinical operations in the CFM. This included a wide variety of units, such as Community Health, Student Health, Occupational and Environmental Medicine, and the residential Diet and Fitness Center. Each unit or division made local modifications to the reporting format and initial review process to fit their setting and personnel, while maintaining the very stringent requirements of a peer review process.

Reviews by each of these units or divisions went to the CFM QI director for further review and coding. If all identified issues had not been sufficiently addressed, the QI director could send the cases back to the unit or division for further analysis and/or corrective action.

When a case was closed, it was cross-referenced in the peer review database of involved providers. This cross-reference was checked on an annual basis as part of the recredentialing process. In order to identify patterns of similar issues, cases for each individual were re-reviewed. Patterns discovered led to provider feedback, action plans, and followup reviews as needed.

Results

In the 11 years since the transition to QI, the voluntary reporting system has facilitated the development of a culture of safety. Numbers of reported concerns have increased 10-fold since

^a Form may be used freely with attribution as to source: Duke University Medical Center, Duke Family Medicine Center.

the initiation of the system (Figure 1), while the number of patient encounters has remained relatively constant.

Figure 2 shows the distribution of error types in 2005 and 2006. In contrast to earlier reports,⁸ problems with studies are by far the most frequent. The most common issues were errors in reporting results to providers and errors in responding to results.

By analyzing error patterns and addressing them, the clinical practices have been able to identify faulty systems and error-prone areas and change processes to prevent recurrences. For example, reported inconsistencies in communication and recommended followup for abnormal Pap tests led to the development of a weekly batch reporting process from pathology, which feeds into a departmental database to track individuals from “index abnormal Pap” through “treatment/resolution.”

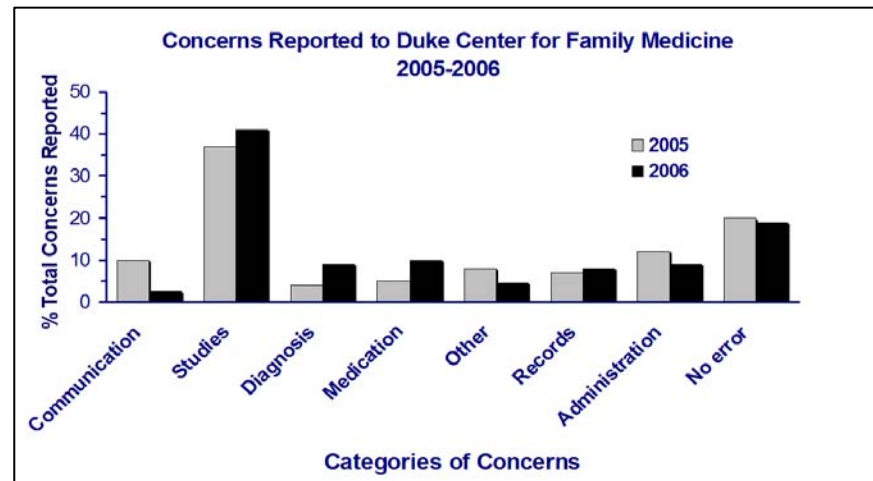


Figure 2. Distribution of error types over 2 years (all CFM clinics).

Another example was difficulty with electronic reporting of cardiac studies to supervising physicians only, bypassing the mid-level providers who had ordered them. This was a serious problem because the mid-level providers function quite independently. Fortunately, a call to the cardiac studies laboratory resolved the problem within a week.

Within each clinical unit, the program described has been supported by a small degree of effort from one clinician (up to 20 percent) and staff (up to 30 percent). Budgeted amounts range from \$0 to \$30,000, depending on the size of the clinical practice, or up to 1 percent of the clinical revenue of each unit. This is considered part of the cost of clinical operations. Additional physician and staff time are needed for coordination and department-level review.

Discussion

Primary care settings vary widely. Academic medical centers, urban clinics, rural physician offices, and suburban practices all differ in their mix of types of providers, patients, payment sources, and administrative resources. When developing patient safety reporting systems, providers should take care to learn from successful practices elsewhere but also keep in mind the individual needs of their environment. The program we describe, which is still evolving, is not

offered as a one-size-fits-all solution for primary care settings, but rather as a practical guideline that can assist others.

Key to any patient safety endeavor is the creation of a reporting system that takes into account limited time, confusion, and blame. In a discussion of common barriers to error reporting, Elder, et al., identify the most significant barrier as time.¹¹ The program described here attempts to alleviate this by making reporting as convenient as possible by accepting both paper and electronic formats. Drop boxes for confidential concern reports are available in all clinic workrooms. Reporters are not criticized if their reports are brief—a simple notation of the patient ID, date, and less than a full sentence on the concern can take under a minute—although some may spend several minutes describing relevant issues and attaching details.

A second common barrier to reporting is fear of “betraying” colleagues. By restructuring the activity to one of reporting “concerns” rather than “errors,” the burden of judgment is removed from the reporter. The process is reframed as helping the practice to identify systems that are not working because “we can’t fix problems we don’t know about.” Reporting may be done anonymously, if desired, through an institutional online system, but this method has been used rarely. Most reporters identify themselves, and many participate in the investigation of a concern. In fact, many providers report themselves when they have questions or concerns about their own actions (“Did I miss something?”), a behavior that is strongly encouraged.

Another barrier to high levels of reporting is an apparent lack of benefit to the individual provider. In this program, at the request of the providers, feedback is given directly to reporters at the completion of each case review, indicating the systems changes that resulted from their report. (No specific feedback is given on individual errors or performance of individuals other than the reporter.) For example, a provider who reported a delay in treatment because of failed notification of an abnormal study result might be told that his or her report was one of several that led to collaboration with radiology for a revised notification system. Providers who report an unexpected death of one of their patients might be notified that the peer review identified no flaws in their care. On the other hand, they might be given some concrete suggestions. Reporters are explicitly thanked for their contributions, even when the analysis reveals no error.

Identification of patterns of problems is critical. It is rarely cost effective or desirable to change systems in response to every single event. Some near-miss events have high enough risk that they must be addressed immediately; other minor glitches may not warrant action unless they recur. When numbers of reports are small, it is easy for those involved to identify clusters around similar issues. Once volume increases, a classification system becomes more helpful. The taxonomy developed here is functional for this clinical setting. It enables a practice to identify and quantify its most frequent problems.

The most common errors reported in one setting may not match other settings. Indeed, our most common errors—those relating to diagnostic studies—are different from the category most commonly cited in prior studies—i.e., medication errors.⁸ Some of the issues with diagnostic studies have related to the complexities of a teaching practice and the difficulty of ensuring communication with both trainees and their supervisors. Medication errors may occur less frequently due to an emphasis in the electronic medical record on medication lists, although

electronic prescribing is not yet in use in this setting. Other factors may include supervisors rechecking trainees' prescriptions, involvement of the pharmacist on staff, or the system not functioning successfully in capturing these errors in concern reports.

In some cases, neither reporting the patterns nor creating quality improvement initiatives will easily solve the problem. This is particularly true for more systemic problems involving multiple stakeholders, both within and outside our own clinics. For example, Kripalani, et al.,¹⁴ wrote about a problem common for many primary care settings: poor communication with hospitals and specialists outside the primary care practice. They found that results of tests pending at discharge from hospitals often do not make it back to primary care settings, resulting in delayed or missed care. This matches our experience. One effort to address this problem involved changing the discharge summary format to highlight pending items and abnormalities needing followup.

A delicate consideration is the use of case reviews in recredentialing. As mentioned above, cases are cross-referenced to individual providers and reviewed at time of recredentialing. This raises the specter of potential punitive consequences. No provider has been penalized for having large numbers of cases. In fact, as reporting has been encouraged, high-volume providers have often had sizeable numbers. Indeed, those who frequently self-report often have the highest numbers. In these instances, cases may be considered again looking for patterns. In the vast majority of recredentialing reviews (65 per year, on average), the results show a small number of understandable human errors, for which feedback has been given and appropriately received. In some cases, a pattern may be detected (perhaps of unhappy patients, suggesting issues with interpersonal style) and trigger some feedback. Only clear outliers with an unusual pattern and severity of issues may receive a formal corrective action.

Over the decade since this program was started, the CFM has experienced decreased liability claims. While a direct causal link cannot be proven and multiple factors are certainly involved, the culture change produced by this improvement program was likely a contributing factor.

The limitations of this report are two-fold. As a description of a system developed real-time in an active clinical practice, there is no rigorous study design, and the data are not suitable for statistical analysis. In addition, legal and confidentiality issues surrounding patient information restrict what information can be shared. As more small- and medium-size primary care environments share best practices and qualitative information in the literature, it is hoped that more structured, larger scale studies will be undertaken and offer more scientific rigor to patient safety initiatives in primary care.

Conclusion

Error reporting systems in primary care have the potential of assisting in continuous practice redesign so that patient safety is improved. The system described here has the advantages of being simple and usable in a busy practice setting, while providing enough detail to permit practice redesign and meaningful feedback. Use of simple error tracking systems in primary care sites is encouraged so that primary care, with all its complexities, can be the safest possible medical home.

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References

1. Baker DP, Gustafson S, Beaubien JM, et al. Medical teamwork and patient safety: The evidence-based relation. Washington, DC: American Institute for Research; 2003.
2. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study. *N Engl J Med* 1991; 324: 370-376.
3. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events: Implications for prevention. *JAMA* 1995; 274: 29-34.
4. Phillips D, Christenfield N, Glynn I. Increase in U.S. medication error deaths between 1983 and 1993. *Lancet* 1998; 351: 643-644.
5. Gaba DM. Human error in anesthetic mishaps. *Int Anesthesiol Clin* 1989; 27: 137-147.
6. Bates D, Leape L, Petrycki S. Incidence and preventability of adverse drug events in hospitalized patients. *J Gen Intern Med* 1993; 8: 289-294.
7. McGuire HH, Horsely JS, Salter DR. Measuring and managing quality of surgery. Statistical vs. incidental approaches. *Arch Surg* 1992; 127: 733-737.
8. Elder N, Dovey S. Classification of medical errors and preventable adverse events in primary care: A synthesis of the literature. *J Fam Pract* 2002; 51: 927-932.
9. Bhasale AL, Miller GC, Reid S, et al. Analysing potential harm in Australian general practice: An incident-monitoring study. *Med J Aust* 1998; 169:73-76.
10. Fischer G, Feters MD, Munro AP, et al. Adverse events in primary care identified from a risk-management database. *J Fam Pract* 1997; 45: 40-46.
11. Elder NC, Graham D, Brandt E, Hickner J. Barriers and motivators for making error reports from family medicine offices: A report from the American Academy of Family Physicians National Research Network (AAFP NRN). *J Am Board Fam Med* 2007; 20: 115-123.
12. Pace WD, Staton EW, Higgins GS, et al. Database design to ensure anonymous study of medical errors: A report from the ASIPS collaborative. *J Am Med Inform Assoc* 2003; 10: 531-540.
13. Dovey SM, Meyers DS, Phillips RL Jr, et al. A preliminary taxonomy of medical errors in family practice. *Qual Saf Health Care* 2002; 11:233-238.
14. Kripalani S, LeFevre F, Phillips CO, et al. Deficits in communication and information transfer between hospital-based and primary care physicians: Implications for patient safety and continuity of care. *JAMA* 2007; 297.8:831-841.

Appendix

DUKE FAMILY MEDICINE CENTER DUKE UNIVERSITY MEDICAL CENTER

OFFICE USE ONLY:

Case #:

Date Rec'd:

☐ Pt Related ☐
Admin/System

QI Concern Report Form

Please use this form to report QI concerns/issues.

DATE: _____ **REPORTED BY:** _____

PATIENT NAME: _____ **DH#** _____

 **PLEASE DESCRIBE IN DETAIL THE CONCERN/INCIDENT BEING REPORTED:**

(Attach separate page if necessary)

 **PLEASE INDICATE ACTION(S) TAKEN:**

 **PLEASE INDICATE LEVEL OF PATIENT OUTCOME:**

- 0 = No adverse outcome
- 1 = Minor adverse outcome (non-serious effect, not requiring treatment)
- 2 = Moderate adverse outcome (significant effect, requiring treatment)
- 3 = Serious adverse outcome (permanent adverse effects)
- 4 = Death

 **ATTACHMENT(S)**

☐ Chart Notes ☐ Encounter Form ☐ Correspondence ☐ Bill/Statement ☐ Other

 **IS URGENT ACTION NEEDED?** ☐ Yes ☐ No, routine
(e.g., patient waiting for reply)

PLEASE COMPLETE REVERSE SIDE ALSO!

TYPE OF ERROR

Please check one or more of the following categories to identify the primary thing you believe went wrong in this case.

- ☐ **Communication**
 - 1. problems in interaction with patients or their relatives
 - 2. problems in interaction between health care providers/staff
 - 3. other
- ☐ **Studies**
 - 1. ordered incorrectly (wrong test or not indicated)
 - 2. not ordered when indicated
 - 3. not done as ordered
 - 4. error in reporting results to provider
 - 5. error in responding to results
 - 6. other
- ☐ **Diagnosis**
 - 1. insufficient evaluation for diagnosis
 - 2. wrong and/or missed diagnosis based on available data
 - 3. other
- ☐ **Medication**
 - 1. ordered incorrectly (wrong medication, wrong dose, or not indicated)
 - 2. no medication ordered when indicated
 - 3. not delivered as ordered
 - 4. other
- ☐ **Other treatment or follow-up (excluding diagnostic studies and medications)**
 - 1. ordered incorrectly (wrong treatment, wrong timing, or not indicated)
 - 2. not ordered when indicated
 - 3. not delivered or completed as ordered
 - 4. other
- ☐ **Records**
 - 1. incomplete
 - 2. incorrect
- ☐ **Administration**
 - 1. errors in handling/transmission of messages
 - 2. errors in appointment scheduling
 - 3. other administrative error
- ☐ **No error**
 - 1. adverse outcome, no error
 - 2. unhappy patient, no adverse outcome, no error
 - 3. no error, patient choice

Please fold this form in half and staple it, or place in an envelope with relevant materials, and deliver to any of the QI concern boxes in workrooms.

Beyond Nursing Quality Measurement: The Nation's First Regional Nursing Virtual Dashboard

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Abstract

This paper describes the data reporting infrastructure of the California Nursing Outcomes Coalition (CalNOC), including the system's capacity to provide member hospitals with seamless, interactive access to sophisticated reports in a secure environment. By leveraging the data repository to create both standardized and customized reporting capacity, CalNOC significantly improves the responsiveness and strategic value of the data to members, who create query-driven customized reports generated directly from the dataset. CalNOC measures and reporting tools include 7 of the 15 National Quality Forum-endorsed nursing-sensitive measures for inpatient care, as well as pressure ulcer prevention measures from the Institute for Healthcare Improvement's 5 Million Lives campaign. CalNOC is well positioned to add other tools and measures as appropriate. The resulting capacity for a virtual dashboard, the first in the nursing quality measurement arena, is unique in the field and a model for further study and emulation.

Introduction

Executive dashboards are transforming health care clinical services and management as leaders monitor organizational performance and drill down and diagnose problem areas to establish priorities and design interventions for change.^{1, 2, 3, 4, 5} Dashboards differ from report cards in that dashboards provide data on structure, process, and outcome variables, whereas report cards typically provide final reports on outcomes for external constituents.⁶

Executive dashboards are generally characterized as tools that enable a leadership team to briefly visualize strategic metrics to guide decisionmaking grounded in actionable information. Closely tied to effective strategic benchmarking, dashboards provide clinical leaders with continuous information that is timely and focused on both internal performance and marketplace comparisons that enable leaders to put their internal data in comparative perspective.⁷

Recent public reporting initiatives and the pay-for-performance demonstration project funded by the Centers for Medicare & Medicaid Services (CMS) represent the report-card strategy in which hospital performance is judged by external constituents incorporating incentives for performance improvement. However, emerging efforts that compare performance increase the demand for and imperatives related to the use of performance dashboards.⁸

In order to review and improve performance on public report cards, hospitals construct internal dashboards to review performance and identify areas in need of change. Benchmarking—the perpetual search for evidence-driven practice improvements in the quest for exceptional competitive performance with other similar hospitals in a confidential context—is an important element in this process.^{6, 7, 9}

The California Nursing Outcomes Coalition (CalNOC), the Nation’s largest regional nursing quality measurement network, is a collaborative effort of the American Nursing Association-California (ANA/C), the Association of California Nurse Leaders (ACNL), and the CalNOC Steering Committee. Its mission is to advance improvements in patient care by:

- Building and sustaining a valid and reliable statewide outcomes database.
- Conducting research to advance evidence-based interventions to achieve quality.
- Serving as a vendor of data on behalf of member hospitals and researchers.
- Synthesizing and disseminating data to shape public policy, practice, and education.

The CalNOC project has been described in detail elsewhere.¹⁰ CalNOC membership is voluntary and open to all acute care hospitals in the State of California, as well as to selected hospital groups nationwide. Currently, over 180 of California’s 366 acute care hospitals participate in CalNOC—in addition to hospitals from Nevada, Arizona, Oregon, and Hawaii—resulting in a convenience sample of hospitals with rolling site accrual.

CalNOC’s unit-level nursing quality indicators are collected quarterly from adult and pediatric critical care, step-down, and medical and/or surgical units, as well as from post-acute rehabilitation and skilled nursing units. Table 1 provides a comprehensive list of nursing quality indicators organized into categories of measures related to nurse staffing; RN education level, certification, and years of experience; patient falls; pressure ulcer prevalence; restraint prevalence; central line-associated blood stream infections; and medication administration accuracy.

This paper describes the data-reporting infrastructure of the CalNOC system, examining its capacity to provide member hospitals with seamless, interactive access to CalNOC data in a secure environment that authorizes users and controls access privileges. By leveraging the data repository to create both standardized and customized reporting capacity, the CalNOC system significantly improves the responsiveness and strategic value of the data to members, who are able to generate query-driven customized reports directly from the dataset.

The resulting capacity for a virtual dashboard is unique in the field, providing opportunities for users to examine associations between staffing and outcome variables and to explore and analyze factors associated with performance variation. CalNOC hospitals develop their own facility dashboards, combining reports from the Web site’s virtual dashboard with those from other data sources for a combined tool to display operational, quality, and satisfaction indicators on a single document.¹

Table 1. CalNOC variables for the virtual dashboard

Staffing, skill mix, and workload measures	
Staffing hours	• Total hours/patient day. • RN hours/patient day. • Licensed hours/patient day.
Ratios	• Number of patients/RN. • Number of patients/licensed staff.
Skill mix	• Percent RN hours of care. • Percent LVN hours of care. • Percent other hours of care. • Percent contract hours of care.
Additional staffing and workload measures	• Sitter hours as percent of total care hours (not including sitter hours). • Patient (bed) turnover as a percent of total patient days. • RN voluntary turnover as a percent of total RN employees. • LVN/aide voluntary turnover as a percent of total LVN/aide employees. • Total voluntary turnover as a percent of total employees.
RN education level	• Percent of RNs with BSN degree or higher. • Percent of RNs with national certification.
Patient outcome variables	
Patient falls and injury falls	• Patient falls/1,000 patient days. • Injury falls/1,000 patient days.
Fall prevention process variables	• Percent patients who fell assessed at risk for falling. • Percent patients with fall prevention protocol in place at time of fall.
Pressure ulcer prevalence variables	• Percent of patients with any ulcers. • Percent of patients with stage II+ ulcers. • Percent of patients with suspected deep tissue injury.

Table 1. CalNOC variables for the virtual dashboard (*continued*)

Hospital-acquired pressure ulcer variables

- Percent of patients with hospital-acquired pressure ulcers (all stages).
- Percent of patients with hospital-acquired pressure ulcers stage II+ (1998-2007 definition).
- Percent of patients with hospital-acquired pressure ulcers stage II+ (2007 definition).
- Percent of patients with hospital-acquired pressure ulcers stage III+ (includes unable to stage).
- Percent of patients with hospital-acquired pressure ulcers stages III & IV only.
- Percent of patients with hospital-acquired suspected deep tissue injury.

Pressure ulcer prevention process variables

- Percent of patients with ulcer risk assessment documented within 24 hours of admission.
- Percent of patients with ulcer skin assessment documented within 24 hours of admission.
- Percent of assessed patients identified “at risk” for ulcers at admission.
- Percent of assessed patients currently identified “at risk” for ulcers (time of survey).
- Percent of currently “at risk” patients with risk reassessment on day before survey.
- Percent of currently “at risk” patients with skin reassessment on day before survey.
- Percent of “at risk” patients with prevention protocol implemented at time of survey.

Restraint and sitter variables

- Percent of patients with any restraints.
- Percent of patients in restraint (limb +/- or vest only).
- Percent of patients with sitter.

Catheter-associated blood stream infections – PICC lines

- Catheter-associated blood stream infections – PICC lines/1,000 line days.
-

Hospitals use CalNOC’s Web-based reports throughout the performance improvement process, for a variety of purposes, including:

- Targeting quality improvement initiatives.
- Evaluating current performance in comparison with similar institutions.
- Setting goals for improvement.
- Drilling down to identify the root cause of problems.
- Monitoring the progress of improvement initiatives.¹⁰

The CalNOC virtual dashboard, as described in this paper, is integral to the performance, measurement, and improvement process for member hospitals.

CalNOC Reporting Infrastructure

Since its inception in 1996, CalNOC has considered the quality and value of its reporting to member hospitals to be a strategic priority. Evolving from hardcopy reports delivered by regular mail to electronic benchmarking reports e-mailed to sites, the vision for a virtual, interactive dashboard evolved concurrent with the increasingly sophisticated demand for these data and Web-driven technologies.

Transforming vision into reality was made possible by funding from the Gordon and Betty Moore Foundation in 2004, which enabled CalNOC to upgrade its data operations to create new capacity to capture, analyze, and store data. The core goal was for CalNOC reports to hospitals to be delivered via an integrated Web site and data analysis application (the “CalNOC system”), a comprehensive, secure, multi-tier, Web-based application developed using Microsoft’s .Net (“dot-net”) architecture. The resulting CalNOC system includes two major sub-systems:

- A comprehensive membership management application, where demographic information is maintained for all member facilities and their assigned employees who are associated with CalNOC.
- A data analysis application, where the actual CalNOC data are stored, analyzed, and reported to the CalNOC membership.

Figure 1 illustrates the CalNOC system architecture. The entire infrastructure has been developed over the course of several years, including the acquisition of hardware, software licensing, and application development (system analysis, design, development, testing, and deployment) efforts. The primary features and functionality of the Web site are available only to CalNOC member hospitals and their representatives, who log into their accounts on the Web site prior to accessing the controlled content.

CalNOC Data Analysis Subsystem

Data Infrastructure Overview

The entire data infrastructure for the CalNOC system—including the database, the analytical software, and the Web site itself—is hosted at a centralized location. The system employs a secure Web-hosting facility on a high-speed dedicated server with processing power and storage capacity sufficient for both the database and the Web site. Based on the future growth of the database and the level of use of the Web site, the two roles can be separated into different servers at the same location as needed. This infrastructure consolidation provides a direct and interactive interface into the database via the CalNOC Web site. It enhances the responsiveness and level of service to member hospitals, ensuring that CalNOC has a tightly integrated and scalable computing platform that can grow as needed.

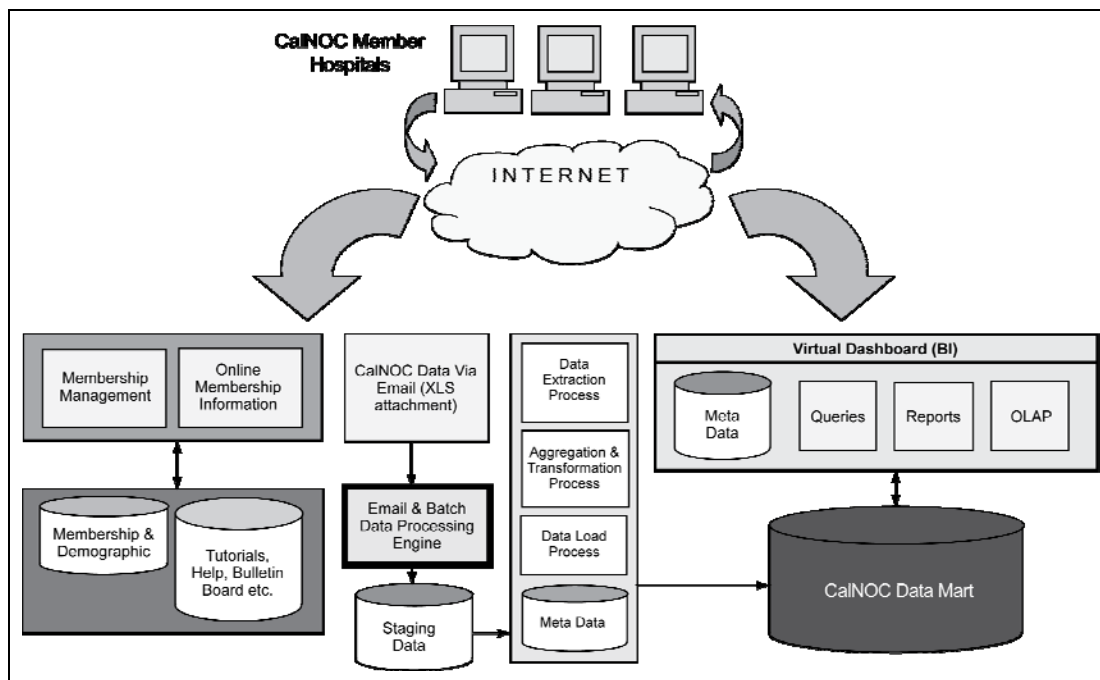


Figure 1. CalNOC system architecture.

The CalNOC system and its underlying data and program code are accessible to CalNOC researchers and the system development group (computer programmers and systems analysts) via a secure Virtual Private Network (VPN) link. Individual access privileges are managed in a manner typical of large corporate LAN environments, using role-based security and a hierarchy of trust relationship. Authorized users access the Web site and the underlying database via a secure link (HTTPS – or HTTP with a secure socket layer) and a user ID/login subsystem that manages user authentication and controls access privileges based on assigned roles. The server is connected to the Internet via a T1 link (1.5 Mbps) to ensure a quick response time for all users and can be upgraded further as required.

The CalNOC system has been developed using industry-standard technologies, including: Microsoft Windows 2003 servers, SQL Server 2000 databases, Microsoft Office productivity suite, and the .Net (“dot-net”) software architecture. CalNOC’s vision of providing member hospitals with seamless and direct interactive access to CalNOC data is driven by the installation of an online analytical processing (OLAP) layer and a dimensional data mart on top of the core database. This approach supports ad hoc queries against the data in a controlled and user-friendly manner, where each user has access to only certain data based on their access privileges.

This function has been implemented with the use of technologies, such as Active Directory for security and Cognos PowerPlay and ReportNet for the analytical services. The Cognos reporting coverage allows standardization of all reports using one-product architecture. All reports are authored in the same environment using the Cognos capacity to combine data from multiple sources. Hospitals can then access the reports authored by the programming team using Cognos, specifying the required data elements, time periods, facility, units, etc. The data analysis subsystem has the following major features:

- **Data input.** Member facilities submit data (e-mailed to CalNOC’s data “in box”) using Excel® spreadsheets with form-driven as well as column-driven cut-and-paste data entry.
- **Data quality validation.** Some basic validation logic (e.g., facility code number, patient age, etc.) is performed on the user side during data entry. Other validations (e.g., facility, unit, unit type matching, etc.) based on the database, are handled at the CalNOC data processing center using the data load subsystem, which processes e-mails with data attachments. If errors are found, the data coordinator contacts the individual facility for correction and/or clarification.
- **Access to raw data.** Authorized users on the CalNOC analytical team have the option to see all data online and generate reports from the database.
- **Customized query-driven reports.** Member hospitals use the Web site to generate customized reports using processed data that are summarized at the unit, unit type, and facility level.

Generating CalNOC Reports

The data analysis subsection of the CalNOC Web site is organized as a “portal,” where all of the reports available are arranged hierarchically in function-specific folders. At the highest level, the folders are related to the type (level) of care provided by a facility (or unit within a facility). Within each of the three “care types” below, data are aggregated by level of care:

- **Adult acute care:**
 - o Medical, surgical, medical/surgical units.
 - o Step down units.
 - o Critical care units.
- **Pediatric acute care:**
 - o Medical, surgical, medical/surgical units.
 - o Step down units.
 - o Critical care units.
 - o Neonatal intensive care units.
- **Post-acute care:**
 - o Hospital-based distinct part skilled nursing units.
 - o Acute rehabilitation unit.

Within each level of care are two categories of reports (folders): one, reports available to all member hospitals and two, reports available to data management staff only. Each user is only able to see and access the specific types of reports that are associated with their access privileges. Furthermore, individuals at each facility can only access reports specific to their own facility and appropriate statistics that are CalNOC-wide (e.g., totals, averages, percentiles). The only exception is the case of hospital “groups,” such as Kaiser-Permanente, Catholic Healthcare West (CHW), and other health care systems, where the group-level administrator can access data and reports pertaining to all of their facilities.

CalNOC's "Virtual Dashboard"

Reports are driven by a "virtual dashboard" concept, in which users are able to create and customize their own reports by specifying the parameters of interest. The CalNOC virtual dashboard provides member hospitals with the capacity to compare their own performance visually and statistically with those of "like" hospitals. Reports are stratified by hospital average daily census or aggregated for all CalNOC hospitals, as selected by the user.

Available reports include trending as well as quartile and percentile reports to aid in setting performance targets and benchmarks. Users are able to see pregenerated reports online for statistics that are of interest to their own facility. Authorized users can create reports in different formats (e.g., pdf and Excel[®]), which is facilitated through the Cognos ReportNet platform. The Web site provides reports for facilities as a whole, by unit type (i.e., critical care, step-down, or medical/surgical units), and for individual units.

The CalNOC dashboard provides three types of query-driven customized reports for the variables listed in Table 1, described in detail and illustrated below:

- **Common (comparison) reports.** A visual presentation comparing hospital performance by selected group (identified by facility code number only).
- **Summary statistics.** Summary reports of all CalNOC indicators for the CalNOC total, average daily census categories, and type of unit in an easy-to-reference format.
- **Facility-specific reports.** Reports for individual hospital and unit performance on the same variables.
 - o Benchmarking reports.
 - o Trend graphs.
 - o Staffing effectiveness graphs.

Getting Started

Each CalNOC member hospital has a designated primary site coordinator who is responsible for data collection, submission, and reporting. We recommend that primary site coordinators meet with patient care leadership to establish their institution's goals and priorities for improvement, internal dissemination plan for CalNOC data, and preference for types of data presentation. Generating sample reports as examples for leadership to review is a good way to get the reporting process started. Each hospital will be asking: "What reports do we need?" or "What do we want to do with the data?" The following sections detail each of the menu-driven reports and the role of each report in enhancing the usefulness of CalNOC data.

Generating and Using CalNOC Reports

Comparison graphs—a picture is worth a thousand words. Comparison graphs provide a visual representation of comparative hospital performance. Figure 2 shows a sample comparison graph for "Falls per 1,000 Patient-Days" for all medical/surgical units in hospitals with an average daily census "under 100" patients. The site coordinator running the report made the following selections:

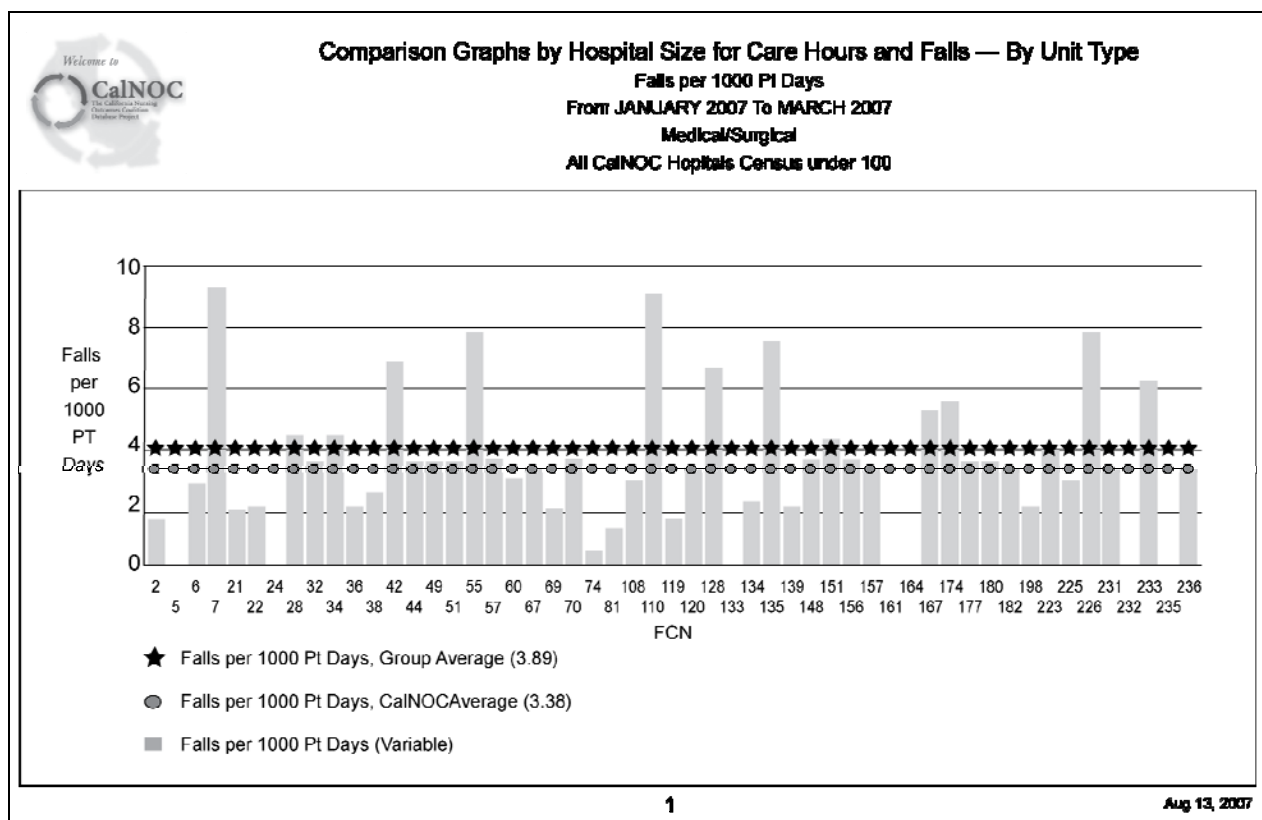


Figure 2. Falls/1,000 patient days; medical/surgical units in hospitals with ADC <100.
ADC = average daily census

- Variable to graph (e.g., falls/1,000 Patient-Days).
- Comparison group (all hospitals with an average daily census under 100 patients).
- Type of unit (medical/surgical units).
- Time period of report (Q1 2007, January-March 2007).

Similar comparison reports are available showing performance of all CalNOC facilities. Graphs can give hospitals a visual representation of the variation among hospitals, a report that lists the actual performance for each hospital by blinded facility code number, the mean and standard deviation for the group of hospitals included in the report, and the overall CalNOC mean for the same variable. The graph shown in Figure 2 illustrates the wide range of hospital performance. Each hospital can identify their own facility code number for their performance.

Summary statistics – a quick reference for aggregated data. Reports that present summary statistics provide member hospitals with a basic reference that includes aggregated statistics for all CalNOC hospitals on all variables. These reports are available by hospital size and unit type, as well as for total facilities. Figure 3 shows summary statistics for nurse staffing data by unit type and hospital average daily census. CalNOC’s online tutorials provide an overview of these statistics and information on how to interpret the data to answer the following questions:

How did the “average” CalNOC hospital perform? The average or mean (calculated by adding the numbers and dividing the sum by the number of items in the list) represents an intermediate value, but the mean can be skewed (“pulled” or distorted) by extreme values in the data set. The median is the middle value, when members in the data set are ordered from smallest to largest (50 percent above the median and 50 percent below). If there are outliers, the median is a better reflection of the middle of the data than the mean.¹¹

How much variation is there between hospitals? The standard deviation is a calculated measure of the variability (dispersion or spread) of any set of numerical values about their arithmetic mean. Some reports also provide minimum and maximum values to establish the data range.

What statistics should we use to set performance targets? Quartiles provide more sophisticated benchmarking than means and medians. Quartiles divide the data into four equal groups and are listed as three values: 25th percentile or lower quartile, 50th percentile or median, and 75th percentile or upper quartile. All three values are framed in the box in the middle of Figure 3. The outlined section of the report shows that in January-March 2007, 25 percent of critical care units in hospitals with an average daily census under 100 had “total hours per patient day” of <14.22, and 25 percent had total hours per patient day >17.67. The box also outlines the same information for “RN hours per patient day.” (Each record comprises data for one hospital for 1 month. Thus, if the report covers 3 months, as in the example below, each hospital’s performance is represented by three records, one for each month in the report.)

CalNOC Summary Statistics by Hospital Size and Unit Type by Quarter with Quartiles

Quarter: Jan - Mar 2007 through Jan - Mar 2007

Quarter: JAN - MAR 2007

ADC CATEGORY*	TYPE OF UNIT	VARIABLE	No. of Hospitals	No. of Records**	Mean	Standard Deviation	Median	Lower Quartile	Upper Quartile
100 or less	CCU	Percent RN Hrs of Care	43	128	96.66	7.08	99.88	96.77	100.00
		Percent LVN Hrs of Care	43	128	0.77	2.72	0.00	0.00	0.00
		Percent Other Hrs of Care	43	128	2.57	5.33	0.00	0.00	1.60
		Percent Contract Hrs of Care	43	128	11.43	13.84	5.84	0.49	16.64
		Total Hrs per Pt Day	43	128	16.25	3.35	15.76	14.22	17.67
		RN Hrs per Pt Day	43	128	15.78	3.69	15.54	13.60	17.37
		Hours of RN per Pt Day	43	128	1.61	0.43	1.54	1.30	1.76
		Licensed Hrs per Pt Day	43	128	15.89	3.58	15.58	13.84	17.47
		No of Pts per Licensed Staff	43	128	1.59	0.37	1.54	1.37	1.73
		Sitter Hrs as Percent of Total Care Hours	31	92	0.69	2.17	0.00	0.00	0.00
		Pt(Bed) Turnover as Pct of Total Pt Days	30	89	46.75	27.17	38.26	26.75	61.54
		RN Voluntary Turnover as Pct of Tot RN Employees	23	68	0.71	1.76	0.00	0.00	0.00
		LVN/Aide Voluntary Turnover as Pct of Tot LVN/Aide Employees	5	14	0.00	0.00	0.00	0.00	0.00
		Tot Voluntary Turnover as Pct of Tot Employees	21	63	0.63	1.29	0.00	0.00	0.00
		Falls per 1000 Pt Days	46	138	1.74	5.19	0.00	0.00	0.00

*ADC = Average Daily Census

**Each record is data for one hospital for one month

Note: Median and quartile statistics divide the total number of records into 4 groups: 25% of all records fall below the lower quartile; 25% fall between the lower quartile and the median; 25% fall between the median and the upper quartile; and 25% fall above the upper quartile. Each record is data for one hospital for one month. Thus if the report covers 6 months, each hospital has 6 records, one for each month in the report.

1

Sep 5, 2007

Figure 3. Summary statistics for staffing by hospital size and unit type.

Percentiles provide an even more accurate way to interpret performance and the way the data are spread or vary across sites. A percentile is a value on a scale of 100 that indicates the percentage (percent) of a distribution that is equal to or below it. A score at the 10th percentile, for example, means that 10 percent of the scores are equal to or below that score. CalNOC's newest reports now include the 10th and 90th percentiles as well as the lower and upper quartiles (i.e., 25th and 75th percentiles). Quartile and percentile data in CalNOC reports are displayed as actual values.

Drilling Down to Hospital and Unit Performance: Hospital-Specific Reports

Facility-level benchmarking reports show summary data for the total facility and by unit type (i.e., critical care, step-down, and medical/surgical units). Figure 4 shows a facility-level benchmarking report for prevalence studies. The box outlines results for “percent of patients with hospital-acquired pressure ulcers stage II and above. One line in a CalNOC benchmarking report provides the hospital’s own overall and unit-type data along with CalNOC statistics, which allows performance targets to be set using this report alone. In addition to the facility’s own performance, the report provides information on comparative performance for both “like” hospitals and all CalNOC hospitals. The statistics in this report, for example, show the facility mean for all units to be 3.74, better (i.e., fewer pressure ulcers) than the “like” hospital mean of 4.49, and slightly better than the CalNOC mean of 3.92. However, the CalNOC lower quartile is

CalNOC Benchmarking Report - Prevalence Most Recent Prevalence Studies for Year 2006 - 2007 Hospital - 3 June - 2007

Date - 09/15/2007

	Unit Type	Avg. Daily Census Group	No of FCN with Data / Total FCN	Facility Mean by Unit Type	Like Hospital Mean by Unit Type	CalNOC Mean by Unit Type	CalNOC Lower Quartile by Unit Type	CalNOC Upper Quartile by Unit Type	Facility Mean All Units	Like Hospital Mean All Units	CalNOC Mean All Units	CalNOC Lower Quartile All Units	CalNOC Upper Quartile All Units
A. % of Pt. with any Ulcers	CCU	300+	19/20	29.75	20.14	21.52	11.11	36.94	13.61	12.55	13.08	6.57	16.86
	Med/Surg			11.27	11.14	11.69	6.66	15.31					
	Step Down			8.66	11.26	12.81	6.67	16.67					
B. % of Pt. with Stage II + Ulcers	CCU	300+	19/20	18.75	15.42	16.41	6.78	21.88	9.69	8.90	8.98	5.86	11.21
	Med/Surg			8.58	7.39	8.03	4.35	10.75					
	Step Down			7.69	6.90	8.73	3.70	12.50					
C. % of Pt. with Hospital Acq. Press. Ulcers (All Stages)	CCU	300+	19/20	12.50	13.42	13.30	0.00	21.83	6.18	7.27	7.02	3.90	9.22
	Med/Surg			8.38	6.13	6.74	2.13	7.94					
	Step Down			4.72	6.67	7.81	2.36	11.11					
D. % of Pt. with Hospital Acq. Press. Ulcers Stage II+	CCU	300+	19/20	7.39	6.51	6.62	0.00	13.86	3.74	4.49	3.92	1.89	5.22
	Med/Surg			3.19	3.41	3.08	0.72	4.75					
	Step Down			3.15	4.07	4.34	0.00	7.14					
E. % of Pt. with Hospital	CCU	300+	19/20	1.25	2.98	2.30	0.00	3.79	1.36	1.33	1.16	0.00	1.67
	Med/Surg												
	Step Down												

Note: Median and quartile statistics divide the total number of records into 4 groups: 25% of all records fall below the lower quartile; 25% fall between the lower quartile and the median; 25% fall between the median and the upper quartile; and 25% fall above the upper quartile. Each record is data for one hospital for one month. Thus if the report covers 6 months, each hospital has 6 records, one for each month in the report.

1

Figure 4. Facility-level benchmarking report for prevalence studies.

1.69, indicating less than 1.69 percent of “patients with hospital acquired pressure ulcers stage II+” in the best performing 25 percent of facilities. Thus, a hospital wishing to be in the best performing quarter for all CalNOC hospitals would select 1.69 as a performance target. Alternatively, summary statistics reports provide quartiles by hospital size, allowing hospitals to set more specific targets based on their own average daily census category, rather than on the CalNOC total.

Quartiles or percentiles can be used as performance goals, as in the above example, or, if the hospital’s performance is already at the desired level, as performance thresholds. If the hospital’s performance had already been in the lowest (best) 25 percent of CalNOC hospitals, the lower quartile could be used as a performance threshold, with a drill-down analysis to determine appropriate improvement actions should performance rise to the 25th percentile (lower quartile) or above. Alternatively, the hospital could reset the performance target to the best 10 percent of CalNOC hospitals, a statistic recently added to new CalNOC reports. As more organizations better understand their performance and drill down on their own data to identify opportunities to improve, group performance might improve. As the group improves, the quartiles would move down. As the bar is raised, a site’s relative performance could deteriorate compared to the group, even though their actual performance had been stable, encouraging setting of new improvement goals.

Unit-level benchmarking reports allow hospitals and unit managers to examine unit performance in detail, including both pressure ulcer prevention process variables (e.g., “percent of patients with ulcer risk documented within 24 hours of admission”) and patient outcomes (e.g., “percent of patients with hospital-acquired pressure ulcers stage II and above”). The first box in Figure 5 shows the following unit-level information for each variable:

- Unit mean.
- Unit numerator (the number of patients with incidence).
- Unit denominator (the number of patients included in calculation of the variable).

These statistics track the actual number of patients with ulcers in addition to the percent. Actual numbers may be more meaningful to unit staff than calculated rates when tracking “never events” by days between events or occurrences. The second box encloses the following statistics, useful for comparisons and goal setting:

- Facility mean by unit type (overall facility data for this unit type).
- “Like” hospital mean by unit type.
- CalNOC mean by unit type.

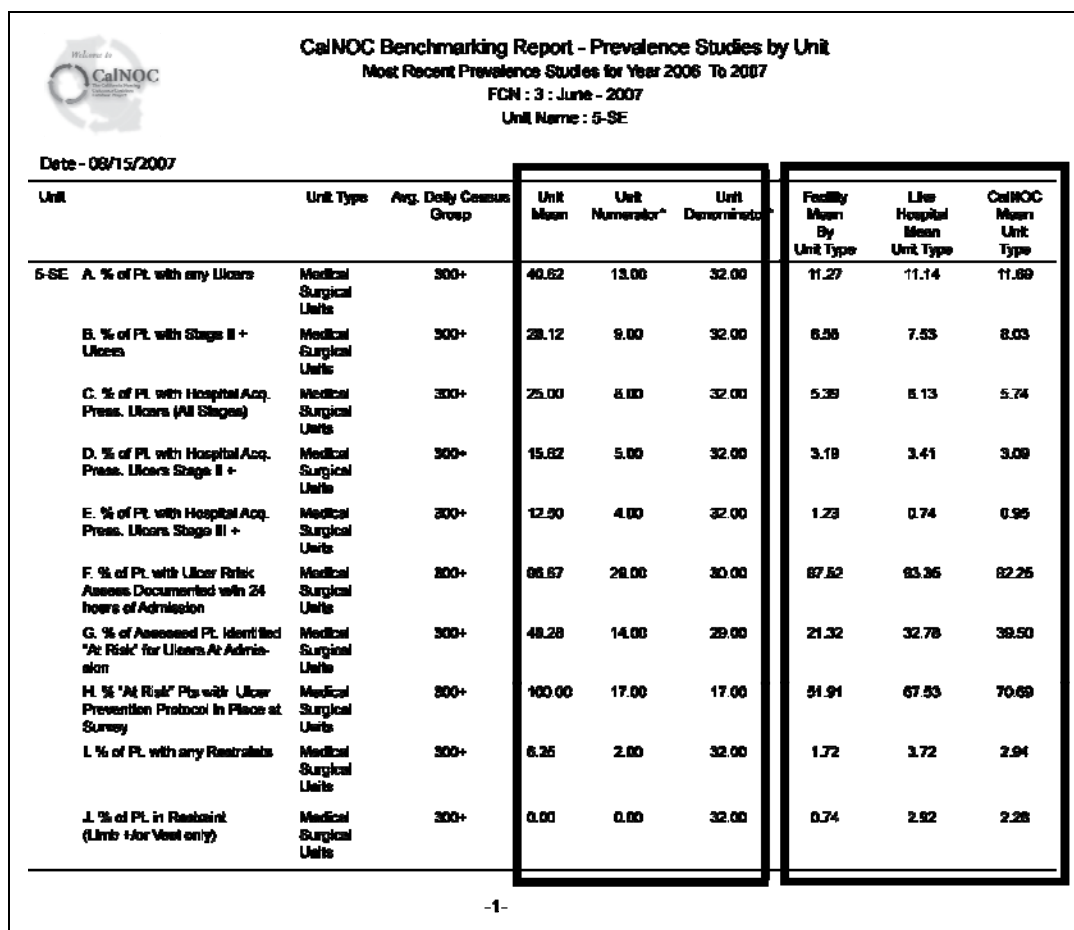


Figure 5. Unit-level benchmarking report for prevalence studies.

Taken together, the statistics on this unit-level report provide a valuable drill-down into both patient outcomes and the pressure ulcer prevention process.

Trend reports, each including both a graph and a statistical report, can be generated at the hospital level, unit type level, or for an individual unit. Figure 6 provides an example of a hospital trend report for “falls per 1,000 patient days” for the most recent 15 months for one hospital. Examination of the data shows a decrease in recent months (bars) followed by a spike in March 2007. Both the facility average and CalNOC average for the selected time period are shown by lines across the graph. The report includes the graph shown, followed by a table listing the actual numeric fall rates for each month. Using trend charts such as the one in Figure 6 can help hospitals understand their ongoing performance over time. Watching the slope of the bars can show whether performance is improving, declining, or stable compared to the same hospital each month or quarter.

Staffing effectiveness reports, including both a graph and a numeric report, allow CalNOC hospitals to trend two CalNOC indicators (e.g., staffing and patient outcomes) on the same graph for any time period desired. The reports can be generated either for the total facility, by unit type (i.e., medical/surgical, step-down, or critical care), or for individual units.

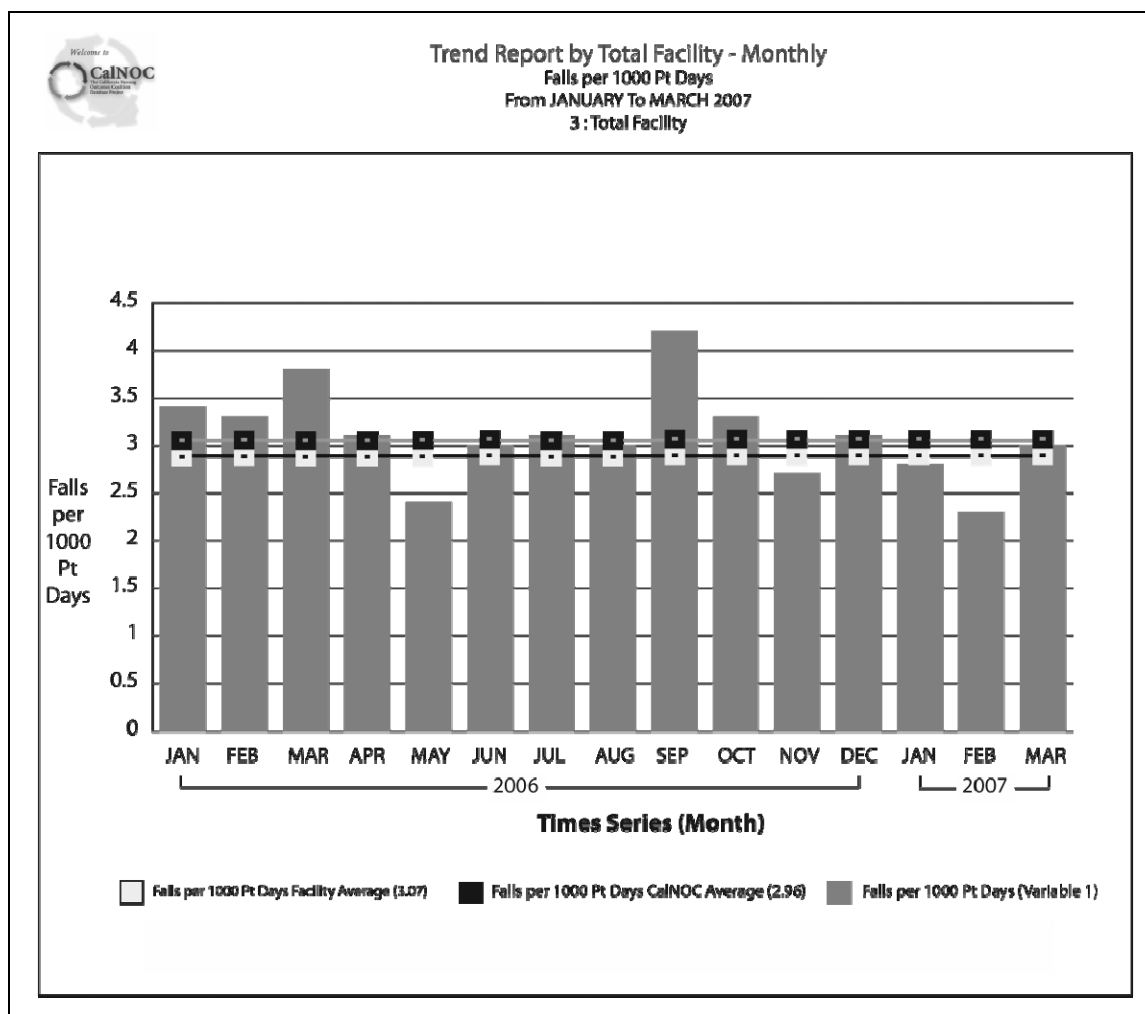


Figure 6. Hospital trend report for falls per 1,000 patient days.

The slope of the data shows if performance is improving, declining, or stable compared to past performance on the graph.

Figure 7 shows a sample staffing effectiveness graph examining the potential relationship between total hours/patient day and falls/1,000 patient days on a single unit. The report shows monthly performance on both variables for both the unit and also the total CalNOC average. CalNOC has provided “staffing effectiveness reports” to help hospitals meet The Joint Commission’s Human Resources Standard.¹²

Additional Tools Available to Download

In addition to the query-driven reports detailed above, the CalNOC Web site makes additional tools available for hospitals to download and use to analyze and display their data and drill down into potential relationships among staffing and outcome variables. Figure 8 shows an example of a quartile analysis tool that allows hospitals to visualize their quartile status on multiple staffing variables in one graph. In the example shown, the hospital ranks in the 4th (highest) quartile for

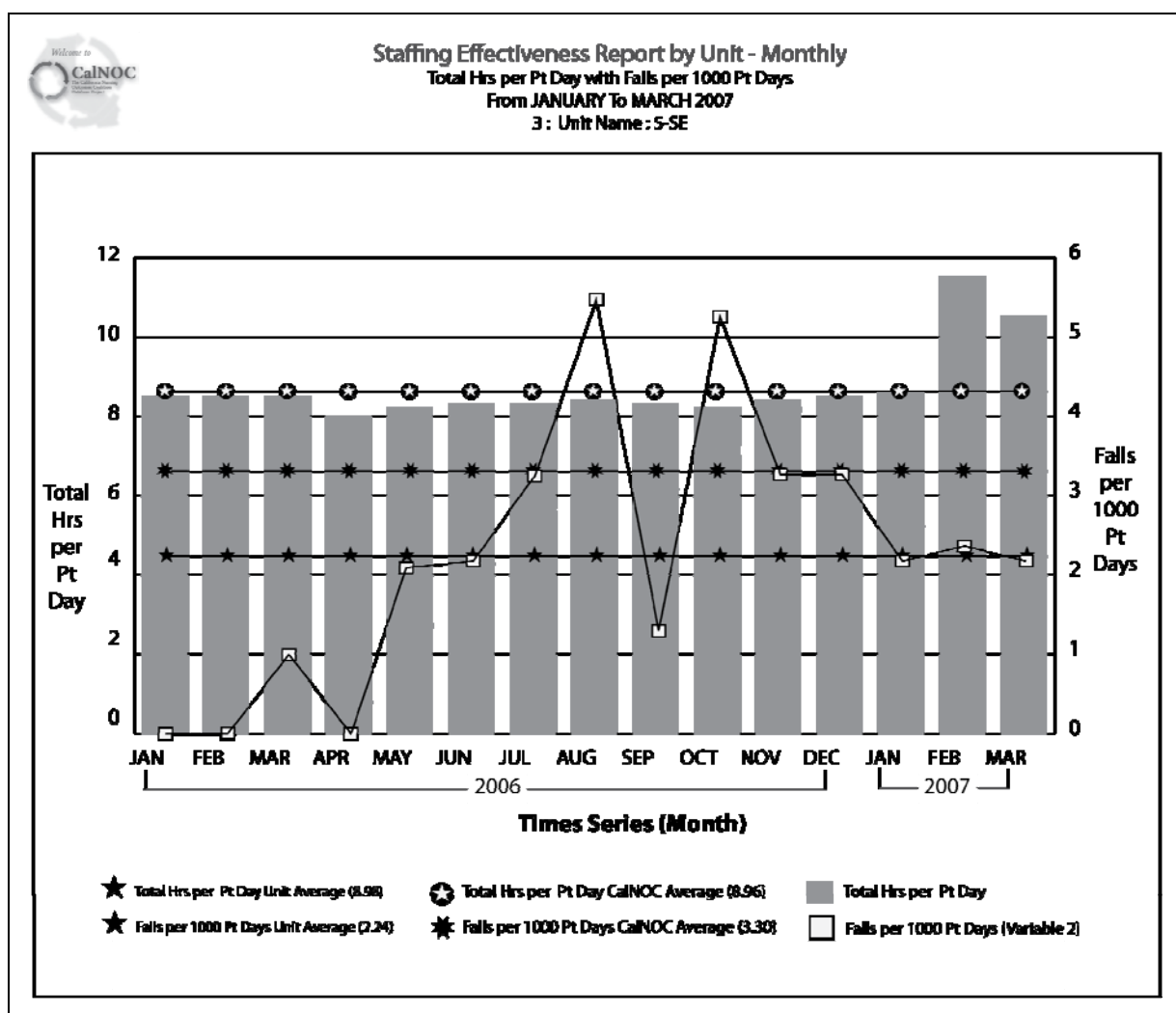


Figure 7. Unit-level staffing effectiveness report for total hours per patient day and falls for 1,000 patient days.

RN skill mix (“percent RN hours of care”), but it also ranks in the highest quartiles for staff turnover and “percent contract hours of care.” Similar tools are available to view CalNOC process and outcome measures. Using these together can help hospitals link their staffing performance with both process and outcomes and identify potential areas for improvement.

Responding to a Changing Health Care Environment

In 2003, the National Quality Forum (NQF) endorsed 15 consensus-based, nursing-sensitive measures for inpatient care.¹³ The Joint Commission completed their Technical Implementation Guide for the NQF’s 15 measures in 2005 and is currently conducting a 2-year project to test the use of the NQF 15 as a measure set.¹⁴ CalNOC’s pressure ulcer and restraint prevalence methodology and measurement definitions were accepted by the NQF as two of the 15 measures.

CalNOC data collection and virtual dashboard also include an additional five of the measures for a total of seven of the 15, and CalNOC is well positioned to add others as appropriate. In addition, CalNOC serves as a data repository for participating hospitals for new 2007

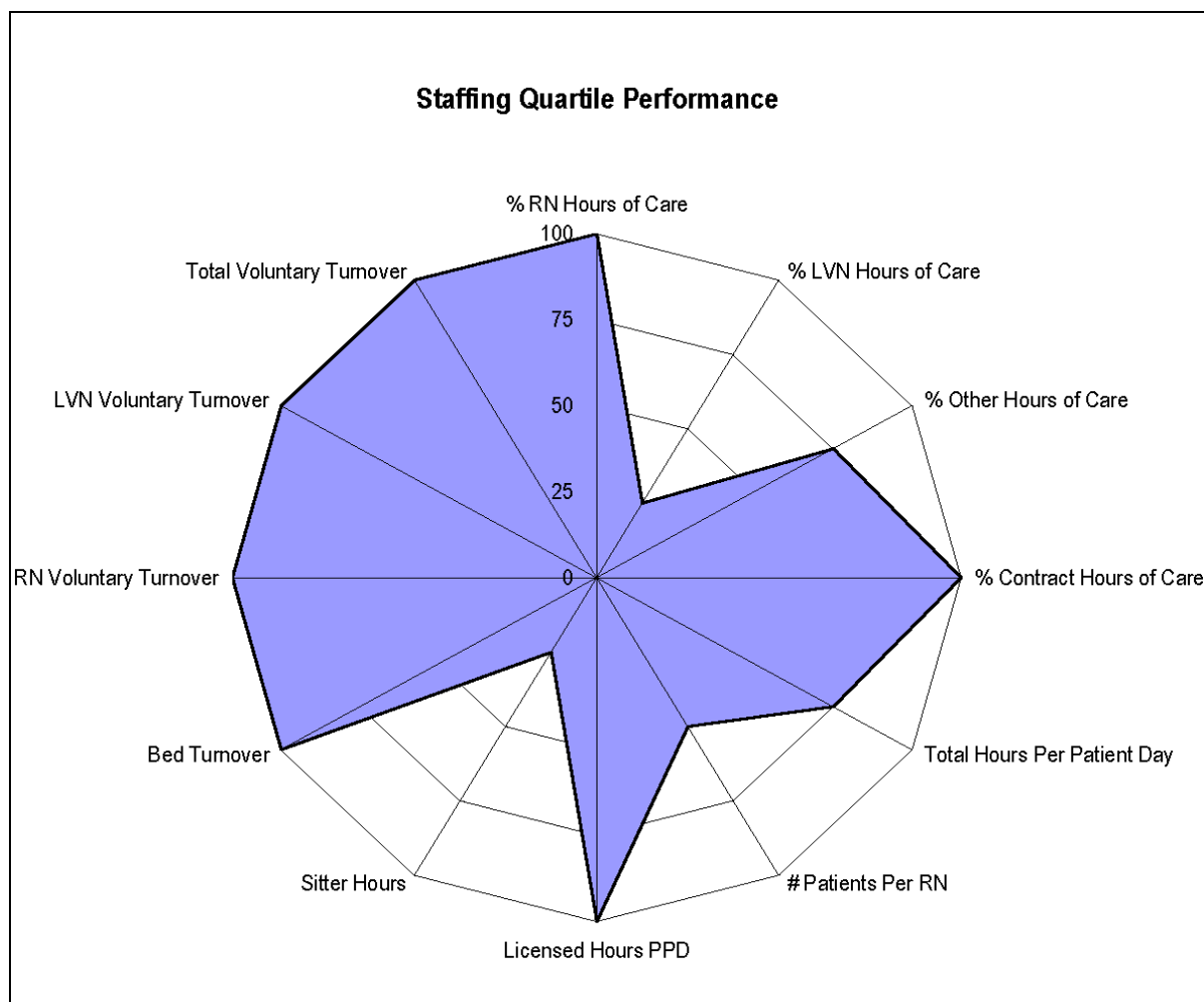


Figure 8. Staffing quartile performance tool.

CMS-required conditions of participation for hospital-acquired pressure ulcers and falls, as well as California’s newly mandated reporting of 27 “never events” (California Senate Bill 1301). To meet these data needs, CalNOC’s reports provide hospitals with the number and percent of patients with hospital-acquired pressure ulcers stages III and IV, as well as fall and injury fall incidence and rates.

In addition to the “report card” measures discussed above, CalNOC also provides detailed data on fall and pressure ulcer prevention processes (Table 1), allowing hospitals to drill down and identify process changes to improve their overall performance. CalNOC’s pressure ulcer measurement guidelines were revised in 2007 to match the National Pressure Ulcer Advisory Panel’s revised staging definitions. CalNOC’s pressure ulcer prevention process variables were developed to match the Institute for Healthcare Improvement’s (IHI) 2006 “Protecting 5 Million Lives from Harm” pressure ulcer prevention initiative. Reports allow participating hospitals to track their progress in implementing prevention strategies detailed in the IHI “Prevent Pressure Ulcers How-to Guide.”¹⁵

Conclusion

This paper describes how CalNOC has leveraged its data repository to create reporting capacity that significantly improves the responsiveness and strategic value of the database to members. CalNOC's virtual dashboard capacity is unique in enabling hospitals to examine their data in query-driven reports that meet their own individual performance needs. In addition to "report card" measures such as the NQF 15 described above, CalNOC's virtual dashboard provides data and analysis tools useful throughout the five steps of the performance measurement process, including: targeting quality improvement initiatives, evaluating current performance in comparison with similar institutions, setting goals for improvement, drilling down to identify the root cause of a problem, and monitoring the progress of improvement initiatives.¹⁰

CalNOC continues to expand its data collection and reporting capacity to meet the needs of the evolving health care regulatory and reporting environment, creating a virtual dashboard that is unique in the field and a model for other regions developing similar initiatives.

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References

1. Donaldson N, Brown DS, Aydin CE, et al. Leveraging nurse-related dashboard benchmarks to expedite performance improvement and document excellence. *J Nurs Adm* 2005; 35: 163-72.
2. Rosow E, Adam J, Coulombe K, et al. Virtual instrumentation and real-time executive dashboards. Solutions for health care systems. *Nurs Adm Q* 2003; 27: 58-76.
3. The Advisory Board. Enfranchising nursing in cost reform: Best practices for migrating to a new standard. Washington, DC: The Advisory Board; 2000.
4. The Advisory Board. First do no harm: Executive briefing on medication safety. Washington, DC: Clinical Initiatives Center; 2000.
5. Schaffner JW, Alleman S, Ludwig-Beymer P, et al. Developing a patient care model for an integrated delivery system. *J Nurs Adm* 1999; 29: 43-50.
6. Gregg AC. Performance management data systems for nursing service organizations *J Nurs Adm* 2002; 32: 71-78.
7. Watson GH. Strategic benchmarking. New York: John Wiley & Sons; 1993.
8. Lindenauer PK, Remus D, Roman S, et al. Public reporting and pay for performance in hospital quality improvement *N Engl J Med* 2007; 356: 486-96.

9. Scanlon DP, Darby C, Rolph E, Doty HE. Performance measures and quality improvement. *Health Serv Res* 2001; 36: 619-21.
10. Aydin CE, Burnes Bolton L, Donaldson N, et al. Creating and analyzing a statewide nursing quality measurement database. *J Nurs Sch* 2004; 36: 371-378.
11. Dixon WJ, Massey FJ. Introduction to statistical analysis (4th ed). New York: McGraw-Hill; 1983.
12. The Joint Commission. Environment of Care Standard EC.1.30. Standard: HR.1.30; 2001. Available at http://www.jointcommission.org/NR/rdonlyres/979B4315-F409-476B-810C22F0F0CB3BD5/0/hap_cah_sii_hr130.pdf. Accessed April 14, 2008.
13. Nursing performance measurement and reporting: a status report. National Quality Forum. July 2007. http://www.qualityforum.org/pdf/news/IB_july2007.pdf. Accessed January 12, 2008.
14. National Quality Forum (NQF) endorsed nursing-sensitive care performance measures. The Joint Commission; 2007. Available at: www.qualityforum.org/nursing/#endorsed. Accessed January 12, 2008.
15. Getting started kit: Prevent pressure ulcers how-to guide. Institute for Healthcare Improvement; 2006. <http://www.ihl.org/IHI/Programs/Campaign/Campaign.htm?TabId=2#PreventPressureUlcers>. Accessed January 12, 2008.

Using ICD-9-CM Codes in Hospital Claims Data to Detect Adverse Events in Patient Safety Surveillance

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Abstract

Background: Adverse events (AEs) are significant and common sources of harm to inpatients. International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes, assigned to virtually all inpatient discharges, could provide a readily available surveillance system capable of detecting a variety of AEs. **Objectives:** To determine the positive predictive value (PPV) of selected ICD-9-CM codes (flagged codes) in identifying inpatient AEs and AEs causing admission to the hospital. **Methods:** Samples were drawn from two distinct patient groups in calendar years 2001 and 2003: 7,070 inpatients from all acute care hospitals in Utah and 6,895 surgical inpatients from selected hospitals in Missouri. Structured chart review and abstraction identified all AEs and whether a flagged ICD-9-CM code represented an AE. AE codes were grouped into six categories to facilitate analysis: adverse drug events, surgical adverse events, misadventures, infections, device events, and other adverse events. **Results:** Among all inpatients, 4,416 of 11,619 flagged codes represented AEs (38 percent); 1,789 of the flagged codes were inpatient AEs (15 percent). Flagged code PPVs were higher for surgical inpatients, with 11,990 of 16,816 flagged codes representing AEs (74 percent), and 7,507 codes (46 percent) indicating inpatient AEs. There was wide variability among AE PPV categories, both for all inpatients (15 - 77 percent) and surgical inpatients (62 - 92 percent). **Conclusions:** Flagged AE codes were consistently more likely to indicate AEs in surgical inpatients than in all inpatient types. Given this, and the striking performance differences within and among AE code categories, ICD-9-CM codes are best suited to targeted AE surveillance.

Introduction

Adverse events (AEs) in the hospital setting carry with them significant patient morbidity and increased health care costs.^{1, 2, 3, 4} There is increasing interest in improved methods of AE surveillance as payers of medical care move towards systems that reward high quality and avoid paying for iatrogenic harm. The challenge that AEs, such as nosocomial infections^{5, 6} and adverse drug events,^{7, 8, 9} pose in the hospital setting has been well documented.

Currently available surveillance methods are not well suited to routine use in American health care organizations. Voluntary reporting detects only a small fraction of events.^{10, 11} Chart review can detect a large fraction of harm but is prohibitively expensive.¹⁰ Computerized alerts based on

clinical data have attracted attention but suffer from low accuracy and require sophisticated electronic health record systems available in a small minority of American hospitals.

Virtually all inpatient discharges are assigned International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes.¹² Alerts based on ICD-9-CM codes show promise because all hospital admissions are assigned these codes. ICD-9-CM includes codes that explicitly target some types of iatrogenic harm. The most frequently assigned ICD-9-CM codes are diagnosis codes, external cause of injury codes (E-codes), and procedure codes. In the case of an adverse drug event (ADE), a diagnosis code would be used to indicate the patient's general diagnosis (e.g., 693.0, dermatitis due to drugs and medicines taken internally), while the E-code would indicate the drug class thought responsible for these symptoms (e.g., E933.1, antineoplastic and immunosuppressive drugs causing adverse effects in therapeutic use).

Previous studies have examined the use of ICD-9-CM codes as a means of detecting various inpatient complications,^{13, 14, 15, 16} but the results have been mixed. However, these studies were restricted to specific patient populations (i.e., Medicare patients,^{13, 14, 15} and VA patients with one of three specific diagnoses¹⁶), and records reviewed in these studies were between 10 and 20 years old. AHRQ Patient Safety Indicators appear promising for selected diagnoses, but many have not been fully validated, and only one targets selected ADEs.¹⁷ Nonetheless, a recent study focusing on AEs related to medical devices showed that ICD-9-CM detection compared favorably with other detection systems.¹⁸

Our goal was to develop a comprehensive system of AE codes and then examine the performance of these codes against the reference standard of chart review. We previously reported on performance of ICD-9-CM codes in ADE detection among all inpatients using the same methodology.¹⁹ This manuscript examines all AE types over a longer time period.

Methods

ICD-9-CM Adverse Event Classification

The report "Adverse Events related to Medical Care Utah: 1995-1999" featured 569 codes thought most likely to represent AEs due to medical care.²⁰ Three mutually exclusive main categories were developed: adverse drug events, misadventures, and complications of medical or surgical procedures. ADEs (395 codes) included both poisonings (medication errors) and adverse effects of medications. Misadventures consisted of 65 codes representing events most likely to be medical errors. The remaining events were grouped into complications of medical or surgical procedures (109 codes).

Although these codes were thought to be those most clearly associated with health care-associated injury, examination of the ICD-9-CM code set and existing literature revealed other codes that might be associated. Of the roughly 19,000 ICD-9-CM codes, roughly 1,200 codes were selected for examination. The question, "Realizing that every case is different, how likely is it that this code represents an adverse event?" was then posed to an expert panel of health information management professionals, nurses, pharmacists, and physicians.

Selecting codes rated by reviewers to represent those events most likely to be harmful and due to medical care, 1,003 codes were initially chosen for review.²¹ These codes were grouped into a final classification scheme of six main categories that contains 75 total classes, with each class representing between 2 and 51 ICD-9-CM codes:

1. Adverse drug events.
2. Surgical events.
3. Misadventures.
4. Device events.
5. Infections.
6. Other adverse events.²²

Study Population and Sample Design

The review was conducted in two States, Utah and Missouri. Charts of inpatients admitted in calendar years 2001 and 2003 were selected for review. In Utah, all 41 acute care hospitals participated, while in Missouri, 36 of 123 hospitals were selected to participate. All inpatients were eligible for study inclusion in the Utah population. In Missouri, surgical inpatients served as the pool from which medical charts were selected. At each hospital in both States, randomly selected charts and charts with one or more ICD-9-CM AE flags were selected for review. As inpatient AEs represented the primary focus of this study, charts with AE flags in the secondary diagnosis field and/or E-code field were chosen. As charts could feasibly have both AEs causing admission and inpatient AEs, records selected on the above criteria that also had a flagged principal diagnosis code were not excluded from the sample.

A structured chart review tool based on previous large patient safety studies^{2, 23, 24, 25} was developed and tested on trial charts prior to initiation of formal chart review. Research nurses with ICD-9-CM coding experience used this tool to review the medical charts and to record pertinent information on AEs. The review tool was designed to accommodate multiple AEs, if necessary, for each medical chart.

After fully documenting information on any AEs present in the medical record, the reviewer then turned to the ICD-9-CM codes assigned by the hospital to that inpatient stay. If flagged AE codes were present, the reviewer recorded whether these flagged codes truly indicated AEs. If, in the reviewer's judgment, the flagged code did denote an AE, the reviewer also indicated whether the AE caused patient admission to the hospital or occurred in the inpatient setting subsequent to admission. AEs causing admission were thus AEs present on admission but clearly identified by reviewers as the cause for the hospitalization.

After accounting for any flagged ICD-9-CM codes, the reviewer noted whether any of the remaining unflagged codes assigned by the hospital pointed to an AE. Finally, for AEs that had no associated codes (flagged or unflagged) assigned by the hospital, the reviewer generated and recorded the appropriate code or codes.

The same reviewers were used throughout the chart review process. They underwent extensive training before chart review began in order to achieve consistency when evaluating AEs.²⁶ This

training consisted of both didactic training and review of prescreened medical records. Reviewers were required to demonstrate competency before the chart review began. While formal intra-rater reliability was not calculated, the review coordinators monitored quality throughout the project by reviewing the abstraction forms as they came in, focusing on AE harm/causality ratings and AE descriptions.

Statistical Analysis

Descriptive analysis focuses on positive predictive values (PPVs), which are calculated by the number of confirmed AE codes divided by the total number of corresponding flagged AE codes at each of the code, class, and category levels for both inpatient AEs and AEs causing admission. The overall PPVs equal the sum of PPV for AEs causing admission and AEs occurring in the hospital. All analyses were performed using SAS[®] (SAS Institute Inc., Release 8.2, 2001).

Results

A total of 13,965 charts containing 27,815 flagged codes were reviewed. The all-inpatient sample in Utah consisted of 7,070 charts containing 11,619 flagged codes, while the surgical inpatient sample in Missouri consisted of 6,895 charts with 16,186 flagged codes.

Results were reported both for code performance among all inpatients (Utah sample) and surgical inpatients (Missouri sample). For both patient samples, the initial analysis focused on the six primary AE categories, with overall AE PPVs broken out by inpatient AE PPV and PPV of AEs causing admission. For all six AE categories overall, AE PPV was higher among surgical inpatients than all inpatients (Table 1). ADEs and misadventures had overall PPV between 15 and 23 percent higher in the sample of surgical inpatients than in all inpatients. The difference was even more pronounced in infections, surgical AEs, and other, miscellaneous AEs, with overall PPV among infections and surgical AEs roughly 40 percent higher than that in all inpatients and roughly 60 percent higher in the category of other AEs.

Examining inpatient AE PPV, device events, and misadventures showed roughly equivalent PPV in both the inpatient and surgical patient samples (19 vs. 20 percent, respectively, for device events, and 76 vs. 73 percent, respectively, for misadventures). ADEs were half again more likely in inpatients in the surgical sample (29 percent) than in the sample of all inpatient types (20 percent). The gap in performance in inpatient AE PPV was largest in the three remaining categories of infections, surgical adverse events, and other adverse events. For each of these three categories, inpatient AE PPV was approximately 35 percentage points higher, with PPVs ranging from 7 to 14 percent in all inpatients compared to 42 to 51 percent in surgical inpatients.

Adverse Drug Events

Clinical side effects of drugs. These first four classes describe potential ADEs in terms of specific symptoms rather than the drug or drug class causing the ADE. Among all inpatients, rash performed rather poorly, with an overall PPV of only 20 percent (Table 2). The other three classes showed better performance, with overall PPV between 46 and 68 percent. Of note is the predilection of these three classes for inpatient ADEs in the all-inpatient sample. Drug psychosis

Table 1. Adverse event-positive predictive value for ICD-9-CM codes

Adverse event category		N (%)	
		All patients	Surgical patients
1. ADEs	Inpatient	646/3252 (19.7)	123/417 (29.4)
	Causing admission	1454/3252 (45.1)	243/417 (58.3)
	Total %	64.9	87.8
2. Surgical AEs	Inpatient	411/2982 (13.8)	3847/7576 (50.8)
	Causing admission	343/2982 (11.5)	1161/7576 (15.3)
	Total %	25.3	66.1
3. Misadventures	Inpatient	40/53 (75.5)	313/432 (72.5)
	Causing admission	1/53 (1.9)	33/432 (19.9)
	Total %	77.4	92.4
4. Infections	Inpatient	110/1446 (7.6)	812/1850 (43.9)
	Causing admission	102/1446 (7.1)	371/1850 (20.1)
	Total %	14.7	63.9
5. Device events	Inpatient	19/102 (18.6)	240/1187 (20.2)
	Causing admission	39/102 (38.2)	490/1187 (41.3)
	Total %	56.8	61.5
6. Other AEs	Inpatient	610/4646 (13.1)	2420/5721 (42.3)
	Causing admission	740/4646 (15.9)	2619/5721 (45.8)
	Total %	29.0	88.1

Table 2. Adverse drug event ICD-9-CM class positive predictive values

Class		N (%)	
		All patients	Surgical patients ^a
1. Drug psychosis	Inpatient	73/262 (27.9)	12/37 (32.4)
	Causing admission	77/262 (29.4)	22/37 (59.5)
	Total %	57.3	91.9
2. Dermatitis	Inpatient	37/74 (50.0)	4/31 (12.9)
	Causing admission	17/74 (17.6)	25/31 (80.6)
	Total %	67.6	93.5
3. Maternal causes of perinatal morbidity & mortality, drug reactions & intoxications specific to newborn	Inpatient	17/41 (41.5)	—
	Causing admission	2/41 (4.9)	—
	Total %	46.3	—

Table 2. Adverse drug event ICD-9-CM class positive predictive values (continued)

Class		N (%)	
		All patients	Surgical patients ^a
4. Rash	Inpatient	7/83 (8.4)	9/21 (42.9)
	Causing admission	10/83 (12.0)	9/21 (42.9)
	Total %	20.5	85.7
5. Poisoning by antibiotics and other anti-infectives	Inpatient	4/18 (22.2)	—
	Causing admission	9/18 (47.4)	—
	Total %	72.2	—
6. Poisoning by hormones and synthetic substitutes	Inpatient	3/84 (3.6)	—
	Causing admission	60/84 (71.4)	—
	Total %	75.0	—
7. Poisoning by primary systematic agents	Inpatient	2/51 (3.9)	—
	Causing admission	19/51 (37.3)	—
	Total %	41.2	—
8. Poisoning by agents primarily affecting blood constituents	Inpatient	14/44 (31.8)	—
	Causing admission	17/44 (38.6)	—
	Total %	70.5	—
9. Poisoning by analgesics, antipyretics, antirheumatics	Inpatient	20/295 (6.8)	—
	Causing admission	163/295 (55.3)	—
	Total %	62.0	—
10. Poisoning by anticonvulsants and anti-Parkinsonism drugs	Inpatient	3/73 (4.1)	—
	Causing admission	58/73 (79.5)	—
	Total %	83.6	—
11. Poisoning by sedatives & hypnotics	Inpatient	7/102 (6.9)	—
	Causing admission	72/102 (70.6)	—
	Total %	77.5	—
12. Poisoning by other CNS depressants, stimulants, anesthetics	Inpatient	9/72 (12.5)	—
	Causing admission	35/72 (48.6)	—
	Total %	61.1	—
13. Poisoning by psychotropic agents	Inpatient	6/317 (1.9)	—
	Causing admission	221/317 (69.7)	—
	Total %	71.6	—
14. Poisoning by agents primarily affecting the cardiovascular system	Inpatient	4/40 (10.0)	—
	Causing admission	32/40 (80.0)	—
	Total %	90.0	—
15. Poisoning by other agents	Inpatient	13/153 (8.5)	—
	Causing admission	68/153 (44.4)	—
	Total %	52.5	—

Table 2. Adverse drug event ICD-9-CM class positive predictive values (continued)

Class		N (%)	
		All patients	Surgical patients ^a
16. Adverse effects of antibiotics and other anti-infectives	Inpatient	72/172 (41.9)	11/44 (25.0)
	Causing admission	53/172 (30.8)	32/44 (72.7)
	Total %	72.7	97.7
17. Adverse effects of hormones and synthetic substitutes	Inpatient	29/156 (18.6)	15/26 (57.7)
	Causing admission	63/156 (40.4)	6/26 (23.1)
	Total %	59.0	80.8
18. Adverse effects of primarily systematic agents	Inpatient	29/95 (30.5)	5/11 (45.5)
	Causing admission	36/95 (37.9)	4/11 (36.4)
	Total %	68.4	81.8
19. Adverse effects of agents primarily affecting blood constituents	Inpatient	16/84 (19.0)	12/46 (26.1)
	Causing admission	39/84 (46.4)	25/46 (54.3)
	Total %	65.5	80.4
20. Adverse effects of analgesics, antipyretics, antirheumatics	Inpatient	77/241 (32.0)	16/72 (22.2)
	Causing admission	89/241 (36.9)	45/72 (62.5)
	Total %	68.9	84.7
21. Adverse effects of anticonvulsants and anti-Parkinsonism drugs	Inpatient	9/76 (11.8)	1/6 (16.7)
	Causing admission	44/76 (57.9)	2/6 (33.3)
	Total %	69.7	50.0
22. Adverse effects of sedatives and hypnotics	Inpatient	20/57 (35.1)	7/13 (53.8)
	Causing admission	19/57 (33.3)	6/13 (46.2)
	Total %	68.4	100.0
23. Adverse effects of other CNS depressants, stimulants, anesthetics	Inpatient	62/133 (46.6)	2/23 (8.7)
	Causing admission	38/133 (28.6)	21/23 (91.3)
	Total %	75.2	100.0
24. Adverse effects of psychotropic agents	Inpatient	29/158 (18.4)	3/6 (50.0)
	Causing admission	76/158 (48.1)	2/6 (33.3)
	Total %	66.5	83.3
25. Adverse effects of agents primarily affecting the cardiovascular system	Inpatient	35/175 (20.0)	10/27 (37.0)
	Causing admission	83/175 (47.4)	12/27 (44.4)
	Total %	67.4	81.5
26. Adverse effects of other drugs, biological, & medicinal substances in therapeutic use	Inpatient	53/236 (22.5)	15/47 (31.9)
	Causing admission	90/236 (38.1)	29/47 (61.7)
	Total %	60.6	93.6

a Classes with five or fewer reviewed cases are not reported.

codes had an inpatient PPV of 28 percent and PPV of ADEs causing admission of 29 percent. The class “maternal causes of perinatal morbidity and mortality/drug reactions and intoxications specific to newborn,” as well as the “dermatitis” class, actually were more likely to detect inpatient ADEs (42 percent inpatient PPV vs. 5 percent causing admission PPV for the maternal/newborn class; 50 percent inpatient PPV vs. 18 percent causing admission PPV for the dermatitis class).

Poisonings. These codes for medication errors are used relatively infrequently. None of the codes in these poisoning classes sampled greater than five times in the surgical sample, so that reported results are for the all-inpatient type sample only. On the whole, the poisoning classes had a high overall positive predictive value for ADEs. Overall PPV for these classes ranged from 40 percent to 90 percent, with overall PPV in 7 of the 11 poisoning classes above 70 percent.

However, the poisoning codes were much more likely to detect ADEs causing admission than those ADEs that occurred in the hospital. Only 4 of 11 poisoning classes had an inpatient PPV of 10 percent or greater: poisoning by agents primarily affecting blood constituents (32 percent); poisoning by antibiotics and antiinfectives (22 percent); poisoning by other CNS depressants, stimulants, and anesthetics (13 percent); and poisoning by agents primarily affecting the cardiovascular system (10 percent).

Of note, the two codes evaluated most frequently in the best-performing inpatient PPV class “Poisoning by agents primarily affecting blood constituents” were 964.2 “Poisoning by anticoagulants” and E858.2 “Accidental poisoning by agents primarily affecting blood constituents.” Although E858.2 is a catch-all code, 964.2, perhaps not surprisingly, includes the anticoagulants heparin and warfarin. Both of these codes had an inpatient PPV of 35 percent, and in addition, both codes pointed even more frequently to ADEs causing hospital admission.

Adverse effects. Used more commonly than the poisoning codes, the adverse effect codes (denoting adverse drug reactions) showed relatively uniform overall predictive value in all inpatients (59 percent to 75 percent, with 9 of 11 classes between 66 percent and 75 percent) and surgical inpatients (50 percent to 100 percent, with 10 of 11 classes between 80 percent and 100 percent) (Table 2). These codes were also more likely than poisoning codes to indicate inpatient ADEs, with the inpatient PPV for all adverse effects codes equal to 27 percent among all inpatient types and 30 percent among surgical inpatients. Seven of the 11 classes were more likely to indicate inpatient ADEs than ADEs causing admission in both all inpatients and surgical inpatients.

Surgical Events

This category shares the most codes with other AE categories, as some infection, misadventure, and device event codes are also represented in the category of surgical AEs. In addition, although these codes are targeted at surgical patients, some codes reflect procedures/conditions that can occur in patients who did not have surgery. For each surgical class, both overall AE PPV and inpatient AE PPV are higher in the surgical population than in the all-inpatient sample (Table 3). For the surgical patient sample, the overall AE PPV was 66 percent and the inpatient AE PPV was 51 percent, markedly higher than the all-inpatient sample (overall AE PPV of 25 percent and inpatient AE PPV of 14 percent).

Table 3. Surgical event ICD-9-CM class positive predictive values

Class		N (%)	
		All patients ^a	Surgical patients
1. Reopening of surgical site	Inpatient	11/31 (35.5)	126/257 (49.0)
	Causing admission	1/31 (3.2)	34/257 (13.2)
	Total %	38.7	62.3
2. Control of post-procedure hemorrhage	Inpatient	–	43/67 (64.2)
	Causing admission	–	6/67 (9.0)
	Total %	–	73.1
3. Perforation or laceration	Inpatient	7/94 (7.4)	68/175 (38.9)
	Causing admission	13/94 (13.8)	43/175 (24.6)
	Total %	21.3	63.4
4. Bloodstream infections	Inpatient	19/245 (7.8)	176/442 (39.8)
	Causing admission	24/245 (9.8)	97/442 (21.9)
	Total %	17.6	61.8
5. Other infections	Inpatient	91/1201 (10.8)	636/1408 (36.8)
	Causing admission	78/1201 (8.6)	274/1408 (21.9)
	Total %	19.3	58.7
6. Acute myocardial infarction	Inpatient	5/128 (3.9)	91/214 (42.5)
	Causing admission	5/128 (3.9)	35/214 (16.4)
	Total %	7.8	58.9
7. Pulmonary embolism and infarction	Inpatient	6/89 (6.7)	2/9 (22.2)
	Causing admission	15/89 (16.9)	4/9 (44.4)
	Total %	23.6	66.7
8. Heart disease	Inpatient	5/38 (13.2)	43/91 (47.3)
	Causing admission	4/38 10.5	7/91 (7.7)
	Total %	23.7	54.9
9. Disease of respiratory system	Inpatient	122/647 (18.9)	729/1265 (57.6)
	Causing admission	81/647 (12.5)	132/1265 (10.4)
	Total %	31.4	68.1
10. Postoperative gastrointestinal disorders	Inpatient	–	15/57 (26.3)
	Causing admission	–	9/57 (15.8)
	Total %	–	42.1
11. Complications peculiar to specified procedures	Inpatient	15/96 (15.6)	222/577 (38.5)
	Causing admission	34/96 (35.4)	129/577 (22.4)
	Total %	51.0	60.8
12. Other complications of procedures	Inpatient	62/182 (34.1)	466/709 (65.7)
	Causing admission	29/182 (21.4)	73/709 (10.3)
	Total %	55.5	76.0

Table 3. Surgical event ICD-9-CM class positive predictive values (continued)

Class		N (%)	
		All patients ^a	Surgical patients
13. Accidental cut, puncture, perforation or hemorrhage during procedure	Inpatient	11/17 (64.7)	262/361 (72.6)
	Causing admission	0/17 (0.0)	28/361 (7.8)
	Total %	64.7	80.3
14. Other misadventures of surgical and medical care	Inpatient	—	51/71 (71.8)
	Causing admission	—	5/71 (7.0)
	Total %	—	78.9
15. Surgical operation/procedure as cause of abnormal reaction or later complications	Inpatient	32/139 (23.0)	641/1299 (49.3)
	Causing admission	36/139 (25.9)	191/1299 (11.5)
	Total %	48.9	60.8
16. Other procedures without mention of misadventure at time of procedure	Inpatient	20/66 (30.3)	276/574 (48.1)
	Causing admission	12/66 (18.2)	94/574 (16.4)
	Total %	48.5	64.5

a Classes with five or fewer reviewed cases are not reported.

Misadventures

The misadventure codes are used less frequently than all other AE codes discussed in this paper, with less than 1/100 inpatient discharges assigned one of these codes.²⁰ Because these codes are so rarely used, they are divided into only two classes: accidental cut, puncture, perforation, or hemorrhage during procedure; and other misadventures of medical or surgical care. These two classes have the highest overall PPV and inpatient PPV for both all-inpatients and surgical inpatients (Table 4). The inpatient PPV is remarkably consistent for both patient types for these two classes. For accidental cut, etc., the inpatient PPV was 74 percent for the all-inpatient sample and 73 percent for the surgical inpatient sample. For the other misadventures category, the surgical inpatient PPV was 73 percent (fewer than 20 codes reviewed in the all-inpatient sample).

Infections

These codes performed relatively poorly in the all-inpatient sample, with inpatient PPV for the three classes between 4 percent and 11 percent and overall PPV between 9 percent and 19 percent (Table 4). Performance was better in surgical patients, with inpatient PPV between 37 and 58 percent. In addition to the higher overall PPV in the surgical sample, for each of three classes codes were more likely to detect infections that had occurred during that hospital stay. For bloodstream infections, 40 percent of cases were inpatient AEs vs. 22 percent for cases causing admission, while for the miscellaneous class of other infections, we found 37 percent for inpatient AEs vs. 22 percent for AEs causing admission. Pneumonia showed the highest overall PPV and strongest predilection for inpatient AEs, with an overall AE PPV of 74 percent, which comprised 58 percent of inpatient AE PPV and 16 percent PPV for pneumonia cases causing admission.

Table 4. Positive predictive values for misadventure, infection, and device event ICD-9-CM classes

Class		N (%)	
		All patients	Surgical patients ^a
Misadventure codes			
1. Accidental cut, puncture, perforation or hemorrhage during procedure	Inpatient	37/50 (74.0)	262/361 (72.6)
	Causing admission	1/50 (2.0)	28/361 (19.7)
	Total %	76.0	92.2
2. Other misadventures of medical or surgical care	Inpatient	3/3 (100.0)	313/432 (72.5)
	Causing admission	0/3 (0.0)	33/432 (19.9)
	Total %	100.0	92.4
Infection codes			
1. Bloodstream	Inpatient	19/245 (7.8)	176/442 (39.8)
	Causing admission	24/245 (9.8)	97/442 (15.7)
	Total %	17.6	61.8
2. Pneumonia	Inpatient	28/617 (4.5)	322/555 (58.0)
	Causing admission	28/617 (4.5)	87/555 (21.9)
	Total %	9.1	73.7
3. Other	Inpatient	63/584 (10.8)	314/853 (36.8)
	Causing admission	50/584 (8.6)	188/853 (21.9)
	Total %	19.3	58.7
Device codes			
1. Cardiac and vascular	Inpatient	5/22 (22.7)	130/296 (43.9)
	Causing admission	7/22 (31.9)	53/296 (17.9)
	Total %	54.5	61.8
2. Orthopedic	Inpatient	3/30 (10.0)	24/111 (21.6)
	Causing admission	16/30 (53.3)	36/111 (32.4)
	Total %	63.3	53.0
3. Renal and genitourinary	Inpatient	2/6 (33.3)	41/104 (39.4)
	Causing admission	1/6 (16.7)	30/104 (28.9)
	Total %	71.4	68.3
4. Nervous system	Inpatient	1/7 (14.3)	—
	Causing admission	4/7 (57.1)	—
	Total %	50.0	—
5. Miscellaneous	Inpatient	8/37 (21.6)	295/675 (43.7)
	Causing admission	11/37 (29.7)	121/675 (17.9)
	Total %	51.3	61.6

a Classes with five or fewer reviewed cases are not reported.

Device Events

Among the five device classes, the four classes reviewed had consistent overall AE PPV of 50 to 70 percent for both all inpatient types and surgical inpatients (Table 4). The class of codes describing complications of nervous system devices was reviewed fewer than five times in the surgical inpatient sample and so is reported only for the all inpatient sample. Because AEs related to permanent implantable devices can manifest long after hospital discharge from the initial surgery in which the device was implanted—and indeed, may cause hospital readmission—and because device event codes are by nature relatively specific, it is not surprising that both inpatient AE PPV and AE PPV of device events causing hospital admission are relatively high for device AE codes.

Miscellaneous Adverse Events

This category of codes represents codes that did not seem to naturally group with the previous five categories. Like other categories, surgical inpatient AE PPV (88 percent) was far higher than that of all inpatients (29 percent). Events were split roughly evenly between inpatient AEs and AEs causing admission. As these classes showed wide variability in terms of event type, there was a correspondingly wide range of overall AE PPVs, from 9 to 75 percent among all inpatients and 61 to 100 percent among surgical inpatients (Table 5).

Decubitus ulcers—a problem in both long-term care facilities and hospitals and a frequent target of quality improvement efforts—were AEs in over 70 percent of surgical inpatients; 37 percent of these were inpatient events, and 33 percent were events causing admission. Accidental falls in the hospital represent another iatrogenic event that hospital patient safety programs have attempted to prevent via mechanisms, such as identifying patients at high risk for falls and implementing appropriate precautions. Among all inpatients, this is a poor AE indicator with an overall PPV of 9 percent. However, among surgical inpatients, the overall AE PPV was 61 percent, with inpatient AE PPV at 54 percent.

Discussion

This report enumerates the PPV of selected ICD-9-CM codes across a wide variety of targeted iatrogenic AEs. A panel of clinicians and patient safety experts selected the codes prior to any data collection. They were evaluated against chart review in nearly 14,000 patients in two States. The results show that with a few exceptions (e.g., infections), the selected ICD-9-CM codes have good PPV for iatrogenic AEs that occurred during or prior to a hospital admission. In decisions to use these codes as part of a surveillance system, several factors should be considered.

The PPV of ICD-9-CM codes varied widely among the classes of AEs and the patient populations. Because PPV is a function of specificity, it is not surprising that codes more specific for iatrogenic AEs performed better than nonspecific codes. For example, arguably the most specific iatrogenic adverse event codes—the “misadventure” codes—reflected inpatient AEs with patient harm in over 70 percent of cases in both the Utah and Missouri samples. Similarly, specific ICD-9-CM codes such as 292.12, “Drug induced hallucinosis” and 693.0, “Dermatitis

Table 5. Adverse event positive predictive value for ICD-9-CM miscellaneous codes

Class		N (%)	
		All patients ^a	Surgical patients ^a
1. Endocrine disorders	Inpatient	2/64 (3.1)	–
	Causing admission	6/64 (9.4)	–
	Total %	12.5	–
2. Metabolic and immunity disorders	Inpatient	94/1408 (6.7)	588/1054 (55.8)
	Causing admission	233/1408 (16.5)	301/1054 (28.6)
	Total %	23.2	84.3
3. Anemias, coagulation defects, & hemorrhagic conditions	Inpatient	7/103 (6.8)	101/176 (57.4)
	Causing admission	38/103 (36.9)	53/176 (30.1)
	Total %	43.7	87.5
4. Disorders of the nervous system	Inpatient	17/113 (15.0)	30/76 (39.5)
	Causing admission	21/113 (18.6)	38/76 (50.0)
	Total %	33.6	89.5
5. Diseases of veins and lymphatics, other diseases of circulatory system	Inpatient	23/127 (18.1)	120/340 (35.3)
	Causing admission	9/127 (12.5)	185/340 (54.4)
	Total %	25.2	89.7
6. Diseases of respiratory system	Inpatient	122/647 (18.9)	414/1272 (32.5)
	Causing admission	81/647 (7.1)	729/1272 (57.3)
	Total %	31.4	89.8
7. Acute GI ulcer, GI bleed, & other GI disorders	Inpatient	7/248 (2.8)	107/196 (54.6)
	Causing admission	64/248 (25.8)	70/196 (35.7)
	Total %	28.6	90.3
8. Nausea, vomiting, diarrhea	Inpatient	87/373 (23.3)	144/298 (48.3)
	Causing admission	59/373 (15.8)	135/298 (45.3)
	Total %	39.1	93.6
9. Disorders of urinary system	Inpatient	7/206 (3.4)	176/378 (46.6)
	Causing admission	45/206 (21.8)	145/378 (38.4)
	Total %	25.2	85.0
10. Complications occurring mainly in the course of labor and delivery	Inpatient	52/239 (21.8)	62/148 (41.9)
	Causing admission	1/239 (0.4)	84/148 (56.8)
	Total %	22.2	98.7
11. Complications of the puerperium	Inpatient	34/48 (70.8)	–
	Causing admission	2/48 (4.2)	–
	Total %	75.0	–
12. Decubitus ulcer	Inpatient	6/60 (10.0)	68/184 (37.0)
	Causing admission	6/60 (10.0)	62/184 (33.7)
	Total %	20.0	70.1

Table 5. Adverse event positive predictive value for ICD-9-CM miscellaneous codes (continued)

Class		N (%)	
		All patients ^a	Surgical patients ^a
13. Urticaria	Inpatient	12/37 (32.4)	—
	Causing admission	9/37 (24.3)	—
	Total %	56.7	—
14. Alterations in mental status	Inpatient	11/412 (2.7)	127/192 (66.1)
	Causing admission	80/412 (19.4)	34/192 (17.7)
	Total %	22.1	83.8
15. Epistaxis, hemorrhage from throat	Inpatient	7/26 (26.9)	8/15 (53.3)
	Causing admission	7/26 (26.9)	7/15 (46.7)
	Total %	53.8	100.0
16. Shock	Inpatient	9/63 (14.3)	75/189 (39.7)
	Causing admission	9/63 (14.3)	78/189 (41.3)
	Total %	28.6	81.0
17. Hemoptysis	Inpatient	2/29 (6.9)	16/31 (51.6)
	Causing admission	3/29 (10.3)	10/31 (32.3)
	Total %	17.2	83.9
18. Sudden death	Inpatient	—	—
	Causing admission	—	—
	Total %	—	—
19. Respiratory arrest	Inpatient	14/43 (32.6)	4/10 (40.0)
	Causing admission	2/43 (4.7)	5/10 (50.0)
	Total %	37.3	90.0
20. Certain adverse effects not elsewhere classified	Inpatient	10/68 (14.7)	2/8 (25.0)
	Causing admission	33/68 (48.5)	6/8 (75.0)
	Total %	63.2	100.0
21. Complications affecting specified body systems	Inpatient	77/251 (30.7)	290/936 (31.0)
	Causing admission	26/251 (10.4)	600/936 (64.1)
	Total %	41.1	95.1
22. Complications of medical care, not elsewhere classified	Inpatient	9/22 (40.9)	17/86 (19.8)
	Causing admission	2/22 (9.1)	64/86 (74.4)
	Total %	50.0	94.2
23. Accidental falls	Inpatient	1/58 (1.7)	66/122 (54.1)
	Causing admission	4/58 (6.9)	8/122 (6.6)
	Total %	8.6	60.7

a Classes with five or fewer reviewed cases are not reported.

due to drugs and medicines taken internally,” were reviewed over 40 times each and had high overall AE PPVs (88 and 77 percent, respectively).

On the other hand, ICD-9-CM codes selected to identify hospital-acquired infections performed poorly. Despite a few exceptions, ICD-9-CM appears to lack codes specific to iatrogenic infections. The differences in PPV between the Utah general and the Missouri surgical population are interesting. Generally, PPV was much higher in the Missouri surgical population. It is not clear whether this finding is driven by the difference in coding practices or patient care in the two States or differences in the care of surgical patients compared with other patients. Examining infections, where the discrepancy between surgical inpatients (44 percent inpatient AE PPV) and all inpatients (8 percent inpatient PPV) was high, one reasonable supposition is that clearly elective surgery patients suffering from an active infectious process would have their surgery delayed. This would eliminate many of these “false-positives” from the surgical inpatient sample and help explain the much higher specificity.

The AE codes for surgical inpatients perform better than those for all inpatients, not just for surgical events, but also for the overwhelming majority of events. Misadventure codes had the highest overall PPV among all six AE categories, both for all inpatients and for surgical inpatients. Infections codes had the lowest overall PPV among all inpatients, whereas device codes’ PPV was the lowest among surgical patients. Poisoning ADE codes indicating medication errors were more likely to detect AEs that caused admission, while adverse drug reaction codes were more likely to record inpatient adverse events. Second to the misadventure codes, the surgical codes detected slightly higher than half of confirmed AEs among inpatients whose discharge records were flagged by one of the surgical AE codes.

It should be noted that while PPV is linked to both sensitivity and specificity, given the number of AE categories and classes examined in this study, sensitivity and specificity were not addressed. In our previous work solely examining ADE flagged codes,¹⁹ specificity was high (97 percent) for both inpatient ADEs and ADEs causing admission. Sensitivity was much higher for ADEs causing admission (55 percent) than inpatient ADEs (10 percent), paralleling the PPV results reported in this paper.

One interesting finding is that the selected ICD-9-CM codes have high PPV for both inpatient and outpatient ADEs. Four distinct adverse effects of antibiotics codes (including adverse effects caused by penicillins and cephalosporins) were reviewed and had overall AE PPVs over 70 percent. For each of these codes, both the inpatient AE PPV and outpatient AE PPV were over 30 percent. At the time of the study, there was no mechanism to distinguish whether a code represented an event that the patient suffered during or prior to hospitalization in Utah or Missouri. However, the National Uniform Billing Committee (NUBC) adopted the present on-admission indicator to be used as a modifier for ICD-9-CM diagnosis codes in 2005, with hospital implementation beginning in 2007.²⁷ A recent study found that adding the present on-admission field to existing administrative data improved the value of the administrative data.²⁸ If this field is widely adopted by medical coders and all other factors remain equal, the PPV of nearly all ICD-9-CM codes will greatly increase for both the inpatient and outpatient sites of origin. A quick review of the tables shows that being able distinguish these AEs present on

admission will result in inpatient AEs roughly doubling for categories, such as adverse drug events and device events.

While making this present-on-admission designator a standard element in ICD-9-CM could be considered an incremental step forward, the next iteration—ICD-10-CM—has greater capability to describe AEs. In addition to more refined codes for AEs, specific locations, such as hospital or nursing home as place of occurrence, can be identified. The National Center for Health Statistics (NCHS), under authorization by the World Health Organization, released the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) in July 2007. The American Health Information Management Association has strongly recommended that Congress pass legislation enabling adoption and implementation of the ICD-10-CM and ICD-10-PCS classification by no later than October 1, 2011.²⁹

How can ICD-9-CM codes currently be incorporated into surveillance systems? Obviously, these codes can only be used for retrospective chart review. They will rarely be useful for identifying and treating patients who recently suffered an AE. They could, however, be very useful for facilitating retrospective reviews of AEs. The PPVs in this report provide information regarding the resources that can be saved by using these codes, as opposed to reviewing all charts. PPV can be translated into a number needed to review by dividing 100 by the PPV. Given that the prevalence of many of the individual targeted AEs is less than 1 percent,³⁰ chart reviews may be reduced by a corresponding factor. These codes may greatly facilitate evaluation of the need for, and efficacy of, a targeted quality improvement initiative designed to reduce AEs.

Another application of these codes could be to serve as the basis of new patient safety indicators. For some events, exposure information is reflected in procedure or diagnostic codes. For example, currently there are no specific codes for surgical site infections. A reasonable approach to target these nosocomial infections would be to screen for patients with both an infection code and a procedure code for selected surgical procedures. However, for other AEs, discharge ICD-9-CM codes do not provide adequate exposure information. ADEs are one notable category of event without specific exposure codes. Nonetheless, it is possible to derive exposure information for some types of therapy—such as exposure to anticoagulants—and construct useful surveillance rules.³⁰

Despite the benefits listed above, the characterization of the ICD-9-CM codes has limitations. First, this report does not provide enough information about sensitivity to allow these codes to be used for rate estimation. It may be tempting to multiply the number of positive codes per admission by the PPV and declare a proportion of admissions with the event. This would be a mistake because it is unknown how many events would be missed by the codes. For some types of events, such as ADEs, more information on the test characteristics of the codes is available.¹⁹ However, the sensitivity and specificity of most codes are too low to reliably estimate rates for an institution. Moreover, their validity and reliability for estimating changes in rates over time and among institutions are unknown. It is premature to use these codes for benchmarking.

With the exception of infections, ICD-9-CM codes have PPVs that are high enough to be useful in a variety of surveillance activities. The application of present on-admission codes may greatly increase the utility of ICD-9-CM codes in the surveillance of iatrogenic harm in both the

outpatient and inpatient settings. More characterization of these codes is needed before they can be used for rate estimation or benchmarking.

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References

1. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med* 1991; 324: 377-384.
2. Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care* 2000; 38: 261-271.
3. Thomas EJ, Studdert DM, Newhouse JP, et al. Costs of medical injuries in Utah and Colorado. *Inquiry* 1999; 36: 255-264.
4. Wilson RM, Runciman WB, Gibberd RW, et al. The Quality in Australian Health Care Study. *Med J Aust* 1995; 163: 458-471.
5. Weinstein RA. Nosocomial infection update. *Emerg Infect Dis* 1998; 4: 416-420.
6. Jarvis WR. Infection control and changing health care delivery systems. *Emerg Infect Dis* 2001; 7: 170-173.
7. Leape L, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. *JAMA* 1995; 274: 35-43.
8. Classen DC, Pestotnik SL, Evans RS, et al. Adverse drug events in hospitalized patients: Excess length of stay, extra costs, and attributable mortality. *JAMA* 1997; 277: 301-306.
9. Nebeker JR, Hoffman JM, Weir CR, et al. High rates of adverse drug events in a highly computerized hospital. *Arch Intern Med* 2005; 165: 1111-1116.
10. Jha AK, Kuperman GJ, Teich JM, et al. Identifying adverse drug events: Development of a computer-based monitor and comparison with chart review and stimulated voluntary report. *J Am Med Inform Assoc* 1998; 5: 305-314.
11. Lowe N, Scott W. Medical device reporting for user facilities. Available at: www.fda.gov/cdrh/mdruf.pdf. Accessed March 1, 2008.
12. U.S. Department of Health and Human Services. International classification of diseases, 9th revision, clinical modifications (ICD-9-CM), 6th edition. DHHS Publication No. (PHS) 96-1260. Washington, DC: Health Care Financing Administration; 1997.
13. McCarthy EP, Iezzoni LI, Davis RB, et al. Does clinical evidence support ICD-9-CM diagnosis coding of complications? *Med Care* 2000; 38: 868-876.

14. Lawthers AG, McCarthy EP, Davis RB, et al. Identification of in-hospital complications from claims data – Is it valid? *Med Care* 2000; 38: 785-795.
15. Weingart SN, Iezzoni LI, Davis RB, et al. Use of administrative data to find substandard care – Validation of the complications screening program. *Med Care* 2000; 38: 796-806.
16. Geraci JM, Ashton CM, Kuykendall DH, et al. International Classification of Diseases, 9th revision. Clinical modification codes in discharge abstracts are poor measures of complication occurrence in medical inpatients. *Med Care* 1997; 35: 589-602.
17. AHRQ Quality Indicators – Guide to patient safety indicators, Revision 1. AHRQ Publication No. 03-R203. Rockville, MD: Agency for Healthcare Research and Quality; 2003.
18. Samore M, Evans RS, Lassen A, et al. Surveillance of medical device-related hazards and adverse events in hospitalized patients. *JAMA* 2004; 291: 325-370.
19. Hougland P, Xu W, Pickard S. Performance of international classification of diseases, 9th edition, clinical modification codes as an adverse event surveillance system. *Med Care* 2006; 44: 629-636.
20. Shah HG, Rolfs RT, Xu W, et al. Adverse events related to medical care, 1995-1999. Salt Lake City: UT: Utah Health Data Committee, Center for Health Data; 2001. Available at http://health.utah.gov/hda/Reports/adverse_events.pdf. Accessed March 14, 2008.
21. National Expert Panel of the ICD-9-CM Adverse Event Classification, Utah/Missouri Patient Safety Consortium. The ICD-9-CM adverse event classification. Available at: health.utah.gov/psi/icd9.htm. Accessed March 1, 2008.
22. Utah/Missouri Patient Safety Project. Utah/Missouri Adverse Event ICD-9-CM Classification, final 2008 version. Available at: http://health.utah.gov/psi/ps_grant.htm. Accessed June 30, 2008.
23. Hiatt HH, Barnes BA, Brennan TA, et al. A study of medical injury and medical malpractice. *N Engl J Med* 1989; 321: 480-484.
24. Woloshynowych M, Neale G, Vincent C. Case record review of adverse events: A new approach. *Qual Saf Health Care* 2003; 12: 411-415.
25. Kivlahan C, Sangster W, Nelson K, et al. Developing a comprehensive adverse event reporting system in an academic health center. *Jt Comm J Qual Improv* 2002; 28: 583-594.
26. Silver MP, Hougland P, Elder S, et al. Statewide identification of adverse events using retrospective nurse review: Methods and outcomes. *J Nurs Meas* 2007; 15: 220-232.
27. Pickett D. UB-04 present on admission indicator, definitions and reporting guidelines. Available at: www.nahdo.org/documents/21stmeeting/3A-Pickett.pdf. Accessed March 1, 2008.
28. Pine M, Jordan HS, Elixhauser A, et al. Enhancement of claims data to improve risk adjustment of hospital mortality. *JAMA* 2007; 297: 71-76.
29. American Health Information Management Association. AHIMA's position statement on ICD-10. Available at: www.ahima.org/icd10/documents/MicrosoftWord-ICD-10StatementApproved7-18-2007.pdf. Accessed March 1, 2008.
30. Nebeker JR, Yarnold PR, Soltysik RC, et al. Developing indicators of inpatient adverse events through nonlinear analysis using administrative data. *Med Care* 2007; 45: S81-S88.

Adaptation of AHRQ Patient Safety Indicators for Use in ICD-10 Administrative Data by an International Consortium

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Abstract

Objective: The Agency for Healthcare Research and Quality (AHRQ) developed Patient Safety Indicators (PSIs) for use with ICD-9-CM data. Many countries have adopted ICD-10 for coding hospital diagnoses. We conducted this study to develop an internationally harmonized ICD-10 coding algorithm for the AHRQ PSIs. **Methods:** The AHRQ PSI Version 2.1 has been translated into ICD-10-AM (Australian Modification), and PSI Version 3.0a has been independently translated into ICD-10-GM (German Modification). We converted these two country-specific coding algorithms into ICD-10-WHO (World Health Organization version) and combined them to form one master list. Members of an international expert panel—including physicians, professional medical coders, disease classification specialists, health services researchers, epidemiologists, and users of the PSI—independently evaluated this master list and rated each code as either “include,” “exclude,” or “uncertain,” following the AHRQ PSI definitions. After summarizing the independent rating results, we held a face-to-face meeting to discuss codes for which there was no unanimous consensus and newly proposed codes. A modified Delphi method was employed to generate a final ICD-10 WHO coding list. **Results:** Of 20 PSIs, 15 that were based mainly on diagnosis codes were selected for translation. At the meeting, panelists discussed 794 codes for which consensus had not been achieved and 2,541 additional codes that were proposed by individual panelists for consideration prior to the meeting. Three documents were generated: a PSI ICD-10-WHO version-coding list, a list of issues for consideration on certain AHRQ PSIs and ICD-9-CM codes, and a recommendation to WHO to improve specification of some disease classifications. **Conclusion:** An ICD-10-WHO PSI coding list has been developed and structured in a manner similar to the AHRQ manual. Although face validity of the list has been ensured through a rigorous expert panel assessment, its true validity and applicability should be assessed internationally.

Introduction

Patient safety is a critical component of health care quality that has been widely studied.^{1, 2, 3, 4, 5} Assessments of patient safety are traditionally done through chart reviews, surveys, and voluntary hospital reporting of adverse events and medical errors. These data collection methods focus on specific types of events, often collect data that may not be generalizable to any population of interest, cover limited geographic areas, and may be too labor-intensive for widespread use. Therefore, researchers have become interested in using routinely collected administrative data for population-based studies of adverse events.

In response, the Agency for Healthcare Research and Quality (AHRQ) and the University of California-Stanford Evidence-based Practice Center developed patient safety indicators (PSIs) for use with hospital administrative data coded using the International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM), which are readily available and relatively inexpensive to use.⁶ The AHRQ PSIs were developed through a literature search, review of ICD-9-CM manuals, consultation with physician panels, and empirical data analyses. Over 200 ICD-9-CM codes representing potential patient safety problems were identified, and 48 indicators were labeled as the most promising PSIs by the AHRQ research team. Of these, 20 hospital-level and seven area-level PSIs were recommended by one or more multispecialty panels as a set of “accepted” indicators.⁶ The first set of AHRQ PSIs was released in 2003 and has been updated periodically since then.

The 20 hospital-level indicators are used to identify potential inpatient complications that might represent events related to patient safety. The seven area-level indicators are designed to detect patient safety events on a regional level such as “Foreign body left during procedure.” Although the seven area-level indicators are closely related to the 20 hospital-level measures, the method of defining these seven area-level indicators is different. Area level indicators are designed to estimate the prevalence of each PSI in a jurisdiction or region. Therefore, the denominator includes the entire eligible population of a region, rather than just cases treated in a particular hospital. The numerator is based on both principal and secondary diagnoses, whereas for hospital-level indicators, the numerator is based only on secondary diagnoses.⁶ Inclusion of principal diagnoses in the area-level numerators captures patients who were admitted due to complications that occurred in previous hospitalizations or outpatient care episodes.

To facilitate utilization of the PSIs, AHRQ developed and distributes (at no cost) SAS[®] and Windows[®]-based software tools. These tools can be used to help hospitals identify potential adverse events that might need further study and also to enable users to assess the occurrence of in-hospital adverse events using routinely collected ICD-9-CM hospital discharge abstract data.

The PSI tools for ICD-9-CM cannot be applied to ICD-10⁷ data because ICD-10 uses an alphanumeric system, and many codes are not directly convertible. The ICD-10 classification has been developed and is maintained by the World Health Organization (WHO). Updates to the ICD-10 are based on recommendations of the Update and Revision Committee that meets annually to discuss and ratify proposals. Major updates (e.g., new codes) are implemented every 3 years, while minor updates (e.g., corrections) are implemented annually. Implementation of ICD-10 began in 1994, but it has not yet been adopted for morbidity coding in the United States. The major differences between the ICD-10 and ICD-9-CM coding systems are:

- The tabular list of diseases in ICD-10 has 22 chapters, compared to 19 chapters in ICD-9-CM. The chapter on diseases of the nervous system and sense organs in ICD-9-CM is expanded to three chapters in ICD-10, including diseases of the nervous system, diseases of the eye and adnexa, and diseases of the ear and mastoid process. ICD-10 specifies certain conditions in more detail than ICD-9-CM by adding anatomical sites and type of injury (open or closed).
- The codes in ICD-10 are alphanumeric, whereas codes in ICD-9-CM are numeric. Each code in ICD-10 starts with a letter (i.e., A - Z), followed by two numeric digits, a decimal point, and a digit (e.g., acute bronchiolitis due to respiratory syncytial virus is J21.0). In contrast, codes in ICD-9-CM begin with three-digit numbers (i.e., 001 - 999) followed by a decimal and up to two digits (e.g., acute bronchiolitis due to respiratory syncytial virus is 466.11).

Canada, Australia, New Zealand, and many European and Asian countries have used the ICD-10 to code hospital discharge diagnoses since the system was introduced, but the development of quality indicators based on ICD-10-coded data has lagged behind. Starting in 2004, the Canadian Institute for Health Information began evaluating the AHRQ PSIs and selected a subset for public reporting on health system performance.⁸ Concurrently, Drösler and colleagues in Germany mapped the AHRQ PSIs from ICD-9-CM to ICD-10 and licensed this mapping to the German subsidiary of 3M, so that German hospitals could monitor their rates of potential safety-related events.⁹ Demand from potential users of the AHRQ PSIs in these and other countries prompted us to conduct this study to develop an internationally harmonized ICD-10 coding algorithm for the PSIs.

This study was spearheaded by the International Methodology Consortium for Coded Health Information (IMECCHI), an international group of experts dedicated to the development and validation of health research methodologies for coded health data.¹⁰ At its meeting in 2005, IMECCHI members identified the development of ICD-10 WHO coding algorithms for PSIs as a high priority initiative. Coincidentally, the Organization for Economic Cooperation and Development (OECD) launched its Health Care Quality Indicator (HCQI) Project in 2001, and identified five priority areas for initial development of indicators that could be used to explore quality differences across 23 participating countries: (1) cardiac care, (2) diabetes mellitus, (3) mental health, (4) patient safety, and (5) prevention/health promotion combined with primary care.

To identify and evaluate potential indicators of patient safety, the OECD convened a Patient Safety Panel, which then solicited indicators covering “five core domains of patient safety”: (1) hospital-acquired infections, (2) sentinel events, (3) operative and postoperative complications, (4) obstetrics, and (5) other care-related adverse events. Fifty-nine indicators from seven different sources were evaluated through a nominal group process; the Panel agreed on a final list of 21 indicators (including 12 AHRQ PSIs) that were deemed suitable, based on both importance and scientific soundness.¹¹ In followup, the OECD convened health ministerial representatives from its member countries and experts to collaborate around patient safety data systems on June 29 and 30, 2006, in Dublin, Ireland.¹² At the meeting, international harmonization of ICD-10 PSI definitions was identified as an urgent task, and the OECD Secretariat agreed to facilitate this undertaking.

Methods

Selection of PSIs for Translation

Defining PSI events (numerators) requires searching diagnosis and procedure code fields in hospital discharge abstract data, but defining denominators often requires the use of diagnosis-related groups (DRGs) to identify eligible hospitalizations. For example, the events coded as “foreign body left during procedure” (PSI 5) are found by searching for the ICD-9-CM codes 998.4 and 998.7 in secondary diagnosis fields. The denominator for this indicator includes all surgical and medical discharges, which are determined by specific surgical and medical DRGs.

To develop ICD-10-WHO (World Health Organization version) definitions for each PSI, we therefore needed to consider the following realities:

Reality 1. Various country-specific ICD-10 versions are available. Canada, Australia, Germany, and other countries have enhanced ICD-10 by adding more specific codes and released country-specific versions, such as ICD-10-CA (Canadian modification¹³), ICD-10-AM (Australian modification¹⁴) and ICD-10-GM (German modification¹⁵). The National Center for Health Statistics has developed ICD-10-CM for eventual use in the United States, but these codes “are not currently valid for any purpose or use.”¹⁶ The basic ICD-10-WHO structure, scope, and code definitions are not altered in these country-specific modifications, which mainly extend code character levels, from the third and fourth levels of ICD-10 to fourth-, fifth-, or sixth-character levels (e.g., “O10.0 pre-existing essential hypertension complicating pregnancy, childbirth, and the puerperium” in ICD-10-WHO subsumes “O10.001 pre-existing essential hypertension complicating pregnancy, childbirth, and the puerperium - delivered, with or without mention of antepartum condition” in ICD-10-CA). ICD-10 country-specific modifications also include a few additional third- and fourth-level codes, consistent with the existing classification structure. Some countries do not adopt all codes from the chapter “External causes of morbidity and mortality” (e.g., 22 codes in ICD-10-GM vs. 1,366 codes in ICD-10-WHO).

Reality 2. Each country uses its own distinct procedure coding system, limiting data comparability because ICD-10-WHO classifies medical conditions only, not procedures. For example, Switzerland uses a procedure coding system derived directly from ICD-9-CM.¹⁷ Canada developed its own procedure classification (the Canadian Classification of Health Interventions [CCI]¹³). Australia developed the Australian Classification of Health Interventions (ACHI),¹⁸ and Germany developed the German procedure classification (OPS).¹⁹

Reality 3. Various patient classification systems have been utilized across countries. Australia has developed ICD-10 DRGs based on ICD-10-AM; Germany has introduced the G-DRG system based on ICD-10-GM. The Canadian Institute for Health Information (CIHI) developed ICD-10-CA/CCI case-mix groups (CMG +) to predict resource utilization; this new methodology was implemented on April 1, 2007.²⁰ Switzerland currently uses All Patient-Diagnosis Related Groups (AP-DRGs) but will adopt the German DRG system soon.

Considering these three realities, we focused on developing ICD-10-WHO coding algorithms for PSIs that mainly rely on diagnosis codes for defining PSI inclusion and exclusion criteria. We finally selected 15 PSIs (Table 1). However, country-specific procedure codes are required for

adapting the coding algorithms to define some of these PSIs, such as “Postoperative physiologic and metabolic derangement.”

Process of Translation

The following three major steps were taken to develop ICD-10 coding algorithms.

Step 1: Searching ICD-10 Diagnosis Codes

The original ICD-9-CM codes embedded in the AHRQ PSIs were converted to ICD-10 codes using currently available Australian and German ICD-9 and ICD-10 crosstable mapping algorithms. Our Australian investigators used a conversion table between ICD-9-CM and ICD-10-AM, while our German investigator used a conversion table to ICD-10-GM and manually reviewed the results for each code.^{21, 22} All ICD-10 codes identified in both translations were combined additively to generate a diagnosis code master list. All country-specific codes that extended original ICD-10-WHO codes were truncated, and country-specific additional codes were excluded to maintain ICD-10-WHO formatting. All codes were described using their titles as listed in the ICD-10-WHO manual.

Step 2: Panel Review and Assessment

Twenty-one members of the PSI working group—including physicians, health services researchers—and coding professionals, independently (or as a geographic research team) reviewed the comprehensive code list. Each reviewer compared ICD-10-WHO codes with AHRQ’s ICD-9-CM codes, using the AHRQ PSI Technical Manual (Version 3.0a)⁶ to clarify AHRQ’s intent with respect to each code. The reviewers were asked to rate each diagnosis code as “Include,” “Exclude,” or “Uncertain.” For those who reviewed as a team, a final rating was made after internal discussions.

The German results have been tested on large national databases; substantial concordance was shown between German PSI rates calculated in ICD-10 and the U.S. rates published by AHRQ.²³ However, we could not be certain that the coding list generated using Australian and German conversion tables would capture every relevant ICD-10-WHO code. Therefore, we asked reviewers to propose diagnosis codes that might have been omitted from the master list of codes.

Step 3: Face-to-Face Meeting

The purpose of the face-to-face meeting was to discuss codes for which consensus was not reached at the second step. Because of inconsistencies in coding practices across countries and code descriptions between ICD-9-CM and ICD-10, the following guidelines were established before voting:

Rule 1. Codes were selected for detailed discussion when consensus was not reached due to differences in country-specific coding standards. If coders in one country were advised to use code A for a specific condition, but in another country they were advised to use code B for the same condition, then both codes A and B were retained.

Table 1. Selected PSIs and denominator definitions
 (Adopted from AHRQ Technical Specifications, Version 3.0a, May 1, 2006.
 See AHRQ manual for further exclusions.)

PSI title	Selected PSI for ICD-10-WHO translation	Denominator population	Major diagnosis category (MDC) exclusion	Procedure codes requirement
PSI 1: Complications of anesthesia	Yes	All surgical discharges age ≥18 years or MDC 14 (pregnancy, childbirth, and puerperium)	No	No
PSI 2: Death in low-mortality	No, because it heavily relies on DRG			
PSI 3: Decubitus ulcer	Yes	All medical and surgical discharges age ≥18 years, length of stay >4 days	MDC 9 (skin, subcutaneous tissue, and breast); MDC 14 (pregnancy, childbirth, and puerperium)	Yes, debridement or pedicle graft
PSI 4: Failure to rescue	No, because many procedure codes are required			
PSI 5: Foreign body left during procedure	Yes	All surgical and medical discharges age ≥18 years or MDC 14 (pregnancy, childbirth, and puerperium)	No	No
PSI 6: Iatrogenic pneumothorax	Yes	All surgical and medical discharges age ≥18 years		Yes, diaphragmatic surgery repair, thoracic surgery, lung or pleural biopsy, or cardiac surgery
PSI 7: Selected infections due to medical care	Yes	All surgical and medical discharges age ≥18 years	No	No

Table 1. Selected PSIs and denominator definitions (continued)
(Adopted from AHRQ Technical Specifications, Version 3.0a, May 1, 2006.
See AHRQ manual for further exclusions.)

PSI title	Selected PSI for ICD-10-WHO translation	Denominator population	Major diagnosis category (MDC) exclusion	Procedure codes requirement
PSI 8: Postoperative hip fracture	Yes	All surgical discharges age ≥18 years	MDC 8 (diseases and disorders of the musculoskeletal system and connective tissue); MDC14 (pregnancy, childbirth, and puerperium)	Yes, hip fracture repair
PSI 9: Postoperative hemorrhage or hematoma	No, because many procedure codes are required			
PSI 10: Postoperative physiologic and metabolic derangement	Yes	All surgical discharges age ≥18	MDC 14 (pregnancy, childbirth, and puerperium)	Yes, dialysis
PSI 11: Postoperative respiratory failure	No, because many procedure codes are required			
PSI 12: Postoperative pulmonary embolism or deep vein thrombosis	Yes	All surgical discharges age ≥18	MDC 14 (pregnancy, childbirth, and puerperium)	Yes, interruption of vena cava
PSI 13: Postoperative sepsis	Yes	All elective (defined by the admission type) surgical discharges age ≥18 years and length of stay >3 days	MDC 14 (pregnancy, childbirth, and puerperium)	No

Table 1. Selected PSIs and denominator definitions (continued)
 (Adopted from AHRQ Technical Specifications, Version 3.0a, May 1, 2006.
 See AHRQ manual for further exclusions.)

PSI title	Selected PSI for ICD-10-WHO translation	Denominator population	Major diagnosis category (MDC) exclusion	Procedure codes requirement
PSI 14: Postoperative wound dehiscence	No, because many procedure codes are required			
PSI 15: Accidental puncture or laceration = <i>Technical difficulty with procedure</i>	Yes	All surgical and medical discharges age ≥18 years	MDC 14 (pregnancy, childbirth, and puerperium)	No
PSI 16: Transfusion reaction	Yes	All surgical and medical discharges age ≥18 years or MDC 14 (pregnancy, childbirth, and puerperium)	No	No
PSI 17: Birth trauma – injury to neonate	Yes	All liveborn births (newborns)	No	No
PSI 18: Obstetric trauma – vaginal delivery with instrument	Yes (PSI 18 and 19 are joined to form one PSI)	All vaginal delivery discharge patients	No	Yes, obstetric trauma repair
PSI 19: Obstetric trauma – vaginal delivery without instrument				
PSI 20: Obstetric trauma – cesarean delivery	Yes	All cesarean delivery discharges	No	Yes, obstetric trauma repair; cesarean section

Rule 2: When additional codes relevant to the AHRQ indicator concept—or codes included in the AHRQ indicator concept that did not seem relevant—were identified, modifications or improvements of AHRQ ICD-9-CM definitions were recommended to AHRQ.

Rule 3: Additional ICD-10 codes with incomplete matching with ICD-9-CM were included if these codes matched the clinical concept of the PSI.

Rule 4: When there was no ICD-10-WHO code corresponding to an ICD-9-CM code, recommendations to improve or modify ICD-10-WHO were made to the WHO Update and Revision Committee.

We also developed guidelines for decisionmaking on additional codes proposed by the reviewers (Figure 1). Before rating for inclusion or exclusion, participants in the face-to-face meeting discussed and accepted these guidelines. Six reviewers who had the greatest experience with and understanding of the PSIs rated each code after discussions and consultations with other experts, including a member of the WHO Update and Revision Committee.

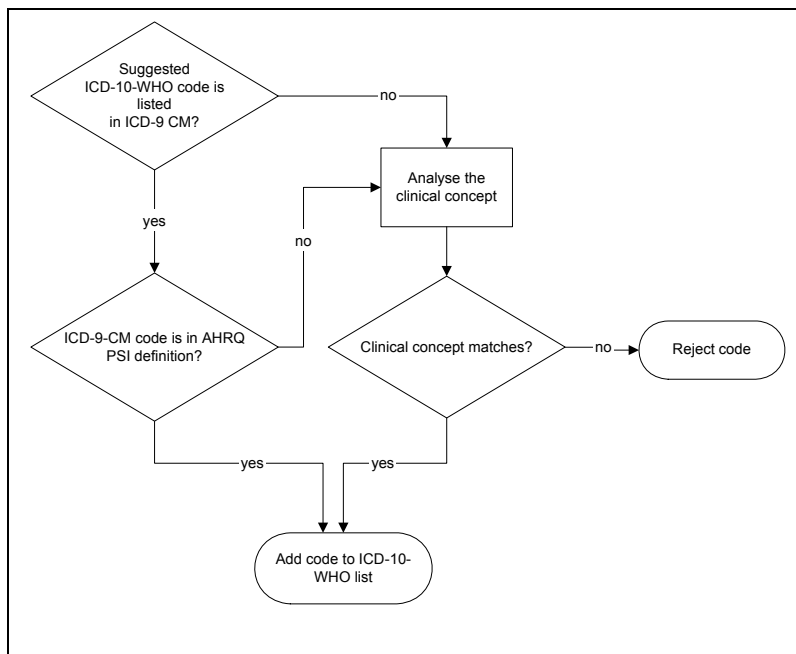


Figure 1. Assessment process of proposed additional diagnosis codes to PSIs.

A modified Delphi method^{24, 25} was employed to achieve consensus. After discussion, reviewers rated each code as “Include,” “Exclude,” or “Uncertain.” When there were discrepancies among raters, reviewers explained their decisions, and further discussion among all members ensued. After a second round of discussion, the reviewers voted again. This 2-day process involved frequent reference to the ICD-9-CM and ICD-10 manuals, published crosswalk tables, and technical documents from AHRQ.

Results

Three documents were generated from this work: (1) ICD-10-WHO coding algorithms for PSIs, (2) recommendations to AHRQ for adjustments to the ICD-9-CM PSIs, and (3) recommendations to the WHO Update and Revision Committee for refinement of ICD-10-WHO.

During the time between the Consortium meeting and this publication, all of these recommendations to AHRQ and WHO have been discussed, and some are being implemented.

ICD-10-WHO Coding Algorithms

A list of 2,569 ICD-10 codes invoked by the PSI algorithms was generated using the ICD-9-CM-to-ICD-10-AM and ICD-10-GM crosstables. After the first individual or team rating, we reached consensus for inclusion or exclusion of 1,775 codes, leaving 794 codes for which there was disagreement among the six raters. Another 2,541 codes (not identified from crosswalk tables) were then proposed by raters as potential codes for inclusion in the PSI algorithms. At the face-to-face meeting, panelists therefore discussed and rated 3,335 (i.e., 794 + 2,541) codes and generated the list of ICD-10-WHO codes required to define inclusion and exclusion criteria of 15 PSIs (available at www.chaps.ucalgary.ca/sas.htm).

In the translation process, we found that some ICD-10-WHO codes did not match ICD-9-CM codes but met PSI clinical definitions. Table 2 shows these additional codes for the numerator inclusion of PSI 1 and the denominator exclusion of PSI 8. These codes were proposed to enhance the sensitivity of PSIs in the ICD-10-WHO coding algorithm.

Table 2. Additional ICD-10-WHO codes to enhance PSIs in ICD-10 data

ICD-10	Description
For PSI 1, Poisoning by other central nervous system depressants and anesthetics, numerator inclusion	
Y70.0	Anesthesiology devices associated with adverse incidents, diagnostic and monitoring devices
Y70.1	Anesthesiology devices associated with adverse incidents, therapeutic (nonsurgical) and rehabilitative devices
Y70.2	Anesthesiology devices associated with adverse incidents, prosthetic and other implants, materials, and accessory devices
Y70.3	Anesthesiology devices associated with adverse incidents, surgical instruments, materials and devices (including sutures)
Y70.8	Anesthesiology devices associated with adverse incidents, miscellaneous devices, not elsewhere classified
T48.1	Poisoning by skeletal muscle relaxants (neuromuscular blocking agents)
For PSI 8, Postoperative hip fracture, denominator exclusion of coma	
E03.5	Myxedema coma

Recommendations to AHRQ

The American representatives to our Consortium described some validity concerns about the indicator complications of anesthesia (PSI 1) because it was heavily (>99 percent) dependent on External Cause of Injury (E) codes. Only 16 of the 36 States that contributed to AHRQ's State Inpatient Databases (SID) in 2002 required reporting of E-codes, plus 3 States (CA, SC, WA) did not require reporting of E870-E879 (including E876.3 for "endotracheal tube wrongly placed during anesthetic procedure," which is in the PSI definition). Empirical analyses have confirmed that the apparent prevalence of this PSI highly depends on the number of diagnosis fields used in the analysis because E-codes are often appended after a long list of other diagnosis codes. Others have criticized this indicator because of its weak association with inpatient mortality and length-of-stay²⁶ and its high "nonpreventable" rate based on chart review.²⁷

We recommend that AHRQ consider moving PSI 1 to its "experimental" list. Specific codes for intubation difficulties during pregnancy, childbirth, and the puerperium were not included in the AHRQ PSI 1 (complications of anesthesia) definition. Consequently, maternal hospitalizations should be excluded from the population at risk.

For decubitus ulcer (PSI 3), a major exclusion group covers hemiplegias and other neurologic problems that limit mobility. AHRQ may have missed one rare ICD-9-CM diagnosis code for hemiplegia: 334.1 (hereditary spastic paraplegia). This code (which matches G11.4 in ICD-10) should be added to AHRQ's denominator exclusion list.

The title for PSI 7 (selected infections due to medical care) suggests a broader set of infections than are actually captured, despite use of the adjective "selected." In fact, only catheter and infusion-related infections are included, so AHRQ should consider a more specific indicator name.

Regarding postoperative hip fracture (PSI 8), based on Canadian chart review experience, it was suggested that 996.44 (periprosthetic fracture around prosthetic joint, corresponding to ICD-10 code M96.6, fracture of bone following insertion of orthopedic implant, joint prosthesis, or bone plate) should be added with a denominator exclusion.

Regarding the existing denominator exclusions for this indicator, which are intended to exclude patients at high risk of falling in the hospital, even with appropriate care, the codes for stroke should include vertebrobasilar insufficiency (ICD-9-CM 435.0, 435.1, 435.3); and the codes for alteration of consciousness should include 070.0 (viral hepatitis A with hepatic coma), 070.2 (viral hepatitis B with hepatic coma), 070.4x (other specified viral hepatitis with hepatic coma), 070.6 (unspecified viral hepatitis with hepatic coma), 070.71 (unspecified viral hepatitis C with hepatic coma), and 780.09 (other drowsiness, semicoma, unconsciousness, somnolence, stupor).

The group of experts also raised the global conceptual concern that the denominator exclusion for PSI 8 was somewhat counterintuitive. The patients excluded are precisely those for whom a "safe" hospital could institute safeguards to prevent falls and hip fractures in the hospital. AHRQ should revisit the large block of denominator exclusions identifying patients at risk for falls, since many of these diagnoses could be removed from the denominator exclusion list to produce an indicator that would capture a larger percentage of all in-hospital hip fractures. For example, the ICD-9-CM codes for poisoning in PSI 8 are very broad; patients with poisonings due to

agents that would not affect alertness and awareness could be excluded. These poisonings—such as 960 (poisoning by antibiotics), 961 (poisoning by anti-infectives), and 962 (poisoning by hormones and synthetic substitutes)—should not affect patients’ risk of iatrogenic hip fracture. ICD-9-CM codes for delirium and other psychoses also capture many diagnoses with no discernible effect on, or association with, alertness and presumably no effect on the risk of falling. For example, 296 codes (episodic mood disorders) with a subtitle indicating “in remission” (5th digit of 5 or 6) should not be on the exclusion list.

Conversely, ICD-9-CM codes for acute alcohol and drug intoxications were omitted from the PSI 8 exclusion criteria, even though such intoxications are likely to be associated with increased risk of falling. Of course, such intoxications are also unlikely to affect postoperative patients because any alcohol or drugs taken at home would wear off before surgery, and these agents are not administered in hospital. For example, the current ICD-9-CM exclusion list includes 291.4 (idiosyncratic alcohol intoxication – pathologic: alcohol intoxication, drunkenness), but it omits 303.00-303.02 (acute alcoholic intoxication – acute drunkenness in alcoholism) and 305.00-305.02 (alcohol abuse – drunkenness NOS). The current exclusion list includes 292.1x (drug-induced psychotic disorders) and 292.2 (pathologic drug intoxication), but it omits 305.30-305.02 (hallucinogen abuse – acute intoxication from hallucinogens)

In the numerator definition for postoperative sepsis (PSI 13), ICD-9-CM 785.59 (other shock without mention of trauma) should be removed because it no longer refers to an infectious disorder (i.e., effective October 2003, “septic shock” was assigned to a separate code 785.52). Denominator exclusion criteria of several PSIs include infection diagnosis codes. Our comparison of ICD-9-CM with ICD-10 revealed that two types of infection had been moved from nonbacterial sections in ICD-9-CM to bacterial sections in ICD-10-WHO, suggesting that they should now be added to the list of denominator exclusions (based on a presumption of pre-existing bacterial infection).

This change may reflect new thinking about the nature of the pathogens, including *Bartonella henselae*, which causes cat-scratch disease (078.3), and *Leptospira* species, which cause leptospirosis (100.xx). We also identified the following conditions that are currently on AHRQ’s denominator exclusion list (Appendix P) but do not actually represent bacterial infections (although they are grouped with other bacterial diagnoses): 376.00 (acute inflammation of orbit, unspecified; cellulitis is coded separately), 386.30 (labyrinthitis, unspecified, a viral infection), 386.31 (serous labyrinthitis, diffuse labyrinthitis), 386.32 (circumscribed labyrinthitis, focal labyrinthitis), 598.0x (urethral stricture due to infection), and 686.01 (pyoderma gangrenosum; commonly associated with Crohn’s disease and leukemias).

Recommendations to WHO Update and Revision Committee

ICD-9-CM was specifically designed to code clinical conditions in morbidity databases. Therefore, classification of certain conditions in ICD-10-WHO is not as clinically precise as in ICD-9-CM. Although there are specific codes for decubitus ulcer (PSI 3) in both ICD-9-CM and ICD-10-WHO, the ICD-10-WHO code L89 (decubitus ulcer) does not specify the site of the ulcer, while M70 codes describe unspecified “soft tissue disorders related to use, overuse, and pressure.” To prevent misleading users of the classification, an exclusion notice for decubitus

ulcer should be added to the M70 group; additional subcodes under L89 should be considered to specify ulcer location and/or stage.

For defining iatrogenic pneumothorax (PSI 6), a new specific code for iatrogenic pneumothorax should be added. This is a concept that exists in ICD-9-CM, but there is no exact match in ICD-10-WHO. The suggested placement of this code is J95.6 (under J95, “postprocedural respiratory disorders not elsewhere classified”). Currently, some country versions of ICD-10 include a specific code for this diagnosis (e.g., J95.80 for “iatrogenic pneumothorax” in Germany and “postprocedural pneumothorax” in Canada). In Switzerland and France, coders are instructed to use a combination of S27.0 (traumatic pneumothorax) and Y60.x (unintentional cut, puncture, perforation, or hemorrhage during surgical and medical care) instead of J95.8.

The inclusion term for “endotoxic shock” under R57.8 (other shock) should be deleted. It might mislead, since the code A41.9 (septicemia, unspecified) contains an inclusion of “septic shock,” which includes endotoxin-mediated shock. Furthermore, the code A41.9 is listed as an exclusion under R57. There should be an instruction within the ICD-10 at code T81.4 to use an additional code to identify septicemia. A wide range of postprocedural infections are classified to this code, making its use as a patient safety indicator questionable.

Discussion

We developed ICD-10-WHO diagnosis coding algorithms for defining 15 AHRQ PSIs through an explicit and diligent review process of the ICD-9-CM and ICD-10-WHO codes by an international expert panel. Before applying the coding algorithms, users should consider several challenges and issues, which are presented below.

Procedure Codes and Major Diagnostic Category

The ICD-10-WHO coding algorithms are insufficient by themselves because defining the population at risk often requires procedure codes and/or DRGs. Defining surgical discharges requires identification of major therapeutic operations.

Some procedures are required in the definition of PSI events—e.g., postoperative hemodialysis to identify end-stage renal failure. Furthermore, the screening of a few PSI events (numerators) relies on coding of procedures that reflect a complication or a reopening (e.g., perineal laceration repair, vena cava filters).

Major Diagnostic Categories (MDCs) are sometimes used to delineate the at-risk population (Table 1). The MDC is assigned to each case during the DRG grouping process, based primarily on the major or principal diagnosis. Some countries (e.g., Germany) provide public domain tables unfolding which ICD-10 codes trigger certain MDCs.²⁸ Similar tables may be available in other countries that use DRG-based systems for hospital payment.

Diagnosis Codes

Several AHRQ PSIs cannot be translated directly from ICD-9-CM to ICD-10-WHO because of differences in the architecture of these coding systems. For example, the ICD-10-WHO coding

algorithm for PSI 1 (complications of anesthesia) does not include T88.4 (failed or difficult intubation) in the numerator definition, since there is no corresponding ICD-9-CM code. Instead, we included the ICD-10 code Y65.3 because it matches the ICD-9-CM code E876.3 (endotracheal tube wrongly placed during anesthetic procedure). However, external cause codes, which are labeled E codes in ICD-9-CM and Y codes in ICD-10-WHO, are not mandatory in several countries and are underused in other countries. The term “failed” in the description of T88.4 matches with “wrongly placed” in E876.3, but the term “difficult” in T88.4 has neither a corresponding description in ICD-9-CM nor an association with medical error. When users analyze ICD-10 hospital discharge data, they should make a decision on inclusion or exclusion of T88.4, based on whether the data contain codes for external causes of morbidity and mortality.

For the numerator definition of iatrogenic pneumothorax (PSI 6), no ICD-10-WHO code matches the ICD-9-CM code 512.1 (iatrogenic pneumothorax). Two proximate ICD-10-WHO codes of J93.8 (other pneumothorax) and J95.8 (other postprocedural respiratory disorders) do not explicitly refer to iatrogenic pneumothorax. Some country-specific versions of ICD-10 use their own codes for pneumothorax related to medical care, as described above. In Switzerland and France, coders are told to use a combination of S27.0 (traumatic pneumothorax) and Y60 (unintentional cut, puncture, perforation, or hemorrhage during surgical and medical care) to indicate that the event is related to medical care. In countries using S27.0 to identify iatrogenic pneumothorax, this code should be deleted from the denominator exclusion list (except if used as the principal diagnosis).

Several ICD-10 codes are not sufficiently precise to identify some exclusion conditions, such as gastrointestinal hemorrhage. For example, I98.2 (esophageal varices in diseases classified elsewhere) does not indicate whether bleeding was present, which is integral to the definition of gastrointestinal hemorrhage. Some countries use a supplementary subdivision to improve the specificity of this code. The ICD-10 codes for diverticular disease (K57.x) have similar limitations.

Timing of Occurrence

The AHRQ PSIs are used to detect complications or adverse events resulting from medical care. When applying this definition to U.S. hospital discharge abstract data, the hospital-level PSI numerators are based only on “secondary” diagnosis codes,⁶ because the principal diagnosis is defined in the Uniform Hospital Discharge Data Set (UHDDS)²⁹ as “that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care.” However, some countries do not follow the UHDDS definition. For example, Canada classifies diagnoses using diagnosis-type definitions: type (M) for the most responsible, type (1) for pre-admit comorbidity; type (2) for post-admit comorbidity; and type (3) for secondary diagnoses.¹³ The most responsible diagnosis is defined as “the one diagnosis or condition that can be described as being most responsible for the patient’s stay in hospital. If there is more than one such condition, the one held most responsible for the greatest portion of the length of stay or greatest use of resources (e.g., operating room time, investigative technology) is selected.” A secondary diagnosis refers in Canada to a condition for which a patient may or may not have received treatment that does not satisfy the requirements for determining comorbidity. France also defines the principal diagnosis as the diagnosis that contributed the most to the care provided to the patient during hospitalization.

Employing a diagnosis-type definition to identify conditions that develop after admission improves the validity of the PSIs in any data system. CIHI has adopted PSI 8 (“postoperative hip fracture,” renamed as “In-Hospital Hip Fracture Rate”) and publicly reported it in its annual Health Indicators Report since 2004. In CIHI’s definition, the indicator only includes events that are coded as postadmission (diagnosis type 2).³⁰ Naessens, et al.,³¹ analyzed 2005 hospital discharge data from Mayo Clinic Rochester to determine the frequency of PSIs after distinguishing conditions diagnosed before and after admission. They reported that 63.1 percent of the cases identified by 20 PSI numerators occurred during hospitalization, but this percentage was only 22 percent for PSI 8. Similar results were obtained from statewide studies in New York and California, the two States that pioneered mandatory diagnosis-type reporting.³² For this reason, the 2007 version of the AHRQ manual encourages users who have data with “present-at-admission” indicators to exclude secondary diagnoses that preceded the admission of interest.⁶

Data Quality

While acknowledging the potential usefulness of the PSIs in clinical quality improvement, it is necessary to call attention to the issue of data quality. Data quality is a common concern in all indicator-related analysis and reporting. Given the nature of the PSIs—which rely on ICD-coded diagnoses and/or procedures for both outcome ascertainment and risk-adjustment—they are even more vulnerable to this challenge than indicators of mortality.³³ Sedman, et al.,²⁷ applied AHRQ PSI ICD-9-CM coding algorithms to children’s hospital administrative data in the United States and reviewed the medical records of a sample of flagged cases. Of the 11 PSIs studied, only two (failure to rescue and death in low-mortality DRGs) did not represent preventable errors in the majority of pediatric cases. Romano, et al.,³⁴ assessed the validity of ICD-9-CM administrative data in recording obstetric complications with 1,611 clinical delivery records (postpartum and antepartum). They reported that third- and fourth-degree perineal lacerations were recorded accurately in the administrative data with sensitivity exceeding 90 percent and positive predictive value exceeding 85 percent.

Special caution and further validation efforts are needed if these indicators are going to be used for reporting and comparison across national boundaries, given that nations vary widely in the number of allowable diagnosis fields, the use of DRG-based payment systems for resource allocation, and related coding practices. Even within the United States, States with greater E-code usage and more filled diagnosis fields tend to have significantly higher PSI rates than other States.³³ Although validation studies are mandatory for each PSI, they are sensitive to time and location of the available routinely collected data in various jurisdictions.

Limitations

First, validation and comparison of the performance of the AHRQ ICD-9-CM and ICD-10-WHO coding algorithms have not yet been done. In the United States, a validation pilot project is now underway to assess the validity of 10 PSIs through detailed chart review at 48 collaborating hospitals. A separate validation study is also underway in the Veterans Affairs hospital system, following up on a smaller scale linkage study involving data from the National Surgical Quality Improvement Program. The University HealthSystem Consortium has partnered with AHRQ to validate failure-to-rescue,³⁵ postoperative pulmonary embolism or deep vein thrombosis, and postoperative respiratory failure, while the National Association of Children’s Hospitals and Related Institutions has partnered with AHRQ to validate the pediatric versions of the PSIs.²⁷ A

research team is extracting information from inpatient charts in Calgary (Canada) for validating PSIs recorded in the ICD-10-CA administrative data. In addition, a collaborative project involving sites in Lyon (France), Lausanne (Switzerland), and Calgary will focus on validating postoperative pulmonary embolism or deep vein thrombosis in ICD-10 administrative data. Other validation studies at multiple international sites are being planned.

Secondly, we translated diagnosis codes for only 15 of the 20 PSIs. To strengthen international comparisons using the AHRQ PSIs, a uniform, detailed procedure classification system should be developed. Third, we employed AHRQ manuals as the “gold standard” to clarify clinical intent when developing the ICD-10-WHO coding algorithms, but the “true validity” of the PSIs is generally unknown. Finally, PSIs are focused on quality of care but by no means are intended to be comprehensive assessments of quality of care.

Conclusion

A set of algorithms for the AHRQ PSIs using ICD-10-WHO diagnoses has been developed and structured in close relation to the AHRQ PSI documentation. This work should support international applications in ICD-9-CM and ICD-10 data. Although the face/content validity of the list has been ensured through a rigorous expert panel assessment, its “true” validity needs to be assessed internationally. Hospital abstract administrative data have been analyzed for measuring PSIs in Australia, Belgium, Canada, France, Germany, Great Britain, Italy, Spain, Sweden, and Switzerland. It is anticipated that more countries will employ the PSIs for quality of care assessment. We welcome feedback from users regarding their experiences in applying these coding algorithms in order to make them more robust and useful internationally.

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References

1. Thomas EJ, Brennan TA. Incidence and types of preventable adverse events in elderly patients: Population-based review of medical records. *Br Med J* 2000; 320: 741-744.
2. Forster AJ, Clark HD, Menard A, et al. Adverse events among medical patients after discharge from hospital. *CMAJ* 2004; 170: 345-349.
3. Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: The incidence of adverse events among hospital patients in Canada. *CMAJ* 2004; 170: 1678-1686.
4. Romano PS, Geppert JJ, Davies S, et al. A national profile of patient safety in U.S. hospitals. *Health Aff (Millwood)* 2003; 22: 154-166.
5. Baker GR, Norton P, Flintoft V. Knowledge translation and patient safety: The Canadian adverse events study. *Healthcare Policy* 2006; 1: 45-50.
6. Patient Safety Indicators: Technical specifications. Rockville, MD: Agency for Healthcare Research and Quality; 2006. Available at: www.qualityindicators.ahrq.gov/archives/psi/psi_technical_specs_v30a.pdf. Accessed March 10, 2008.
7. World Health Organization. International statistical classification of disease and related health problems, 10th Revision (ICD-10). Geneva: World Health Organization; 1992. Available at: www.who.int/classifications/apps/icd/icd10online/. Accessed March 10, 2008.
8. Patient safety in Canada: An update. Ottawa, ON: Canadian Institute for Health Information; 2007. Available at: secure.cihi.ca/cihiweb/en/downloads/Patient_Safety_AIB_EN_070814.pdf. Accessed March 10, 2008.
9. Drösler SE, Cools A, Kopfer T, et al. [Are quality indicators derived from routine data suitable for evaluating hospital performance? First results using the AHRQ patient safety indicators in Germany]. *Z Arztl Fortbild Qualitatssich* 2007; 101: 35-42.
10. De Coster C, Quan H, Finlayson A, et al. Identifying priorities in methodological research using ICD-9-CM and ICD-10 administrative data: Report from an international consortium. *BMC Health Serv Res* 2006; 6: 77.
11. Millar J, Mattke S. Selecting indicators for patient safety at the health systems level in OECD countries. *Int J Qual Health Care* 2006; 18 Suppl 1: 14-20.

12. Organisation for Economic Co-operation and Development. First OECD Health care quality indicators seminar on improving patient safety data systems: Agenda and presentations, 29-30 June 2006. 2007. Available at: www.oecd.org/document/5/0,2340,en_2649_201185_37159877_1_1_1_1,00.html. Accessed March 10, 2008.
13. Canadian coding standards for ICD-10-CA and CCI for 2007. Ottawa, ON: Canadian Institute for Health Information; 2007. Available at: secure.cihi.ca/cihiweb/products/Canadian_Coding_Standards_2007_e.pdf. Accessed March 10, 2008.
14. ICD-10-AM. Lidcombe, NSW Australia: National Centre for Classification in Health; 2007. Available at: nis-web.fhs.usyd.edu.au/ncch_new/2.6.aspx. Accessed March 10, 2008.
15. ICD-10-GM. Cologne, Germany: German Institute of Medical Documentation and Information; 2008. Available at: www.dimdi.de/static/en/klasi/diagnosen/icd10/index.htm. Accessed March 10, 2008.
16. About the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM). Hyattsville, MD: National Center for Health Statistics. Available at: www.cdc.gov/nchs/about/otheract/icd9/abtcd10.htm. Accessed March 10, 2008.
17. Classification Suisse des Interventions Chirurgicales (CHOP). Index systématique (ICD-9-CM, Vol. 3), Version 9.0. Neuchâtel, Switzerland: Office Fédéral de la Statistique; 2008. Available at: www.bfs.admin.ch/bfs/portal/fr/index/news/publikationen.Document.102347.pdf. Accessed March 10, 2008.
18. Bruce ACT, Australia: Australia Institute of Health and Welfare. Australian Classification of Health Interventions (ACHI); 2007. Available at: meteor.aihw.gov.au/content/index.phtml/itemId/335419. Accessed March 10, 2008.
19. German Procedure Classification. 2007. Cologne, Germany: German Institute of Medical Documentation and Information. Available at: www.dimdi.de/static/en/klasi/prozeduren/ops301/index.htm. Accessed March 10, 2008.
20. Gilardi F, Fuglister K, Luyet S. Learning from others: The diffusion of hospital financing reforms in OECD countries. Presented at the workshop "The diffusion of policies and institutions"; Nicosia, Cyprus; 25-30 April 2006. Available at: www.unil.ch/webdav/site/iepi/users/anicolay/public/gilardi_et_al_ECPR.pdf. Accessed March 10, 2008.
21. The International Statistical Classification of Diseases and Related Health Problems, 10th Revision, Australian Modification (ICD-10-AM), Vol. 5 ICD-10-AM Australian Coding Standards 2nd Edition. Sydney, NSW, Australia: National Centre for Classification in Health; 2000.
22. Crosswalks for ICD-10. Cologne, Germany: German Institute of Medical Documentation and Information; 2007. Available at: www.dimdi.de/static/en/klasi/diagnosen/ueberl/index.htm. Accessed March 10, 2008.
23. Drösler SE, Cools A, Köpfer T, et al. Are quality indicators derived from routine data suitable for evaluating hospital performance? First results using the AHRQ Patient Safety Indicators in Germany. *ZaeFQ* 2007; 101: 35-42.
24. Goodman CM. The Delphi technique: A critique. *J Adv Nurs* 1987; 12: 729-734.
25. Brook RH, Chassin MR, Fink A, et al. A method for the detailed assessment of the appropriateness of medical technologies. *Int J Technol Assess Health Care* 1986; 2: 53-63.
26. Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. *JAMA* 2003; 290: 1868-1874.
27. Sedman A, Harris JM, Schulz K, et al. Relevance of the Agency for Healthcare Research and Quality Patient Safety Indicators for children's hospitals. *Pediatrics* 2005; 115: 135-145.
28. Institut für das Entgeltsystem im Krankenhaus gGmbH (InEK). German Diagnosis Related Groups, Ver. 2006. Definitionshandbuch, Vol. 1-5. Available at: www.g-drg.de/. Accessed March 10, 2008.
29. Official ICD-9-CM guidelines for coding and reporting. Available at: www.eicd.com/Guidelines/Default.htm. Accessed March 10, 2008.
30. Health system performance. Ottawa, ON: Canadian Institute for Health Information; 2006. Available at: www.cihi.ca/cihiweb/dispPage.jsp?cw_page=pwtwg_2006_e. Accessed March 10, 2008.
31. Naessens JM, Campbell CR, Berg B, et al. Impact of diagnosis-timing indicators on measures of safety, comorbidity, and case mix groupings from administrative data sources. *Med Care* 2007; 45: 781-788.
32. Houchens RL, Elixhauser A, Romano PS. How often are potential patient safety events present on admission? *Jt Comm J Qual Saf* 2008; 34: 154-163.
33. Raetzman S, Stranges E, Coffey RM. Patient safety in hospitals in 2004: Toward understanding variation across States. Rockville, MD: Agency for Healthcare Research and Quality; 2007.

34. Romano PS, Yasmeen S, Schembri ME, et al. Coding of perineal lacerations and other complications of obstetric care in hospital discharge data. *Obstet Gynecol* 2005; 106: 717-725.
35. Horwitz LI, Cuny JF, Ceresse J, et al. Failure to rescue: validation of an algorithm using administrative data. *Med Care* 2007; 45: 283-287.

Racial Disparities in Patient Safety Indicator (PSI) Rates in the Veterans Health Administration

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Abstract

Objective: The Patient Safety Indicators (PSIs) developed by the Agency for Healthcare Research and Quality identify potential patient safety events through administrative records. We sought to determine whether there were racial disparities in patient safety event rates in Veterans Health Administration (VHA) hospitals. **Methods:** We explored 5 years of VHA inpatient data for significant differences between racial/ethnic groups in their odds of experiencing PSIs. **Results:** No racial group had consistently higher or lower odds of experiencing PSIs. For example, African Americans had significantly higher odds of decubitus ulcer (OR = 1.35, $P < 0.0001$) and postoperative pulmonary embolism (PE)/deep vein thrombosis (DVT) (OR = 1.23, $P < 0.0001$) but significantly lower odds of accidental puncture or laceration (OR = 0.69, $P = 0.0003$) compared with whites. **Conclusion:** Although significant differences between racial/ethnic groups in the odds of experiencing PSIs were few, the underlying causes of the disparities that were found must be explored to understand how they can be eliminated and to improve patient safety for all patients.

Introduction

Racial disparities in the delivery of health care services are a significant problem. The Institute of Medicine's 2003 Report, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Healthcare*,¹ synthesized the research to date on racial disparities in health and health care and documented large gaps in our understanding of disparities that need to be addressed. Among their recommendations was additional research to identify sources of disparities and to monitor progress toward eliminating those disparities. Although numerous studies have focused on unequal access to services or recommended treatments, little is known about disparities in the delivery of safe inpatient care.²

Patient Safety Indicators (PSIs) were developed by the Agency for Healthcare Research and Quality (AHRQ) and revised by the University of California-Stanford University Evidence-based Practice Center (UCSF-Stanford EPC). PSIs can be used to screen for potential patient safety events in hospital discharge data and are potentially useful for identifying and tracking disparities over time. PSIs have been used within the Veterans Health Administration (VHA) and in the private sector to identify potential patient safety events for the overall patient population^{3, 4, 5} and have been described in detail in numerous articles.^{2, 6, 7} PSIs have been found to be reliable measures, with good construct validity and stability over time.^{3, 4, 5, 8}

Previous research using PSIs has demonstrated that the odds of experiencing an adverse event (AE) vary by patient race in the non-VHA population.^{2, 6, 9, 10} In this article, we explore whether

this is equally true in the VHA, a setting in which previous research has suggested that there are fewer disparities in access to care, utilization, and outcomes,^{11, 12, 13} with some studies showing better outcomes in the VHA for African American than for white veterans.^{14, 15, 16, 17}

This study has important implications for delivery of inpatient care within the VHA. As the largest integrated health care system, the VHA is responsible for providing care to approximately 4 million veterans. If disparities in delivery of safe care exist, then further work will be required to understand why those disparities exist and how systems-level interventions can address them.

Methods

Data

Data were obtained from two VHA administrative databases: the VHA Medical SAS Inpatient Data Files [also known as the Patient Treatment Files (PTF)], and the VHA Medical SAS Outpatient Data Files (also known as the Outpatient Care Files). VHA hospital discharge data (PTF) from FY2001-FY2005 were modified in preparation for running the PSI software, as described previously.⁸ Data from the Outpatient Care Files were used solely to obtain race information for patients when that information was missing from or inconsistent in the PTF.

Sample

Our overall analytic sample consisted of veterans receiving inpatient acute care at one of 128 VHA acute care hospitals between FY2001 and FY2005 (N = 2,281,286 hospitalizations, N = 1,032,103 unique individuals). Due to detailed inclusion and exclusion criteria,¹⁸ only a subsample of all discharges was considered at risk for a given PSI. Patients were excluded if no race could be determined for them, which resulted in 3.4 to 4.8 percent of the patients at risk for each PSI—or 3.6 percent of the overall sample—being excluded from our logistic regression analyses. A more detailed description of how race was determined is described below.

Variables

The main outcome of interest was the PSI, a binary variable indicating whether the AHRQ software had determined that a patient at risk for a given potentially preventable patient safety event had experienced a corresponding patient safety event. Independent variables included age (continuous), sex (binary), race (categorical), and binary indicators for 27 comorbidities. A categorical variable identifying the VHA hospital or hospital group where treatment was received was used to control for clustering at the hospital level. The AHRQ Comorbidity Software¹⁹ also used Diagnosis Related Groups (DRGs) and International Classification of Diseases, 9th Edition, Clinical Modifications (ICD-9-CM) codes to generate the indicators for the comorbidities and risk-adjusted rates for each PSI.

Dependent variables: The PSIs. This research used version 3.0 of the AHRQ SAS PSI Software²⁰ and Version 3.1 of the AHRQ Comorbidity Software.¹⁹ The provider-level PSIs included seven PSIs that were applicable only to surgical patients: postoperative hip fracture (PSI 8), postoperative hemorrhage or hematoma (PSI 9), postoperative physiologic and

metabolic derangements (PSI 10), postoperative respiratory failure (PSI 11), postoperative pulmonary embolism or deep vein thrombosis (PE/DVT) (PSI 12), postoperative sepsis (PSI 13), and postoperative wound dehiscence (PSI 14).

Nine PSIs applied to medical/surgical inpatients: complications of anesthesia (PSI 1), death in low-mortality DRGs (PSI 2), decubitus ulcer (PSI 3), failure to rescue (PSI 4), foreign body left during procedure (PSI 5), iatrogenic pneumothorax (PSI 6), selected infections due to medical care (PSI 7), accidental puncture or laceration (PSI 15), and transfusion reaction (PSI 16).

Four PSIs applied only to obstetric patients, which we excluded in this study due to extremely low numbers of veterans at risk. We also excluded transfusion reaction (PSI 16) due to extremely low incidence. PSIs 1 to 15 were included in these analyses.

Independent variable: Race. To minimize missing race data and to obtain the most accurate data possible, we combined multiple years of inpatient and outpatient race data to obtain one race value for each individual. Self-reported race is by definition the “gold standard” in race identification and is preferable to observed race.^{21, 22} Self-reported race has been available in VHA datasets since 2003, due to VHA Directive 2003-027, which mandated that self-reported race and self-reported ethnicity be gathered separately in VHA.²³ However, outpatient race data²⁴ and self-report data are often missing in VHA datasets. In addition, we knew that there was a strong concordance between observed and self-rated data in these same datasets.²⁵

Therefore, in order to construct one race variable for all patients, the available race information was prioritized in the following manner: (1) self-reported race from inpatient record, (2) observed race from inpatient record, (3) self-reported race from outpatient visits, and then, (4) observed race from outpatient visits. If self-reported race data were available in the inpatient data and were consistent over multiple records (for patients with more than one hospitalization), then those data (six race variables and one for ethnicity) were used to determine final race. If self-reported race values were inconsistent, the race recorded in the majority of cases was used. If no majority could be determined, then race data from the next category were obtained, continuing to move down the categories until no further reliable race information was available.

The self-reported race collected since 2003 is based on six race variables and one ethnicity variable, thereby allowing for various multiracial combinations of race and ethnicity. However, prior to 2003, the observed race data consisted of one variable with seven mutually exclusive categories: Hispanic white, Hispanic black, American Indian, Asian, black, white, and unknown. Therefore, as a final step in constructing one race variable, it was necessary for us to reconstruct the new race data into a single-category race variable that took on the following mutually exclusive values: white, African American, Latino, Asian American/Pacific Islander (whom we refer to henceforth as Asian American), and American Indian/Alaska Native (whom we refer to as American Indian).

We assigned multiracial veterans to a single race category using a standard bridging technique that assigns multiracial individuals to the largest (i.e., most prevalent) minority group of which they are members. This technique has been found to make almost no difference to the sizes of the white and African American groups and little difference to the size of other minority groups,²⁵ thereby allowing us to exclude multiracial individuals from the white reference group. Veterans whose self-reported ethnicity was Hispanic or Latino and self-reported race was white, African

American, or missing were considered Latino, as were those with observed races of Hispanic white or Hispanic black collected prior to 2003.

Control variables: Comorbid conditions. The 27 comorbidities are a subset of the 30 comorbidities identified by Elixhauser, et al., and known to be related to patient utilization, cost, and mortality.²⁶ The comorbidities were generated by running the AHRQ Comorbidity Software (version 3.1)¹⁹ on PTF discharge records and are based on ICD-9-CM codes and DRGs. The comorbidities include congestive heart failure, valvular disease, pulmonary circulation disorders, peripheral vascular disorders, hypertension, paralysis, other neurological disorders, chronic pulmonary disease, diabetes without chronic complications, diabetes with chronic complications, hypothyroidism, renal failure, liver disease, peptic ulcer disease, AIDS, lymphoma, metastatic cancer, solid tumor without metastasis, rheumatoid arthritis or collagen vascular diseases, obesity, weight loss, chronic blood loss anemia, deficiency anemias, alcohol abuse, drug abuse, psychoses, and depression.

Analyses

We ran the AHRQ Comorbidity Software¹⁹ and the AHRQ SAS PSI Software²⁰ on 5 years of VHA discharge data to obtain indicators for the 27 comorbidities and for each PSI and to calculate observed and risk-adjusted rates for each PSI. The risk adjustment uses the Health Care Cost and Utilization Project State Inpatient Databases (HCUP-SID) as the reference population. We then ran a Generalized Estimating Equations (GEE) logistic regression model to examine the relationship between race and the occurrence of a PSI, adjusting for age, sex, and the 27 comorbidities. The GEE model allows us to control for clustering at the hospital level.

Although there may be multiple hospitalizations per veteran, we did not control for repeated measures at the individual level. Instead, we controlled for clustering at the hospital level for two reasons: (1) to make the results more comparable to results outside the VHA, where repeated hospitalizations by the same patient are often treated as independent because data on multiple hospitalizations are not always available; and (2) to adjust for unknown hospital characteristics thought to have an impact on patient safety outcomes in addition to the patient characteristics in our model, such as patient safety culture. All analyses were conducted using SAS[®], ver. 9.1.3 for Windows (SAS Institute Inc., Cary, NC).

Results

Table 1 shows the sample characteristics overall and by race at the hospitalization level. By supplementing inpatient records with outpatient race data, we were able to lower the number of records with missing race from 9.0 percent to 3.6 percent. Overall, our sample was 73 percent white, 19 percent African American, 3.2 percent Latino, 0.8 percent Asian American/Pacific Islander, and 0.5 percent American Indian/Alaska Native. The racial groups differed significantly on all demographic and clinical characteristics examined, including age, percentage of female

Table 1. Sample characteristics by race and overall

	Overall	White	African American	Latino	Asian American/ Pacific Islander	American Indian/ Alaska Native
Hospitalizations (N)	2,198,674	1,664,488	432,721	72,728	17,051	11,686
Mean age (years)	64.94	65.73	62.09	64.20	65.57	61.41
Sex (%)						
Male	96.82	96.87	96.39	98.37	96.6	95.76
Female	3.18	3.13	3.61	1.63	3.40	4.24
Race (%)						
White	72.96					
African American	18.97					
Latino	3.19					
Asian American/ Pacific Islander	0.75					
American Indian/ Alaska Native	0.51					
Comorbidities (%)						
Deficiency anemias	11.46	10.67	14.56	10.87	12.16	12.01
Congestive heart failure	7.22	7.36	6.98	5.49	7.04	6.32
Depression	5.63	6.06	4.18	4.49	5.34	6.81
Diabetes, no chronic complications	21.8	21.4	22.29	26.76	24.9	23.71
Hypertension	47.10	45.93	51.82	46.06	50.31	41.46
Peripheral vascular disease	5.79	6.20	4.50	4.30	5.68	4.35
Obesity	3.20	3.46	2.37	2.22	3.11	3.65
Weight loss	2.39	2.43	2.39	1.70	1.92	3.00

NOTE: ANOVA (for age), and Chi-square analyses (for all other variables), revealed significant differences ($P < 0.0001$) in all sample characteristics across racial groups.

veterans, and the prevalence of comorbidities ($P < 0.0001$ for all). The average age of hospitalized patients was 64.9 years, ranging from 18 to 112 years. On average, only 3.2 percent of hospitalizations were of women, although this varied by race, such that 1.6 percent of Latinos and 4.2 percent of American Indians hospitalized during this time were women. Racial groups also differed in the prevalence of comorbidities. For example, nearly 52 percent of African American veterans had hypertension compared to only 42 percent of American Indians; nearly 27 percent of Latino veterans had diabetes, compared to only 21 percent of white veterans.

Tables 2a and 2b show the number of hospitalizations at risk for each PSI (the denominator), the number who potentially had the AE (the numerator), both overall and by race group. The number of patients at risk for each PSI varied from 93,488 to 2,280,482. However, because of the relatively small percentage of our sample in certain racial groups (in particular, American Indians and Asian Americans, and for a few selected PSIs, Latinos), both the number of hospitalizations at risk for many of the less frequent PSIs and the number of hospitalizations with PSIs were quite low. For example, the number of American Indians in the denominator varied from 507 to 11,678 based on the PSI, and the numerator varied from 1 to 70. Consequently, some events were extremely rare: only one Asian American and two American Indians had a PSI for postoperative sepsis (PSI 13), and no Asian Americans had a PSI for postoperative hip fracture (PSI 8).

The observed and risk-adjusted PSI rates are also shown in Tables 2a and Table 2b, with the exception of the PSIs for death in low mortality DRGs (PSI 3) and foreign body left during procedure (PSI 5), for which only observed rates are reported. The AHRQ PSI software does not generate risk-adjusted rates for these PSIs because their occurrence is thought to be independent of patient risk factors.¹⁸ We found some variation in PSI rates across racial groups, with a wide range in rates for some PSIs [e.g., rates per 1,000 hospitalizations of failure to rescue (PSI 4) ranged from 124.0 for African Americans to 174.5 for Latinos; rates per 1,000 of postoperative hemorrhage or hematoma (PSI 9) ranged from 1.97 for Latinos to 3.12 for African Americans]. Although differences in rates were not necessarily significantly different from each other, every racial group had the highest rate for at least two PSIs, and all minority groups also had the lowest rate for at least two PSIs.

African Americans had the highest rates of all racial groups for postoperative hemorrhage or hematoma (PSI 9) and postoperative PE/DVT (PSI 12), but they had the lowest rates for failure to rescue (PSI 4), foreign body left during procedure (PSI 5), postoperative wound dehiscence (PSI 14), and accidental puncture or laceration (PSI 15). Latinos had the highest rates for death in low mortality DRGs (PSI 2), decubitus ulcer (PSI 3), and failure to rescue (PSI 4), but they had the lowest rates for postoperative hemorrhage or hematoma (PSI 8) and postoperative derangements (PSI 9).

American Indians had the highest rates for the most PSIs (six PSIs), whereas Asian Americans had the lowest rates for the most PSIs (six PSIs). However, the rates for these latter two groups may be less meaningful given the small number of hospitalizations for some of the PSIs in these racial groups. We also looked at PSIs by dividing them into postsurgical PSIs (PSIs 8 to 14) and medical/surgical PSIs (PSIs 1 to 7, 15), but we were not able to discern any pattern by race, with the exception of Latinos seeming to have a higher probability of experiencing the medical/surgical PSIs.

Table 2a. PSI counts and PSI rates by race

PSIs	Overall				White				African American			
	At risk ^a	#PSI ^b	Obs rate ^c	RA rate ^d	At risk	#PSI	Obs rate	RA rate	At risk	#PSI	Obs rate	RA rate
(1) Complications of anesthesia	498,290	370	0.74	0.73	377,382	302	0.80	0.77	77,407	39	0.50	0.52
(2) Death in low mortality DRGs	319,674	905	2.83		234,398	638	2.72		59,983	163	2.72	
(3) Decubitus ulcer	1,008,677	15,331	15.20	16.71	733,735	10,399	14.17	15.92	193,263	3,307	17.11	17.78
(4) Failure to rescue	117,598	16,132	137.18	138.9	80,413	10,776	134.01	137.60	26,726	3,227	120.74	124.02
(5) Foreign body left during procedure	2,281,183	269	0.12		1,664,415	200	0.12		432,700	42	0.10	
(6) Iatrogenic pneumothorax	2,149,966	1,838	0.85	1.08	1,561,928	1,407	0.90	1.13	415,555	298	0.72	0.95
(7) Selected infections due to care	1,673,511	3,255	1.95	1.56	1,244,513	2,402	1.93	1.57	296,214	574	1.94	1.46
(8) Postoperative hip fracture	358,940	140	0.39	0.52	272,075	109	0.40	0.53	56,011	19	0.34	0.46
(9) Postop hemorrhage or hematoma	495,450	1,580	3.19	2.72	375,342	1,199	3.19	2.71	76,829	275	3.58	3.12
(10) Postoperative derangements	240,093	499	2.08	1.84	185,094	391	2.11	1.90	33,599	61	1.82	1.49
(11) Postop respiratory failure	180,072	2,405	13.36	10.26	136,776	1,863	13.62	10.28	26,789	327	12.21	10.01
(12) Postop PE/DVT	494,321	5,580	11.29	9.55	374,634	4,082	10.90	9.40	76,512	1,029	13.45	10.30
(13) Postop sepsis	93,488	617	6.60	6.36	73,133	501	6.85	6.60	12,376	66	5.33	5.23
(14) Postop wound dehiscence	99,095	641	6.47	3.39	73,795	527	7.14	3.61	15,924	68	4.27	2.55
(15) Accidental puncture or laceration	2,280,482	6,749	2.96	4.43	1,663,879	5,222	3.14	4.53	432,607	887	2.05	3.74

a = Number of hospitalizations at risk (denominator); b = Number of hospitalizations at risk with PSI (numerator); c = Observed rate of PSI per 1,000 hospitalizations.; d = Risk-adjusted rate of PSI per 1,000 hospitalizations (AHRQ PSI software does not generate risk-adjusted rates PSIs 2 and 5).

Table 2b. PSI counts and PSI rates by race

PSIs	Latino				Asian/Pacific Islander				American Indian/Alaskan Native			
	At risk ^a	#PSI ^b	Obs rate ^c	RA rate ^d	At risk	#PSI	Obs rate	RA rate	At risk	#PSI	Obs rate	RA rate
(1) Complications of anesthesia	15,853	8	0.50	0.53	4,068	7	1.72	1.69	2,483	1	0.40	0.41
(2) Death in low mortality DRGs	9,999	34	3.40		2,447	3	1.23		1,971	4	2.03	
(3) Decubitus ulcer	33,348	725	21.74	22.63	7,226	95	13.15	14.00	4,952	65	13.13	15.28
(4) Failure to rescue	4,215	803	190.51	174.45	816	93	113.97	129.93	590	70	118.64	125.34
(5) Foreign body left during procedure	72,724	13	0.18		17,050	5	0.29		11,684	2	0.17	
(6) Iatrogenic pneumothorax	68,928	41	0.59	0.85	16,048	13	0.81	1.05	11,074	5	0.45	0.63
(7) Selected infections due to care	54,211	107	1.97	1.57	12,328	17	1.38	1.12	8,875	22	2.48	1.99
(8) Postoperative hip fracture	11,684	5	0.43	0.62	2,972	0	0.00	0.00	1,673	2	1.20	1.97
(9) Postop hemorrhage or hematoma	15,766	36	2.28	1.97	4,042	12	2.97	2.52	2,472	8	3.24	3.00
(10) Postoperative derangements	7,028	10	1.42	1.32	2,060	5	2.43	1.83	1,169	5	4.28	3.44
(11) Postop respiratory failure	5,498	71	12.91	11.07	1,514	18	11.89	9.57	922	18	19.52	16.38
(12) Postop PE/DVT	15,736	148	9.41	8.35	4,043	45	11.13	9.67	2,474	18	7.28	6.46
(13) Postop sepsis	2,653	14	5.28	5.14	767	1	1.30	1.26	525	2	3.81	3.79
(14) Postop wound dehiscence	3,267	15	4.59	2.71	775	5	6.45	3.61	507	5	9.86	5.06
(15) Accidental puncture or laceration	72,712	208	2.86	4.49	17,041	55	3.23	4.56	11,678	34	2.91	4.62

a = Number of hospitalizations at risk (denominator); b = Number of hospitalizations at risk with PSI (numerator); c = Observed rate of PSI per 1,000 hospitalizations.;
d = Risk-adjusted rate of PSI per 1,000 hospitalizations (AHRQ PSI software does not generate risk-adjusted rates PSIs 2 and 5).

Table 3. Odds of PSI for minority vs. white veterans

PSI	Odds ratios			
	African American vs. white	Latino vs. white	Asian American / PI vs. white	American Indian vs. white
(1) Complications of anesthesia	0.63*	0.65	2.19	0.55
(2) Death in low mortality DRGs	1.18	1.32	0.44	0.94
(3) Decubitus ulcer	1.35**	1.60*	0.90	1.02
(4) Failure to rescue	0.98	1.55	0.92	0.91
(5) Foreign body left during procedure	0.84	1.53	2.49	1.46
(6) Iatrogenic pneumothorax	0.88	0.75	0.95	0.56
(7) Selected infections due to care	1.02	1.03	0.73	1.22
(8) Postop hip fracture	0.82	1.09	NA***	3.23
(9) Postop hemorrhage/hematoma	1.13	0.73*	0.93	1.05
(10) Postop derangements	0.76	0.63	0.99	1.89
(11) Postop respiratory failure	1.00	1.05	0.92	1.53
(12) Postop PE/DVT	1.23**	0.89	1.03	0.69
(13) Postop sepsis	0.94	0.83	0.20	0.58
(14) Postop wound dehiscence	0.71*	0.72	0.99	1.46
(15) Accidental puncture or laceration	0.69**	0.94	1.05	0.97

* Significant at $\alpha = 0.05$ level.

** Significant after Bonferroni adjustment for multiple comparisons, $P < 0.00083$.

*** No Asian American patients had a PSI for postoperative hip fracture.

Table 3 summarizes the results of our logistic regressions, showing the odds of a minority veteran having a PSI compared to the odds of a white veteran having the same PSI. Most of the odds ratios were not significantly different from one. However, compared to white veterans, African Americans were significantly more likely to have a PSI for decubitus ulcer (OR = 1.35, $P < 0.0001$) and for postoperative PE/DVT (OR = 1.23, $P < 0.0001$). On the contrary, they were significantly less likely to have a PSI for accidental puncture or laceration (OR = 0.69, $P = 0.0003$), complications of anesthesia (OR = 0.63, $P = 0.0144$), and postoperative wound dehiscence (OR = 0.71, $P = 0.0298$). Compared to white veterans, Latino veterans were also significantly more likely to have a PSI for decubitus ulcer (OR = 1.60, $P = 0.041$) but significantly less likely to have a PSI for postoperative hemorrhage or hematoma (OR = 0.73, $P = 0.0311$). With a Bonferroni adjustment for multiple comparisons, only those ORs with P -values below $\alpha = 0.00083$ were considered significant, which meant that only the first three

differences above were significantly different from those of white veterans. Figure 1 shows these same results but in a graphical format to provide a more visual perspective of the confidence intervals (CIs) for each OR. ORs were significantly different from one another when their CIs

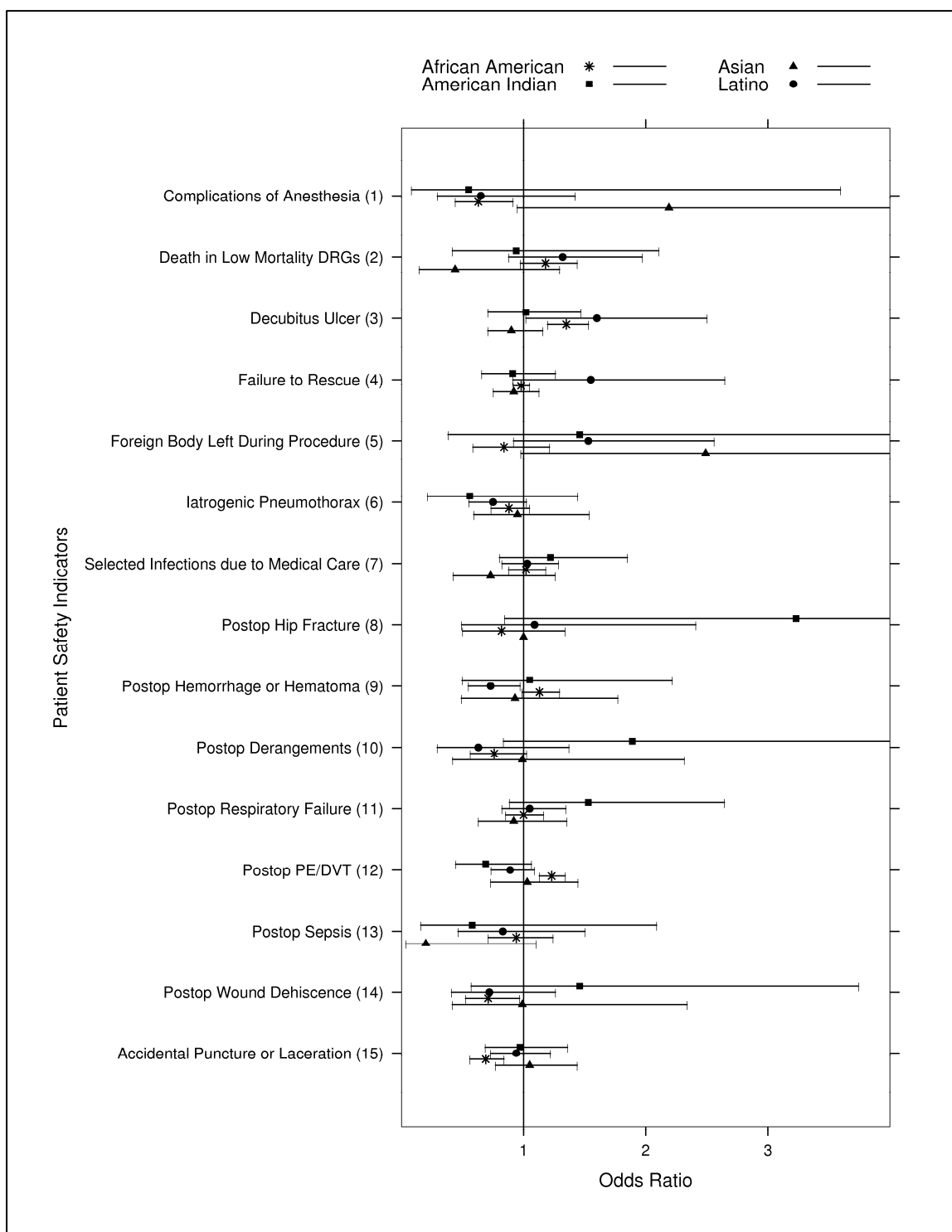


Figure 1. Odds of having a PSI for minority vs. white veterans.

(the horizontal bars) did not overlap with each other and significantly different from 1.0 when the CIs did not overlap with the vertical line representing OR = 1.0. In most instances, the CIs were very wide, overlapping both with the CIs of other racial groups and with OR = 1.0.

Discussion

Our goal was to examine whether patient safety events varied across different races in the VHA. We used PSIs to explore whether the odds of experiencing an AE varied by patient race. We hypothesized that there might be fewer racial disparities in patient safety events due to previous research showing fewer racial disparities in the quality of care and health outcomes in the VHA.^{11, 12, 13} As expected, we found fewer disparities between whites and minorities in the VHA than did previous non-VHA researchers.^{2, 6} Only 7 of 60 ORs comparing the odds of a minority having a given PSI to similar odds for whites were significant at the $\alpha = 0.05$ level. After Bonferroni adjustment for multiple comparisons, only three of these ORs were significant. When we compared PSI rates across groups, no racial groups had consistently higher or lower rates compared to other groups. All racial groups had some of the highest rates and all minority groups had some of the lowest rates. Looking at the PSIs by dividing them into postsurgical and medical/surgical PSIs did not reveal any noteworthy patterns.

It is possible that had our minority subsamples been larger, we might have been able to distinguish clearer patterns in PSI rates and/or more significant differences in the odds of experiencing PSIs. For example, the odds of postoperative hip fracture for American Indians was over three times that for white veterans, but this difference was only marginally significant (OR = 3.23, $P = 0.087$) in the logistic regression analysis. A larger sample of American Indians at risk for this PSI would likely have narrowed the CI for the OR.

One possible explanation for fewer disparities within VHA is that it is more of an equal access system than the hospitals that make up the data set (HCUP-SID) used in prior studies of PSIs in non-VHA hospitals. The VHA is the Nation's largest, fully integrated health care delivery system, as opposed to the community hospitals represented in the HCUP-SID data. The VHA underwent rapid and significant transformation in the late 1990s, including changes in organization, financing, eligibility, and new emphases on performance management and quality improvement (QI).²⁷ Veterans with service-connected disabilities and those who meet VHA means testing criteria are eligible to receive services and prescription drugs for very low or no copayments and, thus, are most likely to rely on VHA care.²⁸ Because of these criteria, those who exclusively utilize VHA services tend to be minority veterans, those with lower incomes or lower levels of education, and homeless veterans.^{27, 28, 29} Veterans receiving their care at the VHA are therefore more socioeconomically homogenous than patients in other settings. Because there are fewer financial barriers to access within VHA, there are likely to be fewer racial disparities in access to care.¹⁵

Coffey, et al.,² also found that after controlling for income, many of the disparities in PSI rates disappeared for Latinos and Asian Americans but remained for African Americans. Interestingly, all three of the ORs that remained significant in our analysis after Bonferroni adjustment ($\alpha = 0.00083$) compared the odds of an African American having a PSI vs. whites. These results are consistent with what might be expected in a more socioeconomically homogeneous population.

However, these results might be due to the small number of veterans in some minority groups. Future work should assess why African American patients might experience significant disparities when other groups do not.

The PSIs for which minorities have significantly higher rates—decubitus ulcer (PSI 3) and postoperative PE/DVT (PSI 12)—tend to be higher frequency PSIs, whereas those for which whites have significantly higher rates—iatrogenic pneumothorax (PSI 6) and postoperative sepsis (PSI 13)—are lower frequency PSIs. The influence of patient safety events primarily depends on the frequency of the event and the potential long-term impact. For example, if the risk-adjusted rate of the PSI for decubitus ulcer in white patients (15.92 per 1,000 hospitalizations) had applied to the African American and Latino hospitalizations, there would have been approximately 360 fewer PSIs for decubitus ulcer among African Americans and 224 fewer among Latinos during the 5-year period. Because African American patients have higher mortality rates from decubitus ulcer than other racial groups,³⁰ and because they are more likely to exclusively rely on VHA for their care,²⁸ preventing these cases takes on added importance.

It might not be possible, however, to lower decubitus ulcer rates to the same level as for white patients. There may be race-related differences in underlying reasons for differences in PSI rates. For example, African American and Latino veterans are at higher risk of decubitus ulcers than whites.³¹ Stage I decubitus ulcers, typically identified by locating nonblanchable erythema of intact skin, can be difficult to identify in patients with dark skin pigmentation³² for whom the blanch response might not be present; other indicators—such as skin darkening or discoloration, warmth, edema, or induration—might be identified instead. If caregivers are not trained to recognize those signs in darker pigmented patients, or if they fail to take the additional time to look for them, then such patients are more likely to have ulcers that progress to stage II (skin breakdown) and beyond and are less likely to have a pre-existing stage I decubitus ulcer documented at the time of admission.³¹ Also, because administrative data cannot completely account for risk factors—such as smoking, body weight, and malnutrition—differences in risk due to racial differences in the distribution of underlying risk factors will appear to constitute a racial difference in preventable AEs. Nonetheless, because of the increased treatment costs, unnecessary suffering, and increased mortality associated with pressure ulcers, in addition to continuing efforts to lower decubitus ulcer rates overall, it is important for the VHA to eliminate racial disparities in pressure ulcer rates.

A few limitations should be noted, including some that are relevant to most studies using the PSIs or administrative data. First, we are in the process of fully validating the PSIs in VHA and do not yet have data on the likelihood that a given PSI has accurately flagged all related preventable AEs that occurred during the index hospitalization. Also, we cannot eliminate the possibility that a patient was admitted with an undocumented condition, such as a stage I decubitus ulcer, present on admission, which would artificially inflate the rate of preventable AEs. Recent research suggests that certain PSIs (such as decubitus ulcer, hip fracture, and PE/DVT) are frequently present on admission.³³ Although we expect that PSIs under- or overestimate AE rates evenly across racial groups, differences in observed PSI rates could arise if there were racial differences in documentation, data coding, or in the frequency or severity of a particular procedure or diagnosis code more often associated with AEs that were not actually preventable.

Second, as mentioned earlier, despite our attempt to create large subgroups by using 5 years of data, the percentage of our sample in the Latino, Asian American, and American Indian groups was very small. Therefore, there were too few cases in the numerator of many PSIs to provide stable estimates of the ORs comparing the odds of experiencing a PSI in these groups to that of white patients.

Third, because we bridged newer self-reported race data with the older observed data that did not provide information on multiple races, the race groups could have varied slightly in size and membership based on the bridging method used. It is possible that the bridging technique we used to merge self-reported race and ethnicity with pre-2003 VHA race data might have influenced our findings. The racial breakdown of our sample differs somewhat from previously reported distributions from a survey of veterans showing the respective distributions to be 79.7 percent white, 13.2 percent African American, 5.2 percent Latino, 0.8 percent Asian American, and 1.1 percent American Indian.³⁴ Our numbers are, however, more similar to the distribution of 78 percent, 18 percent, 5.8 percent, 1.4 percent, and 0.4 percent, respectively, reported by Sohn, et al.,²⁵ when examining race data for all VHA users in 2004, including both self-reported and observed race data.

Fourth, because our analyses were restricted to veterans who were hospitalized within VHA during a 5-year period, differences in race distribution might also reflect racial differences in veterans having access to outside sources of health care, such as private insurance or hospitals reimbursed by Medicare. For example, African American veterans are more likely to rely on VHA as their only source of care,²⁸ and they made up a slightly higher percentage of our sample than would be expected based on prior research.^{25, 34}

Finally, because the VHA system and its patient population differ significantly from the general population, these findings might not be generalizable outside the VHA. VHA patients not only have lower socioeconomic status, they also tend to have greater disease burden, including a higher prevalence of mental health disorders.^{35, 36} Because of the small percentage of veterans who are women of childbearing age, we also were unable to look at disparities in the PSIs related to childbirth.

Conclusion

To summarize, we found fewer racial disparities in PSI rates in the VHA than have been reported outside the VHA. The VHA has invested much energy into improving care and has expended significant resources to improve quality and patient safety through efforts such as the VHA Quality Enhancement Research Initiative (QUERI) program³⁷ and the creation of a VHA National Center for Patient Safety.³⁸ Previous research has shown that minorities receive as good or better treatment with better outcomes for a number of health conditions in the VHA.^{13, 15} Although a number of possible alternate explanations have been presented above, the low number of significant racial differences in PSI rates might very well be another example of more equal treatment and outcomes within VHA. Nevertheless, any differences that suggest patient race might influence the risk of experiencing a patient safety event must be investigated to better understand the underlying reasons for any differences before the differences can be eliminated.

Do these differences arise from unmeasured patient characteristics or disparate treatment within hospitals, or are they the result of segregated health care, which research suggests could result in worse outcomes for black patients?^{39, 40} Future research should delve further into the disparities found, beginning with those PSIs occurring most frequently, identifying their causes and correlates, such as patient risk factors or the organizational characteristics of hospitals that might affect quality of care. Only by doing so will we be able to appropriately target future QI efforts.

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References

1. Smedley BD, Stith AY, Nelson AR, eds. Unequal treatment. Confronting racial and ethnic disparities in health care. Washington, DC: National Academies Press; 2003.
2. Coffey RM, Andrews RM, Moy E. Racial, ethnic, and socioeconomic disparities in estimates of AHRQ patient safety indicators. *Med Care* 2005; 43(3 Suppl): 148-157.
3. Rivard PE, Rosen AK, Carroll JS. Enhancing patient safety through organizational learning: Are patient safety indicators a step in the right direction? *Health Serv Res* 2006; 41(4 Pt 2): 1633-1653.
4. Rosen AK, Rivard P, Zhao S, et al. Evaluating the patient safety indicators: How well do they perform on Veterans Health Administration data? *Med Care* 2005; 43: 873-884.
5. Rosen AK, Zhao S, Rivard P, et al. Tracking rates of Patient Safety Indicators over time: Lessons from the Veterans Administration. *Med Care* 2006; 44: 850-861.
6. Romano PS, Geppert JJ, Davies S, et al. A national profile of patient safety in U.S. hospitals. *Health Aff (Millwood)*. 2003; 22: 154-166.
7. Zhan C, Miller MR. Administrative data based patient safety research: A critical review. *Qual Saf Health Care* 2003; 12 Suppl 2: ii58-ii63.
8. Rivard P, Elwy AR, Loveland S, et al. Applying Patient Safety Indicators across health care systems: Achieving data comparability. *Advances in patient safety: From research to implementation*. Vol 2, Concepts and methodology. AHRQ Pub. 05-0021-2. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol2/Rivard.pdf. Accessed April 4, 2008.

9. National healthcare disparities report. AHRQ Pub. 07-0012. Rockville, MD: Agency for Healthcare Research and Quality; 2006. Available at: www.ahrq.gov/qual/nhdr06/nhdr06report.pdf. Accessed April 4, 2008.
10. National healthcare disparities report. AHRQ Publication No. 06-0017; Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/qual/nhdr05/nhdr05.pdf. Accessed April 4, 2008.
11. Kressin NR, Wang F, Long J, et al. Hypertensive patients' race, health beliefs, process of care, and medication adherence. *J Gen Intern Med* 2007; 22: 768-774.
12. Deswal A, Petersen NJ, Soucek J, et al. Impact of race on health care utilization and outcomes in veterans with congestive heart failure. *J Am Coll Cardiol* 2004; 43: 778-784.
13. Petersen LA, Wright SM, Peterson ED, et al. Impact of race on cardiac care and outcomes in veterans with acute myocardial infarction. *Med Care* 2002; 40(1 Suppl): 186-196.
14. Volpp KG, Stone R, Lave JR, et al. Is thirty-day hospital mortality really lower for black veterans compared with white veterans? *Health Serv Res* 2007; 42:1613-1631.
15. Jha AK, Shlipak MG, Hosmer W, et al. Racial differences in mortality among men hospitalized in the Veterans Affairs health care system. *JAMA* 2001; 285: 297-303.
16. Kamalesh M, Subramanian U, Ariana A, et al. Diabetes status and racial differences in post-myocardial infarction mortality. *Am Heart J* 2005; 150: 912-919.
17. Peterson ED, Wright SM, Daley J, et al. Racial variation in cardiac procedure use and survival following acute myocardial infarction in the Department of Veterans Affairs. *JAMA* 1994; 271: 1175-1180.
18. AHRQ Quality Indicators Guide to Patient Safety Indicators, Ver. 3.0. Rockville, MD: Agency for Healthcare Research and Quality; 2006.
19. AHRQ Comorbidity Software [computer program]. Version 3.1; 2006.
20. AHRQ SAS PSI Software [computer program]. Ver. 3.0; 2006.
21. Provisional guidance on the implementation of the 1997 Standards for Federal Data on Race and Ethnicity: Tabulation Working Group, Interagency Committee for the Review of Standards for Data on Race and Ethnicity; December 15, 2000.
22. Revisions to the standards for the classification of Federal data on race and ethnicity: Washington, DC: Executive Office of the President, Office of Management and Budget (OMB), Office of Information and Regulatory Affairs; October 30, 1997.
23. Veterans Health Administration. VHA Directive 2003-027, Capture of race and ethnicity categories. Washington, DC: Department of Veterans Affairs, Veterans Health Administration; 2003.
24. Jia H, Zheng YE, Cowper DC, et al. Race/ethnicity: Who is counting what? *J Rehabil Res Dev* 2006; 43: 475-484.
25. Sohn MW, Zhang H, Arnold N, et al. Transition to the new race/ethnicity data collection standards in the Department of Veterans Affairs. *Popul Health Metr* 2006; 4: 7.
26. Elixhauser A, Steiner C, Harris DR, et al. Comorbidity measures for use with administrative data. *Med Care* 1998; 36: 8-27.
27. Kizer, KW, Demakis, JG, Feussner, JR. Reinventing VA health care: Systematizing quality improvement and quality innovation. *Med Care* 2000; 38(6 Suppl 1): 17-116.
28. Hynes DM, Koelling K, Stroupe K, et al. Veterans' access to and use of Medicare and Veterans Affairs health care. *Med Care* 2007; 45: 214-223.
29. Nelson KM, Starkebaum GA, Reiber GE. Veterans using and uninsured veterans not using Veterans Affairs (VA) health care. *Public Health Rep* 2007; 122: 93-100.
30. Redelings MD, Lee NE, Sorvillo F. Pressure ulcers: More lethal than we thought? *Adv Skin Wound Care* 2005; 18: 367-372.
31. Rosen J, Mittal V, Degenholtz H, et al. Pressure ulcer prevention in black and white nursing home residents: A QI initiative of enhanced ability, incentives, and management feedback. *Adv Skin Wound Care* 2006; 19: 262-268.
32. Scanlon E, Stubbs N. Pressure ulcer risk assessment in patients with darkly pigmented skin. *Prof Nurse* 2004; 19: 339-341.
33. Houchens R, Elixhauser A, Romano PS. How often are potential "Patient Safety Events" present on admission? Manuscript submitted for publication.
34. Kressin NR, Chang BH, Hendricks A, et al. Agreement between administrative data and patients' self-reports of race/ethnicity. *Am J Public Health* 2003; 93: 1734-1739.
35. Rosen AK, Loveland S, Anderson JJ, et al. Evaluating diagnosis-based case-mix measures: How well do they apply to the VA population? *Med Care* 2001; 39: 692-704.

36. Rosen AK, Loveland S, Anderson JJ, et al. Diagnostic cost groups (DCGs) and concurrent utilization among patients with substance abuse disorders. *Health Serv Res* 2002; 37: 1079-1103.
37. VA Quality Enhancement Research Initiative (QUERI) Web site. Washington, DC: Department of Veterans Affairs; 2007. Available at: www.hsrd.research.va.gov/QUERI/. Accessed April 4, 2008.
38. National Center for Patient Safety. Ann Arbor, MI: Department of Veterans Affairs; 2007. Available at: www.va.gov/NCPS/. Accessed April 4, 2008.
39. Skinner J, Chandra A, Staiger D, et al. Mortality after acute myocardial infarction in hospitals that disproportionately treat black patients. *Circulation* 2005; 112: 2634-2641.
40. Kressin NR. Separate but not equal: The consequences of segregated health care. *Circulation* 2005; 112: 2582-2584.

Challenges and Lessons Learned

Patient Safety Learning Pilot: Narratives from the Frontlines

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Abstract

Although patient safety experts have focused on event reporting and on the role of sensemaking and human factors in learning from events, there has been little study of how these factors are received and used by frontline hospital workers. Consequently in 2003, the Centers for Medicare & Medicaid Services—in collaboration with patient safety experts and the Agency for Healthcare Research and Quality—designed and implemented a patient safety improvement prototype in four hospitals. The prototype included an event reporting system (the Medical Events Reporting System - Total HealthSystem [MERS-TH]); use of collective sensemaking to maximize learning from events; and a focus on the role of human factors engineering in understanding events and in finding remedies for the causes of system failures. Study findings showed that both the MERS-TH methods and tools and collective sensemaking were extremely useful to frontline hospital workers for increasing learning from events. In addition, although frontline workers came to understand the value of human factors engineering in reducing patient harm, they were faced with limited access to this expertise at the community hospital level.

Introduction

The organization and delivery of health care is complex. This complexity includes the delivery of care in the organizational context^{1, 2} of hospitals, as well as that associated with the increasingly complex clinical diagnostic and treatment practices involved in caring for patients.³ Complexity magnifies the opportunity for inevitable human errors to cause harm to patients.⁴ Therefore, a central theme in improving patient safety requires addressing this complexity.

To date, a number of approaches, methods, and tools have been developed to improve patient safety in hospitals. These include, but are not limited to, retrospective methods—such as the reporting and investigation of events and making sense of the findings of these investigations—and applying human factors engineering principles to understand human and system failures and using this information to design improvements. Although patient safety experts have paid considerable attention to designing and planning for the implementation of these methods, how these methods have been received, interpreted, and used by health care professionals working on the frontlines of care in hospitals has been less well-studied.^{5, 6, 7}

In 2003, in order to further our understanding of this component of patient safety, the Centers for Medicare & Medicaid Services (CMS), in collaboration with experts from the Agency for Healthcare Research and Quality (AHRQ) and external patient safety experts, designed a patient

safety improvement prototype, the Medicare Patient Safety Learning Pilot (PSLP). The prototype was designed to include event reporting and principles from the sensemaking and human factors engineering disciplines.

Herein, we describe the components of an intervention, the patient safety improvement prototype, and its implementation in four hospitals. Our assessment of how the components of the prototype were received, interpreted, and used by health care professionals is presented in the form of narratives. These narratives were collected from health care professionals working on the frontlines of clinical microsystems within the hospitals.

Methods

In designing and implementing the Patient Safety Improvement Prototype, our interest was in learning more about how three of the components of the intervention were interpreted and used by frontline workers in four selected hospitals. In this section, we describe the qualitative data collection and analysis methods⁸ used to assess how the intervention was received, interpreted, and used by health care professionals working on the frontlines of clinical microsystems within the hospitals.

The Patient Safety Improvement Prototype

The patient safety improvement prototype included the following components:

- The Medical Events Reporting System-Total HealthSystem (MERS-TH), a reporting system that facilitates process improvement through systematic collection, prioritization, investigation, classification, interpretation, and monitoring of information about near-miss and actual events.
- Methods designed to make sense of near misses or actual events.
- Methods designed to assure that knowledge gained from event investigations and recommendations for improvements are informed by principles from human factors engineering.
- A method for implementing organizational changes.
- Methods for engaging hospital leadership to support clinical microsystem staff.^a

Medical Events Reporting System: Total HealthSystem (MERS-TH)

MERS-TH is an expanded version of the Medical Events Reporting System for Transfusion Medicine (MERS-TM),^{9, 10, 11} developed with funding by the National Heart, Lung, and Blood Institute for use in transfusion medicine. AHRQ funded expansion of MERS-TM to MERS-TH for use in all domains in health care. MERS-TH is a unique reporting system, since it is also a comprehensive error management system.

^a Although we describe the methods for implementing organizational changes and for engaging hospital leadership, we do not report findings on these two components in this report.

MERS-TH has several components. Initially, errors are detected by hospital staff who complete Event Registration and Event Discovery forms in a Web-based database. Appropriate managers and quality assurance or quality/performance improvement personnel are notified of the event via an email containing a link to the event. The manager completes a brief form, and the quality assurance (QA) specialist codes the event type and analyzes a software-generated risk assessment. The QA staff then queries the local database to see if there are similar events that have already been fully investigated.

If matching cases are identified, rather than repeating the causal analysis, the new event is linked to the prior event, and the causal codes are shared. If the new event has not been seen before or is unique, the QA staff carries out an expanded investigation. Based on permissions, events entered into the local database may be accessible for multi-institutional analysis. In this project, however, we used only a local, hospital-based electronic MERS-TH database.

The expanded investigation includes a root cause analysis, which is supported with a visual representation—the “causal tree” (Figure 1). On the failure side (Figure 1), the causal tree, which is constructed retrospectively, represents a map of how the antecedent activities and their root causes unfolded over time to contribute to the consequent or discoverable event. In cases in which there was recovery, as in a near miss, the antecedent activities and decisions provide significant information as to how the recovery occurred. Although it may appear that there is a single root cause, the most fruitful learning comes from a consideration of the combinations of the root causes.⁹

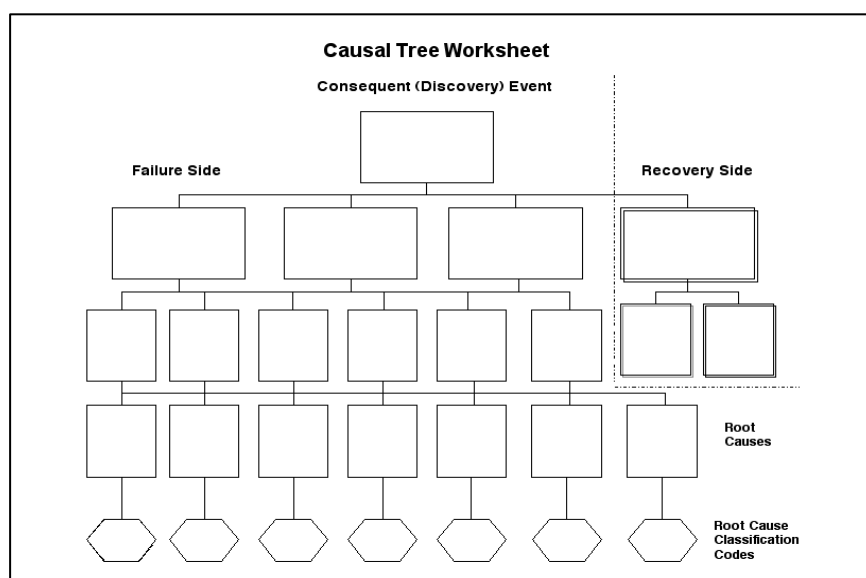


Figure 1. A blank causal tree worksheet, which is used to draw, chronologically, the critical antecedent activities and decisions that lead to an event and possible recovery. Available at:

www.mers-tm.net/support/codes_tools/form_CausalTree_blank.html

Next, root causes are coded using a medical version of the Eindhoven Classification Model.¹² The Eindhoven Classification Model—informed by principles from the human factors discipline and organizational sciences—focuses on three categories of causes of events: technical, organizational, and human.

Sensemaking

“The concept of sensemaking is well named because, literally, it means making of sense,” notes Weick.¹³ Several recent publications have highlighted the role of sensemaking in improving patient safety.^{14, 15, 16, 17} Sensemaking has to do with the way we interrupt our day-to-day activities when we are confronted with an unexpected event and how we pay attention to the reasons for such an event. We want to know why the unexpected event happened so that we can resume our interrupted activity.¹⁷ Insofar as mistakes or errors can be considered to be unexpected disruptions, those confronted with disruptions engage in sensemaking in order to continue their work. This “sensemaking” affords an opportunity for us to learn from mistakes, particularly when individuals share their sensemaking experiences. Sharing how we make sense of events helps reduce individual biases that come into play during our retrospective reconstruction of events. Hence, sensemaking enlarges and deepens our understanding of the underlying causes of the events. Although on the surface sensemaking seems like a simple process, we are just beginning to understand its significance in improving patient safety.

Human Factors Engineering

Human factors engineering is the discipline focused on understanding how the limitations, characteristics, and capabilities of humans should be central considerations in the design of tools, machines, and systems.¹⁸ Human factors engineering uses concepts from other domains such as anthropology, biomechanics, cognitive psychology, and organizational theory.¹⁸ Understanding the causes of events and near misses and how to avoid the harm they cause to patients requires knowledge of human capabilities and limitations. This knowledge moves us from surface level understanding to the next level—i.e., the place where we need to be to make meaningful changes that could improve patient safety.

Implementing Recommended “System” Changes

Although we do not report findings in this paper on how frontline workers received the component on implementing system changes, it is important to note that it was included in the prototype. Improving patient safety involves change, including how we view and organize our work in caring for patients. Although we included the Institute for Healthcare Improvement’s (IHI) rapid cycle improvement methodology¹⁸ for implementing changes required during this project, it is important to note that those who work in patient safety are more conservative about change than has been the case in quality improvement. Patient safety experts are schooled in human factors engineering and organizational sciences, and thus they are acutely aware of the potential for unintended negative consequences of surface changes in complex systems. Because complex organizational systems are resistant to superficial changes, it is important to base system changes on a deep understanding of the causes of events.²⁰

Engaging Hospital Administrative Leaders

Although this paper does not report on how this component of the patient safety improvement prototype was received by health care workers, it is important to note that it is a component of the prototype. We viewed engaging hospital administrative leaders as essential to supporting and sustaining any improvements made in the clinical microsystems. In addition, double-loop learning, essential to developing a learning organization, requires engagement of organizational

leaders.¹⁹ We intentionally cultivated participation by hospital administrative leaders in this project, including, but not limited to, use of the IHI's Executive WalkRounds.^{20, 21, 22}

Patient Safety Improvement Prototype: Intervention Implementation

Given our interest in frontline hospital staff, we chose to implement the prototype within clinical microsystems.^{23, 24, 25} Although at one level of analysis we tend to think of health care workers as carrying out their work in large and complex organizational settings, most of their work is done in small clinical microsystems. These microsystems include small groups of health care professionals providing care on a day-to-day basis for defined patient populations.²⁵ In addition, the patient safety improvement prototype was implemented using the IHI's collaborative model, with three learning sessions and action periods between the learning sessions.²⁶ The action periods were supported with biweekly calls to participating hospitals.

The Medicare Quality Improvement Organizations (QIOs) in Indiana and Wisconsin solicited participation of the four hospitals included in this report. A third QIO in Utah, provided additional support for the project. As a component of their selection for participation, administrators at each of the four hospitals were asked to read and concur with the principles included in the "just culture."²⁷ In addition, they were asked to support their clinical microsystem staff throughout their participation in the project, to attend the three learning sessions, and to install the local MERS-TH electronic database.

Qualitative Methods

Because our primary interest involved learning more about the way hospital frontline staff thought about and used the reporting system, sensemaking, and human factors, we used qualitative methods to collect narrative data throughout the project. Data sources included:

- Hospital presentations at the three learning sessions.
- Notes from biweekly telephone calls with hospitals during the action periods.
- Notes from sensemaking and human factors consultation visits to hospitals.
- Written responses to open-ended items (included in a data collection template) that were discussed during telephone calls with hospitals at the conclusion of the project.

Narratives from the Frontlines

Characteristics of the hospitals, their participating clinical microsystems, and their project aims and goals are summarized in Table 1. In the process of implementing the prototype, each participating hospital formed a project team with members from administration, the patient safety and quality improvement staff, and the clinical microsystem. In addition, the teams included the pilot project lead from the QIO, who played a largely educational role with regard to the components of the patient safety improvement prototype.

The MERS-TH local software was installed within the context of the hospitals' existing reporting systems, which are described in Table 2. Two characteristics common to the existing reporting systems in the four hospitals are of note: limited involvement of frontline staff (i.e., those who may have been the first to discover the event) in active discussions of the findings of

the event investigation, and the absence of a systematic classification system for the causes of events.

The extent to which the existing reporting systems captured near misses on a regular basis was unclear. Each participating hospital entered events in the MERS-TH database for their respective clinical focus areas. The number of events entered and the number of full investigations carried out over a 6-month period for each clinical focus area, respectively, were: anticoagulant management, 55 and 3; pain medication management, 42 and 4; medication management in the pharmacy, 240 and 3; and fall prevention, 55 and 2.

Noticing, Reporting, and Learning from Near Misses

We had considerable focus on near misses throughout the project, which was somewhat new for the participating hospitals. As noted in the two narratives below, although microsystem staff noticed near misses, they expressed hesitancy in reporting them.

“At Hospital C, a major challenge in implementing the patient safety pilot program was nurses’ explicit identification of near misses. Nursing has historically found the role of patient advocate to be at the core of care. Coordinating patient care in a manner that promotes patient safety is an intuitive component of this advocacy role. As such, nurses continuously monitor past, current, and upcoming aspects of their patients’ care and automatically address the issues they recognize to be placing their patients’ safety at risk. When asked to identify recovery steps involved in near misses, our nurses struggled to do so. To address this problem, the pilot team revisited the definition of a near miss. Based on this definition, they then asked staff to report any pain medication-related activities that did not result in an adverse outcome, but left them with an ‘Oh my goodness!’ feeling. Even with this new advice, the volume of near-misses remained low. Another factor leading to the low numbers of identified near misses was that team members acknowledged their difficulty in taking time away from patient care to complete their near-miss reports. This became evident when staff were asked for examples of near misses, and they readily recalled recent near misses. As a consequence, our team began to look for opportunities to encourage dialogue with staff so that near misses could be captured in verbal reports. Our future plans include a focus on verbal reporting of near misses during our safety rounds.”

“At Hospital A, pharmacy staff knew that near misses were more frequent than actual events, but they rarely reported them because they felt that the recoveries that occurred in near misses were evidence of an effective drug distribution system.”

Table 1. Characteristics of hospitals and their clinical microsystems participating in the Patient Safety Learning Pilot Project, 2003-2004

Hospital	Description	Clinical microsystem	Clinical focus	Aim
A	Community hospital with 250 operating beds	Hospital pharmacy	Reduced medication errors originating in the pharmacy	- To improve medication safety through increased reporting of near-miss events. - To reduce patient harm by analyzing near-miss events and implementing system changes based on the results of these analyses.
		- Open 6:00 AM-12:00 AM, 7 days/week. - Between 12:00 AM-6:00 AM, shift director is available; a pharmacist is available by pager. - Staffed by 19 full-time equivalents. - Dispenses 2,800 medication doses/day on average.		
B	Community hospital with 451 operating beds	Orthopedic and neuroscience unit	Reduced patient falls	- To promote a culture of safety by encouraging reporting of near-miss falls. - To identify and implement interventions and strategies to reduce patient falls and harm.
		42-bed unit with 24 private and 18 semi-private beds. - Utilizes a total care model evenings and nights and a care partner model during day shift. - Computerized charting system.		
C	Teaching, tertiary care hospital with 504 operating beds	Acute surgical care unit	Pain medication management (primary problem cited by unit staff)	To promote effective, efficient medication utilization in pain management to assure that patient-centered care is provided in a safe and timely manner.
		48-bed acute surgical care unit providing postoperative care for thoracic, abdominal, and general surgical patients. - Experienced a higher than usual rate of managerial and clinical staff turnover than in previous years.		
D	Community hospital with 181 operating beds	Medical-surgical floor	Managing anticoagulant therapy	To improve anticoagulation therapy using rapid cycle improvement based on findings of root cause analyses and sensemaking sessions, enhanced by fostering a just culture.

Table 2. Description of existing reporting systems and practices in hospitals participating in the Patient Safety Learning Pilot Project, 2003-2004

Hospital	Existing reporting system description
A	“The staff member who first becomes aware of an event completes a written report, which is sent to the Risk Management Department where reports are entered into a database (Midas) for trending and investigation. Trending and investigation reports are produced through the Midas system. Medication errors are voluntarily reported by the health care provider who discovers the event using the Medication Error Report Form. Reporting of both near miss medication events and events that reach the patient are encouraged. Reports are forwarded to the Director of Pharmacy for investigation as well as for entry into an Access® database for trending and reporting. Reports are taken to the Medication Safety Committee and the Pharmacy & Therapeutics Committee for review. System changes are made as issues are identified.”
B	“The staff member who witnessed the event usually completes a handwritten report outlining the details. This report is given to the Manager of the department/unit for immediate investigation and resolution. A copy of the report, along with information from the investigation and actions taken are sent to the Safety Office, where information is entered into a database. The managers and administrators of departments/units receive quarterly reports.”
C	“A diverse incident reporting structure has been developed in an effort to optimize the reporting of actual and near-miss events. The main method used to report incidents consists of a paper incident report, which is completed by the involved staff members at the time that the event is recognized to have occurred. This report is then sent to the supervisor of the areas to complete a more in-depth review of the events surrounding the incident. Finally, the report is sent to the hospital’s risk manager. Additional methods include a telephone hotline for the reporting of adverse drug events and retrospective review of the clinical record for documentation of evidence of an adverse event.”
D	“The reporting system is computer-based and uses both direct online reporting and paper reports; the paper reports also generate information for online data entry. Most clinical units have access and are trained to do online reporting. The online entry is response-defined: responses are requested based on the type of incident initially selected in a table of incident types. Incident types include medication errors, falls, procedure-related incidents, patient care-related incidents, treatment-related incidents, equipment-related incidents, lost/broken patient articles, and other. The response requests are triggered by the initial type selection. Control charts are utilized to monitor trends and processes in using the incident reporting system to channel quality improvement initiatives.”

Note: Hospital A = 250-bed community hospital; Hospital B = 451-bed community hospital; Hospital C = 504-bed teaching, tertiary care hospital; Hospital D = 181-bed community hospital.

Narrative descriptions provided by _____.

The value of noticing and reporting near misses is two-fold: one, it helps us to understand the causes of the failures to the point of recovery; and two, we can better understand the recovery process itself.^{20, 28, 29} However, it would appear that focusing more on the recovery side of near misses than on their potential for patient harm may have the unintended consequence of reducing staff motivation to report near misses. As Sutcliffe has noted, “The capacity for learning and the accumulation of knowledge is directly affected by how potentially dangerous events are interpreted and categorized.”⁵

Noticing, reporting, and investigating near misses in the pharmacy are of particular interest. The pharmacy is responsible for transcribing and dispensing drugs in a complex medication process that originates with prescribing by the physician prior to the pharmacy work and ends with administration after the pharmacy steps. That is, recovery from near misses in the pharmacy may uncover system vulnerabilities outside the pharmacy, as well as in the pharmacy.

Tamuz et al⁶ reported that, although labeling near misses in the pharmacy as “interventions” rather than as reportable incidents increased learning in the pharmacy, when the error was made by a physician during the prescribing process and was intercepted by the pharmacist, the incident was not entered into the hospital reporting system. Hence, an opportunity to learn from the event was limited. One limitation of implementing the patient safety improvement prototype within individual microsystems is that our narrow focus caused us to omit significant “interdependencies” within the hospital context.³⁰

As noted in the narrative from Hospital C, nurses were hesitant to take time away from patient care to report near misses. When asked in meetings to recall near misses, though, they were able to do so. This highlights the difference between noticing and reporting. As noted by Hospital C:

“When a nurse has to make a choice between filling out a report or meeting a patient need, then the patient need should take precedence.”

As Tucker has noted, production pressure may cause health care professionals to participate in “first-order” problem solving, in which short-term remedies are used to “patch” problems. This leads to omission of “second-order” problem solving, in which more long-term solutions seeking to change underlying causes of the problems are implemented.³¹ First-order problem solving, as well as dependence on individual vigilance, is illustrated in the following narrative:

“At Hospital C, our staff leader, Sue, caught a near miss, in which a patient she was discharging was prescribed a pain medication for home use that had not been administered during the patient’s hospitalization. This meant that there had been no prior testing of the effectiveness of this medication for pain management in this patient. Sue contacted the surgeon discharging the patient and noted the problem. As a consequence, the prescription was changed to be consistent with the pain medication the patient had received while in the hospital. Sue was so effective in communicating this example to others on the team that subsequent to her communications about this event to others, close scrutiny revealed that pain medications being prescribed at discharge were consistent with those provided during hospitalization.”

Balancing the immediacy of patient care with concerns about factors “upstream and downstream”⁵ is an ongoing challenge in event reporting. This was echoed in the wisdom of a summary statement by an administrative staff member at Hospital C:

“Finding a methodology that allows staff to report these important events without taking away from patient care is the challenge that we all need to address.”

This tension among frontline workers between taking care of patients’ needs and taking steps to learn from near misses and events is not likely to go away. As noted in this narrative, we will need to find a way to address this issue if we are going to improve patient safety on the frontlines of health care.

Near Misses: Investigating Recovery and Near Failure

Recovery, whether planned or unplanned,²⁸ is an important component of learning from near misses. Recovery is illustrated in the narrative below:

“At Hospital D, we identified a near miss in which a patient’s coumadin was put on hold for several days. To alert the patient’s physician, the patient’s chart was stamped with a reminder for the physician that the patient’s coumadin had been put on hold. As a consequence, the physician wrote an order for the patient to resume receiving coumadin. However, the physician’s order was not transcribed. This meant the order for coumadin was not placed on the electronic medication administration record (eMAR), and hence, the pharmacy did not send the patient’s coumadin to the unit. The RN coming on the p.m. shift, however, reviewed the patient’s anticoagulation flow sheet and noted the discrepancy between the patient’s status as being back on coumadin on the anticoagulation flow sheet but not having any coumadin on the unit to administer to the patient. Upon further investigation, she discovered that the physician’s order for coumadin had not been transcribed. As a consequence, she implemented prompt recovery by getting the coumadin from the pharmacy, assuring that the patient received the coumadin on time as ordered by the physician.”

This was an unplanned recovery by a nurse who was vigilant, or mindful, in her practice. What is particularly noteworthy, though, is that the Hospital D project team did not stop with understanding the recovery. Rather, they moved to understand the causes of the process failures that had occurred and made the recovery necessary.

“What points in the system failed and led to this near miss, in which this patient would not have received the prescribed coumadin therapy? ...As we entered our investigation of the near miss into the (MERS-TH) database, the experience of walking through the consequent event and retrospectively through the antecedents gave us a clear picture of the unfolding of the trail of antecedent activities and decisions that led to the discoverable event. ... Based on the MERS Eindhoven Classification Model, contributing factors included latent organizational issues as a consequence of a newly implemented eMAR change. These changes included the complexity of the procedure itself and staff adjustment to the changes. A component of the change was that the transcribing process was shifted from the clinical unit to the pharmacy department. This modification in

workflow required considerable staff adjustment.... As we continued to move through the MERS event investigational process, we focused on antecedent activities and decisions occurring at the pharmacy. The failure to transcribe the order occurred at the pharmacy, largely due to lack of pharmacy understanding of the procedural changes. Due to the learning curve associated with the changes in the eMAR, it was difficult to determine if inattention or technical performance had contributed to the transcription failure. As we worked through the investigation and assigned the Eindhoven Classifications codes to the root causes, we gained an appreciation of the process involved in bringing our understanding of the near miss to a level of objective study of error. This objective understanding brought us a feeling of shedding the sense of blame that had at times been prominent in past event investigations. In addition, the process helped us focus on developing more substantial strategies for safeguarding our system. By working with the MERS-TH system, it both demanded and enabled a change in our basic thinking. Organizing the event retrospectively through the antecedents and then asking the “why” questions were new for our staff. The process of retrospective reconstruction of event antecedents and root causes generated an overall systems-thinking approach to event detection and investigation.”

Moving from understanding recovery to learning from the failure to the point of recovery is likely to increase the harvest of knowledge from near misses. This narrative also illustrates investment in the investigation required for second-order problem solving.³¹ In addition, the investigative process, as well as the Eindhoven Classification Model, appear to have gained a strong foothold in the minds of frontline workers. Expanding health care workers mental models in this way is likely to increase what they notice in terms of system vulnerabilities.

Collective Sensemaking

Dr. Nancy Dixon visited each hospital to conduct a collective sensemaking session. A narrative from a pharmacy staff member at Hospital A illustrates how the collective sensemaking session was received by hospital staff:

“We were introduced to the concept of sensemaking at our initial meeting of the PSLP in Salt Lake City in April 2003. With subsequent learning sessions and reading, I thought I had a good understanding of this tool of sensemaking. I later found that, until I actually experienced it in action, I never completely understood the insight and value the addition of collective sensemaking could lend to the expanded investigation of an event. With the externally facilitated collective sensemaking session by Dr Nancy Dixon in November 2003, as I was standing in front of my peers, I quickly realized that, although I understood the sensemaking concepts intellectually, I was unsure of how to proceed with facilitating an actual collective sensemaking session. I was getting my root cause investigation techniques confused and intermingled with the collective sensemaking of the findings of the root cause investigation. In addition, I tried to direct the group and individuals instead of soliciting their opinions and perceptions in making sense of the events. Because of this experience, I no longer felt confident in using this tool of collective sensemaking. However, my perception changed as I facilitated a second sensemaking session. At this second sensemaking session, the group sat in a circle. We asked that group members share their personal experiences with errors. This exercise was

valuable in demonstrating to everyone present that we were all on equal footing. Prior to the second meeting, a causal tree for an actual near miss had been constructed and placed on Post-it® notes. These notes, representing the chronological antecedent activities and decisions and root causes for the near miss, were presented to the group. Although discussion of the near miss evolved slowly, members of the group began to open up and more freely discuss the event. Members began to question one another. It became clear to me that the members were trying to make sense of each other's reasoning and contributions. Suggestions for preventing future events were offered, and we collectively developed an action plan. In the end, I felt great satisfaction knowing that the discussion did indeed go beyond the surface understanding of the near miss. In addition, hospital administrative staff present in the group reported that they had gained new insights into the different workflow processes within the pharmacy clinical microsystem. The amount of participation by all members also assured me that the meeting was successful in providing a tone of learning and not blame or defensiveness.”

Four issues emerge from this narrative:

- First, the topic of this planned collective sensemaking activity was a near miss that had been fully investigated, with the findings visually represented on a causal tree. As noted by Kaplan¹⁴ and Battles,¹⁵ the causal tree in MERS is a powerful tool for organizing event information for use in collective sensemaking. As such, it offers an opportunity for making individuals’ thinking about event causes explicit and hence, shareable. However, as pointed out by Weick,¹⁷ the extent to which individuals must hold a common sense in order to act remains open to question.
- Second, the focus shifted from attempts to discover the “right” causal tree to participants questioning others to learn how they had made sense of the event’s causes. That is, the event was brought into being and infused with meaning through the social process involved in the sensemaking session.
- Third, the sensemaking led to a deeper understanding of the causes of the event. As individuals shared their own sense of the event, their multiple interpretations and meanings enriched the collective understanding of the event.
- Fourth, consistent with sensemaking being about the “interplay of interpretation and action,”¹⁷ the activity resulted in an action plan.

Human Factors Engineering

Human factors educational sessions were convened at each of the three learning sessions. In addition, staff from the Utah QIO, with expertise in human factors, visited each of the four hospitals to assist their project staff in understanding how human factors play a role in events. In Hospital B, the focus of the human factors visit was failure of staff to adhere to fall prevention policies and procedures, including use of bed alarms, patient fall risk identifiers, and their staff’s perception of patients’ risk for falling. The narrative below illustrates how they thought about the relation between human factors and improving patient safety:

“We have been analyzing and creating reports of falls with and without injuries for several years. We have used these reports to identify patterns and trends related to when falls occur, as well as common factors contributing to their occurrence. In reviewing

these reports, it was clear that staff were often not compliant with the hospital's fall policy. Prior to participation in this project, however, we had not explored with staff, by requesting their feedback, why they were not complying with the fall policy... The human factors visit (by Utah QIO staff) confirmed for us some of the barriers that the system had put in place that did not allow staff to comply with the fall policy. This experience in learning more about human factors alerted us to several significant documentation requirements for reporting falls that were redundant and inconvenient. These redundancies in reporting interfered with staff compliance with our fall policy and procedures. A second area of concern confirmed for us was how our staff had become desensitized to bed alarms. By virtue of the sheer number of times the alarm goes off, staff became less responsive to the alarms and hence the time between the alarms going off and staff response increased. Through this learning experience, we have come to believe that you must explore the human factors related to events before you can move to a higher level of performance that can directly impact the safety of your patients."

With regard to training in human factors, comments from a manager at Hospital B are of interest:

"Managers will need more extensive training to understand human factors. Understanding human factors will allow managers to gain valuable insight as to why staff respond as they do in particular situations. Without this insight gained through an understanding of human factors, managers may entirely miss the true causes of why an event occurred. This could lead to unnecessary tampering with the system and could actually cause greater potential for future events to occur. In addition, managers will need adequate expertise in human factors to instruct and train staff."

This narrative, typical of those from the other three hospitals, highlights the view of the participating hospitals regarding the significant role human factors engineering plays in both diagnosing and remedying causes of system failures. It is certain, however, that as hospitals come to recognize the need for this expertise, they will encounter significant challenges.

Study Limitations

This was a small demonstration project involving only a few hospitals. We report only narratives from the frontlines. Given these limitations, we cannot be sure that the findings can be generalized to other hospitals. However, several of the findings are consistent with the findings of earlier studies and are consistent with the theoretical underpinnings of patient safety practice.

Conclusion

The findings of this qualitative study suggest that, as patient safety experts continue to develop tools and bring concepts from other disciplines to the field, there will be an ongoing need to understand how these tools and concepts will be thought about and used by those working on the frontlines of health care. As observed in this project, event reporting at the local hospital level is neither simple nor entirely straightforward. The local nuances of how events are defined by those on the frontlines may influence what is noticed, reported, investigated, and acted upon.

Although the value of reporting near misses is well established in terms of understanding the causes of failures to the point of recovery and coming to a better understanding of the recovery process itself, it appears that focusing more on the recovery side of near misses than on their potential for patient harm may have the unintended consequence of reducing the motivation of staff to report near misses. In addition, we observed an ongoing tension between frontline workers taking care of patients' needs and taking steps to learn from near misses and events. It will be essential to address this tension to improve reporting of near misses and events.

We also observed that learning from events requires a shared mental model about their causes. The Eindhoven Classification Model appeared to have gained a strong foothold in the minds of frontline workers, facilitating their learning from events.

To the extent that what is being learned in sensemaking is integrated with our reporting efforts, it is likely that our improvements in patient safety will be significantly magnified. The health care professionals in this study found the use of the causal trees in the MERS-TH reporting system helpful for organizing and sharing event information. The causal trees made the information about events more explicit and hence, shareable in planned collective sensemaking sessions.

The sensemaking process shifted health care professionals' focus from attempting to discover the "right" causal tree for any event to engaging in communication to learn how others had made sense of the events. This led to participants coming to a shared and deeper understanding of the causes of events. It is noteworthy that frontline workers reported that collective sensemaking sessions led to their seeing a wide array of actions they could design to address the causes of the system failures.

With regard to human factors engineering, health care workers came to understand its value in both diagnosing and remedying the causes of system failures. They reported that without understanding human factors engineering, they could not improve system performance. In addition, they came to see that, without this knowledge, their attempts at improvements might result in tampering with the system, which could make things worse. At the same time, they had to confront their limited access to this expertise. This observation appears to suggest that a significant investment will be required to build an infrastructure providing health care professionals with ready access to human factors engineering expertise. In the absence of such access, as highlighted by the frontline hospital workers in this study, the benefits of our best efforts at reducing patient harm are likely to be significantly reduced.

Finally, designing and implementing tools and methods to improve patient safety—although very complex tasks—only represent a first step. These tools and methods will be successful in improving patient safety only to the extent that they are used by frontline health care workers. Hence, understanding how these methods and tools are actually being received, interpreted, and used by frontline workers may well accelerate our efforts at reducing patient harm.

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References

1. Plsek PE, Greenhalgh T. The challenge of complexity in health care. *Br Med J* 2001; 323: 625-628.
2. Plsek PE, Wilson T. Complexity science: Complexity, leadership, and management in healthcare organizations. *Br Med J* 2001; 323: 746-749.
3. Wilson T, Holt T, Greenhalgh T. Complexity science: Complexity in clinical care. *Br Med J* 2001; 323: 685-688.
4. Weick KE, Sutcliffe KM. *Managing the unexpected: Assuring high performance in an age of complexity*. San Francisco: Jossey-Bass; 2001.
5. Sutcliffe KM. Defining and classifying medical error: Lessons for learning. *Qual Saf Health Care* 2004; 13: 8-9.
6. Tamuz M, Thomas EJ, Franchois KE. Defining and classifying medical error: Lessons from patient safety reporting systems. *Qual Saf Health Care* 2004; 13: 13-20.

7. Hoff TJ, Sutcliffe KM. Studying patient safety in health care organizations: Accentuate the qualitative. *Jt Comm J Qual Improv* 2006; 32: 5-15.
8. Ethnograph v5.0. Qualis Research. Available at: www.QualisResearch.com. Accessed February 23, 2008.
9. Kaplan HS, Battles JB, Van der Schaaf TW, et al. Identification and classification of the causes of events in transfusion medicine. *Transfusion* 1998; 38: 1071-1081.
10. Battles JB, Shea CE. A system of analyzing medical errors to improve GME curricula and programs. *Acad Med* 2001; 76: 125-133.
11. Kaplan HS. Event reporting systems: MERS-TM, surveillance—seeing and using the data below the waterline. *Dev Biol (Basel)* 2005; 120: 173-177.
12. Eindhoven classification model: Medical version. Root causes: ECM table. Available at: www.mers-tm.net/support/codes_tools/Codes_Cause_Codes.pdf. Accessed April 21, 2008.
13. Weick KE. Sensemaking in organizations. Thousand Oaks, CA: Sage Publications; 1995. p. 4.
14. Kaplan HS, Fastman BR. Organization of event reporting data for sense making and system improvement. *Qual Saf Health Care* 2003; 12 (Suppl 2): ii68-ii72.
15. Battles JB, Dixon NM, Borotkanics RJ, et al. Sensemaking of patient safety risks and hazards. *Health Serv Res* 2006; 41: 1555-1575.
16. Albolino S, Cook R, O'Connor M. Sensemaking, safety and cooperative work in the intensive care unit. *Cogn Tech Work* 2007; 9: 131-137.
17. Blatt R, Christianson MK, Sutcliffe KM, et al. A sensemaking lens on reliability. *J Organiz Behav* 2006; 27: 897-917.
18. Institute for Healthcare Improvement. Testing changes. Available at: www.ihl.org/IHI/Topics/ChronicConditions/AllConditions/HowToImprove/ChronicTestingChanges.htm. Accessed February 23, 2008.
19. Argyris C. Double loop learning in organizations. *Harv Bus Rev* 1997 Sept-Oct: 115-124.
20. Frankel A, Graydon BE, Neppel C, et al. Patient Safety Leadership WalkRounds. *Jt Comm J Qual Saf* 2003; 29: 16-26.
21. Frankel A, Grillo SP, Baker EG, et al. Patient Safety Leadership WalkRounds at Partners Healthcare: Learning from implementation. *Jt Comm J Qual Saf* 2005; 31: 423-437.
22. Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: The tools to achieve high reliability. *Health Serv Res* 2006; 41: 1690-1709.
23. Mohr JJ, Batalden PB. Improving safety on the front lines: The role of clinical microsystems. *Qual Saf Health Care* 2002; 11: 45-50.
24. Mohr JJ, Barach P, Caverio JP, et al. Microsystems in health care: Part 6. Designing patient safety into the microsystem. *Jt Comm J Qual Saf* 2003; 29: 401-408.
25. Mohr J, Batalden P, Barach P. Integrating patient safety into the clinical microsystem. *Qual Saf Health Care* 2004; 13 (Suppl 2): ii34-ii8.
26. The Breakthrough Series: IHI's collaborative model for achieving breakthrough improvement. Institute for Healthcare Improvement. Available at: www.ihl.org/IHI/Results/WhitePapers/TheBreakthroughSeriesIHI'sCollaborativeModelforAchieving%20BreakthroughImprovement.htm. Accessed February 23, 2008.
27. Marx D. Patient safety and the “just culture”: A primer for health care executives. Funded by a grant from the National Heart, Lung, and Blood Institute National Institutes of Health (Grant RO1 HL53772). Available at: www.mers-tm.net/support/Marx_Primer.pdf. Accessed February 23, 2008.
28. Kanse L, Van Der Schaff, Vrijland ND, et al. Error recovery in a hospital pharmacy. *Ergonomics* 2006; 49: 503-516.
29. Edmundson AC. Learning from mistakes is easier said than done: Group and organizational influences on the detection and correction of human error. *J Appl Behav Sci* 1996; 32: 5-28.
30. Weick KE. The reduction of medical errors through mindful interdependence. In: Rosenthal MM, Sutcliffe KM, eds. *Medical error. What do we know? What do we do?* San Francisco: Jossey-Bass; 2002. p. 177-199.
31. Tucker AL, Edmondson AC. Why hospitals don't learn from failures: Organizational and psychological dynamics that inhibit system change. *Cal Manage Rev* 2003; 45: 55-72.

A Visual Computer Interface Concept for Making Error Reporting Useful at the Point of Care

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Abstract

Reports on errors can be a rich source for understanding their causes, cascades, and consequences, leading to interventions for improvement. There are national and international calls for the development of appropriate error reporting and taxonomy systems that are useful at the point of care. The current momentum and urgency for these developments present an opportunity to harness the benefits of computer visualization that helps structure and illustrate the “story” of an error. This visualization process could help overcome the shortcomings of current reporting methods and could aid in creating an unambiguous international error taxonomy. We present a concept for a visual error reporting interface. The ambulatory care domain is used for illustration. The system has the potential to provide a user friendly, efficient means of reporting errors. Errors reported in this way would populate a “visual database,” providing the ability to disseminate patient safety information in a straightforward, structured format that will be useful to a variety of stakeholders.

Introduction

A huge chasm exists between the potential and actual quality of care delivered by the health care industry. In the United States, this chasm appears to be consistently wide across the Nation and the spectrum of care delivery venues.¹

Creation of a culture of safety is a critical first step for health care organizations that wish to improve quality and safety.² One of the steps in developing a culture of safety is the recognition by staff and clinicians of errors that occur on a regular basis.³ One of the primary drivers to achieve this recognition is error reporting. Reporting systems need to be safe (i.e., free from blame), easy, and worthwhile.^{4, 5} Error reports can be a rich source for uncovering errors, and through further study, can lead to an understanding of causes, cascades, and consequences of errors, in turn leading to the design of interventions for improvement.

Error reports represent the “tip of the iceberg,” as only a small fraction of errors are typically reported, and the information contained in the reports is limited to what reporters perceive and are willing to share. Other methods of analysis, which may be based on error reports, include failure modes and effects analysis, root cause analysis, chart review, and direct observation. These are needed to provide a more complete assessment of risks within an organization. Error

reporting is nevertheless an important modality and should be seen as complementary to the other approaches.

In the United States, the Patient Safety and Quality Improvement Act of 2005⁶ was intended to encourage and facilitate error reporting. The Act calls for the formation of Patient Safety Organizations (PSOs) that can safely collect and analyze data on medical errors without the legal risk of discovery. In conjunction with the president's 2004 call for national implementation of electronic medical records (EMRs) and the creation of the office of the National Coordinator for Health Information Technology, PSOs will be asked to pool their deidentified data, which should support the creation of searchable electronic databases of errors that are secure, involve low medico-legal risk, and can be analyzed and used to develop systemic solutions to health care safety problems.⁷

The collation of error reports into central databases can be useful at two levels. First, and currently the focus of most efforts, is the regional, national, or international level, which we shall refer to as the "macro-system level." These pooled databases have the potential to receive large numbers of reports and, therefore, might be able to detect infrequent errors and track trends in reporting frequencies over time. In addition, since a large number of providers will, it is hoped, submit data, the publication of summary statistics will not compromise the confidentiality of individual providers. In the United States, legislation will help protect these data from medico-legal discovery.⁶

One difficulty with error analysis at the macro-system level is that the generalizations made about national data might not apply (or, be perceived by individual physicians not to apply) to individual practices or hospital floors. The Director of the Agency for Healthcare Research and Quality (AHRQ) has emphasized that quality and safety information needs to be made useful at the point of care to patients and health care providers.⁸ Similarly, the United Kingdom's House of Commons Committee of Public Accounts, in its report "*A safer place for patients: Learning to improve patient safety*," calls for a unified and convenient form for reporting and a taxonomy that encourages feedback on solutions to specific patient safety incidents.⁹ Therefore, in addition to macro-system level data, individual practices/health care sites and organizations need local "micro-system level" information that is directly relevant to them and can be used internally to drive safety improvement. Such information, reported internally for quality and safety improvement purposes, potentially has more legitimacy in the eyes of local staff and clinicians in any health care setting.

The overall purpose of our work is to develop and test a concept for a visual medical error taxonomy, built on visual reporting, that can provide for both macro-system and micro-system level needs. Figure 1 depicts the overall concept in which error reporting at the micro-system level is used internally for safety improvement, as well as being fed seamlessly to a regional, national, or international database that is used to study the epidemiology of errors and to generate alerts. The purpose of this paper is to present the concept of visual reporting. Before presenting this concept, it will be helpful to describe the framework of the error taxonomies that have to be populated by the proposed visual reports.

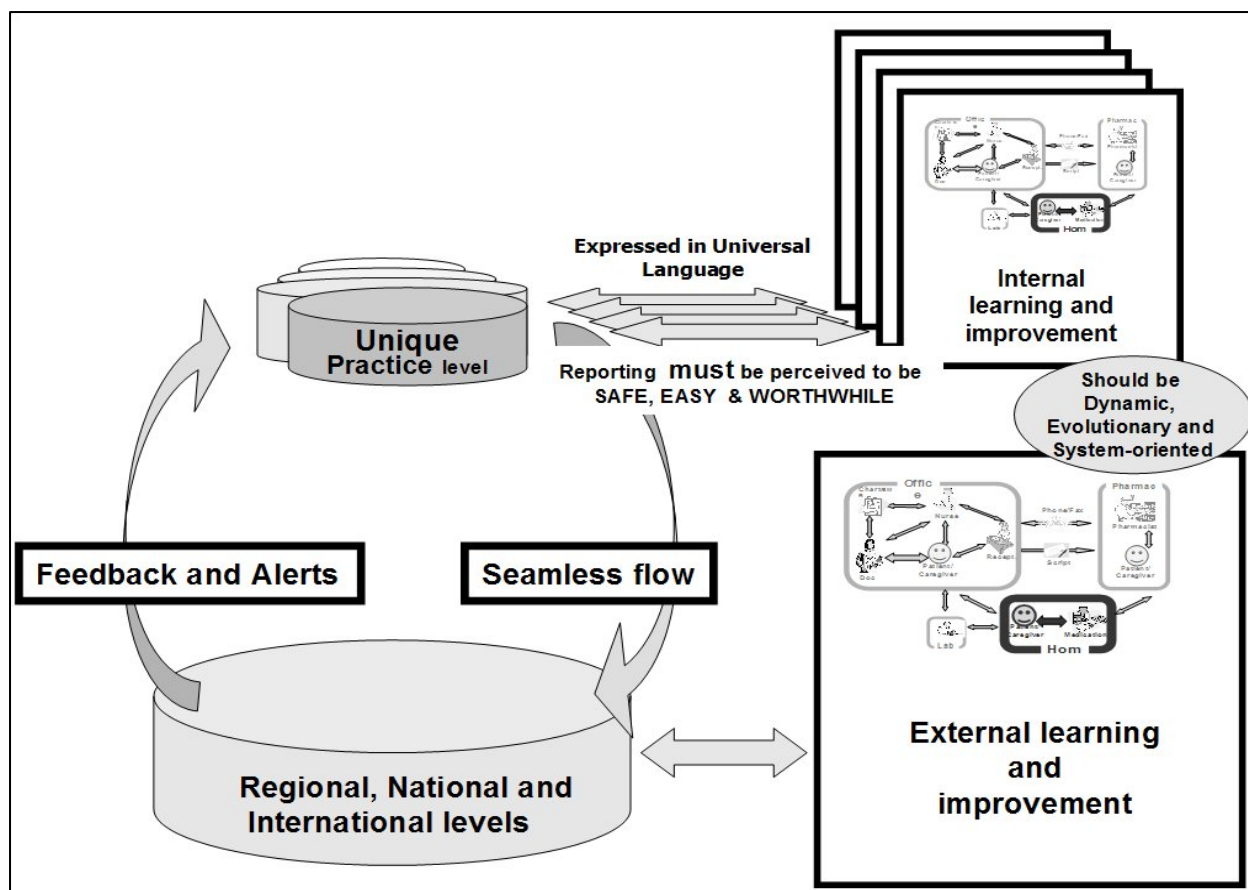


Figure 1. Overview of the concept for visual taxonomy and reporting. Adapted from Singh R, Pace W, Singh S, et al. A concept for a visual computer interface to make error taxonomies useful at the point of primary care. *Infomat Prim Care* 2007; 15:221-229.

Error Taxonomies

A number of error taxonomies have been and are being developed to organize and classify error reports. The Institute of Medicine's (IOM) report "*Patient Safety: Achieving a New Standard for Care*"¹⁰ calls for the development of an event taxonomy. The Joint Commission has proposed a taxonomy¹¹ and is working with the World Health Organization (WHO) to establish a common international system for classification.¹² The International Primary Care Patient Safety Taxonomy Steering Committee has given itself the important and necessary task of developing "*a primary care taxonomy for patient safety, embedded in the International Classification of Primary Care (ICPC-2) and in an episode of care structure, that can operate across settings and vendors, and that maps to other standards and data structures.*"¹³

Current taxonomies are essentially alphanumeric codes that are used to classify and summarize error data (whether at local, regional, national, or international levels) for various purposes including:

- Communication of information about errors and their characteristics, including causative factors, consequences, and severity (keeping in mind that error reporting alone might be insufficient for fully addressing these issues).

- Estimation of frequencies and trends of various error types.
- Identification of needs for safety improvement.

While such taxonomies have been used successfully in primary care and other settings, they have some limitations:

- The coding systems are complex and prone to ambiguity.
- They do not readily meet the point-of-care needs of patients and health care providers to understand, within their own unique micro-systems, the causes, cascades, and consequences of the reported errors.
- They do not fully capture the “story.” By reducing an incident to a series of codes, the flavor of the event is lost. It is the “story” that has the greatest potential to contribute to safety improvements.^{4, 14}
- They often differ in the way they define, count, and track events, and they use different terms, data, coding methods, and analysis. This makes it difficult to compare data that have been collected or coded using different taxonomies.

According to the IOM,¹⁰ a comprehensive National Health Information Infrastructure must provide information flow across three dimensions: (1) personal health, to support individuals in their own wellness and health decisionmaking; (2) health care providers, to ensure access to clinical decision support systems; and (3) public health, to address and track public health concerns and health education campaigns. Items 1 and 2 correspond to the micro-system level, while item 3 is at the macro-system level. Use of a consistent error taxonomy across these levels is imperative.

The need for a consistent error taxonomy at both micro- and macro-system levels presents an opportunity to harness the benefits of computer visualization. Our experience with visualization suggests that this will help create crosswalks between disparate taxonomies. A very important feature of visualization is that it can help structure and illustrate the “story” of an error or event. The proposed visual taxonomy is coded at four main levels, corresponding to the structure of the visual models:¹⁵

- Health care domain.
- Process.
- Sub-process.
- Entity/interaction.

A reported event can consist of one or more errors, together with causes and consequences. Each of these is coded at the above four levels.

Visualization

We take the view that visualization is a universal tool that furnishes a natural common “language.” For instance, it is used effectively for international road signs. It respects and aids inductive (as opposed to linear) perception and decisionmaking that is the natural way that the human brain works.¹⁶ It can provide:

- A fast path to fully engaging the minds of individuals and their teams, including patients.
- Insight into causes, cascades, and consequences of errors.
- A common vision for teamwork, with the potential for improved outcomes.
- An aid for coping with the complexities, fragmentation, and decentralization of the health care system.²
- An aid for mapping across different taxonomies and data structures.¹⁶

Applying a systems engineering/management approach, we have developed visual models at the macro-system and micro-system levels.¹⁷

Macro-System Model

The macro-system model is a high level view (Figure 2) of the health care system. The processes of care are represented by the radials. These processes are recognized to occur in a cyclical fashion, as shown by the clockwise progression around the circle from Assessment to Plan to Implementation, Feedback, Review & Learn and back to Assessment again.¹⁷

These processes in the cycle of care take place in various domains that are depicted by concentric circles. The increasing sizes of the circles depict the enlarging involvement of the system, starting from the patient level at the center to the international health authority level on the outside. The innermost circle represents the patient in his/her own domain (i.e., home/community) and recognizes that this is where most health care actually occurs. International health authorities (e.g., World Health Organization), depicted by the outermost circles, play an important role in devising public health policies that can affect management of patients at all points within the system. Office-based primary care is represented by circle 1. Depending on the system under study, circle 2 might represent the emergency room, and circle 3 might represent the hospital inpatient setting, etc.

The main purpose of this macro-system model is to understand a patient's care in the context of the overall health care system, especially with respect to errors and opportunities for errors, including errors that may occur in transitions between different parts of the system. This is best illustrated through the use of an example. Suppose a 59-year-old male patient with a long history of hypertension arrives at his primary physician's office with intermittent atypical chest pain of 2 days' duration. He is currently having retrosternal burning chest pain.

The scenario therefore begins at point 1A in Figure 2, with the patient in the office setting being assessed by the physician. Based on the history and physical exam, the physician decides to order sublingual nitroglycerine and an EKG; this is the Plan (point 1P). The order is conveyed to the nurse, who gives the patient nitroglycerine, completes the EKG (Implements the Plan, point 1I). The nurse presents the printed EKG to the physician and informs him/her that the patient's pain did not improve despite three doses of nitroglycerine (this is the Feedback, point 1F). The physician reviews the EKG (point 1R) and notices some T-wave inversion in the inferior leads. The physician goes back into the room to reassess the patient (back to point 1A) and finds that the patient's chest pain is getting worse (it has been ongoing for 30 minutes), and the patient is diaphoretic. Now the physician decides (point 1P) to transfer the patient to the emergency room for evaluation to rule out acute coronary syndrome (ACS).

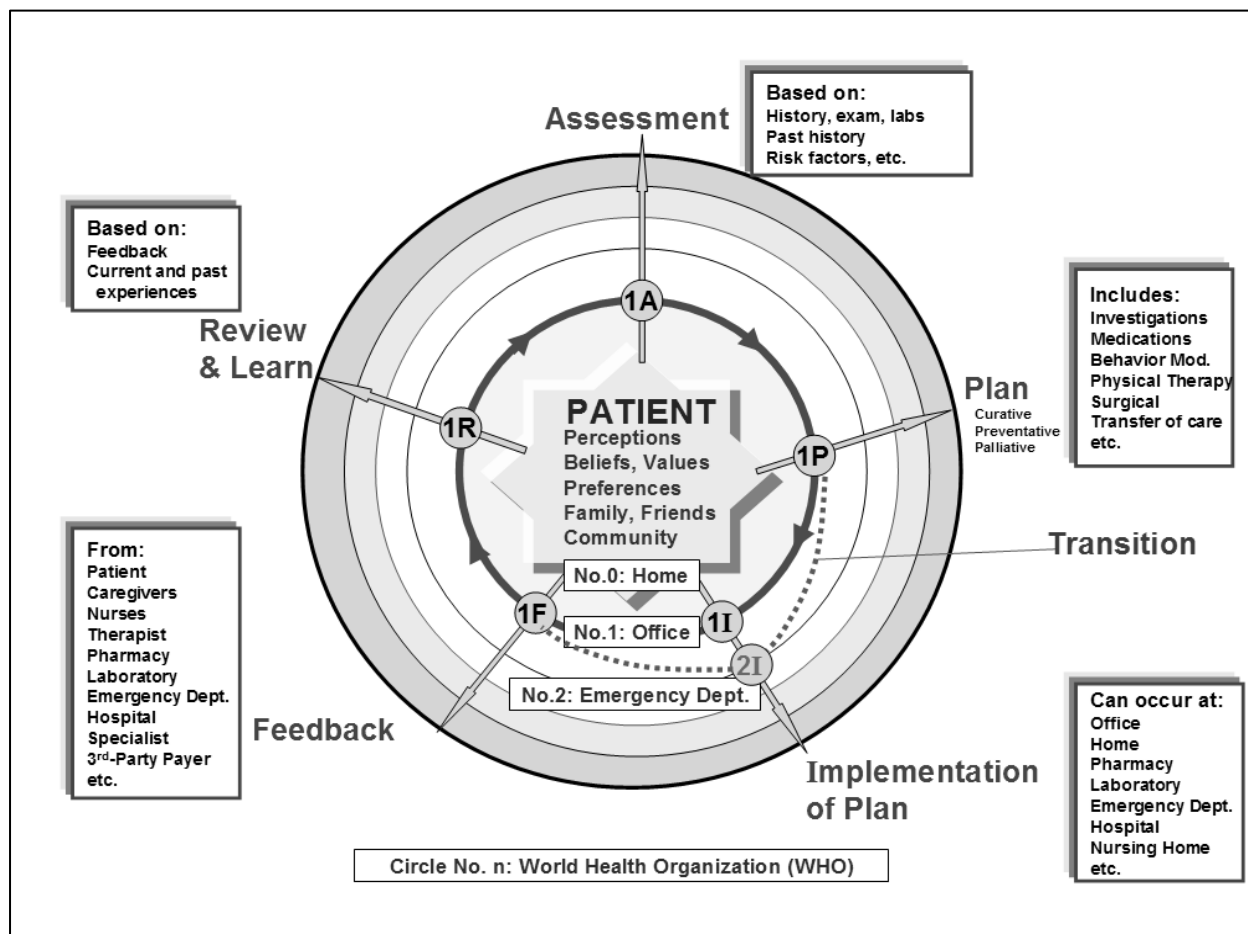


Figure 2. Macro-system model of health care. Adapted from Singh R, Singh A, Fox C, et al, Computer visualization of patient safety in primary care: A systems approach adapted from management science and engineering. *Informat Prim Care*. 2005; 13: 135-144.

The patient makes a transition from the office to the emergency room, shown in Figure 2 by the dotted line from point 1P to point 2I. In the emergency room (circle no. 2), similar cycle(s) of care occur, starting with Assessment (point 2A). The patient is treated in the emergency room according to their “rule out ACS” protocol and discharged home after “ruling out.”

The next day, the primary physician receives a copy of the emergency room record (transition back to point 1F) and reviews it (point 1R). He/she is pleased to learn that the patient did well and has been diagnosed with “probable GERD” after responding well to a “GI cocktail” in the emergency room. As the physician reflects on what happened to the patient (also part of the Review & Learn process, point 1R), he/she realizes that he/she missed the opportunity to give the patient aspirin in the office (which he/she should have done, since the patient was not on aspirin, and he/she was entertaining the diagnosis of ACS). Further, the physician considers whether he/she and his/her colleagues should improve their systems for dealing with chest pain patients, perhaps by using a written protocol for managing chest pain in the office. The following week, the patient returns for followup with the primary physician (point 1A) and the cycle continues.

Thus, cycles of care can occur multiple times in one setting and/or involve transitions between settings. The macro-level view aims to provide the “big picture,” so as to facilitate understanding of the processes of care in different interrelated parts of the system and transitions between these parts, helping the user understand interdependencies and the need for information flow.

Micro-System Models

The micro-system models are close-up views of the system; each may represent one or more points within the macro-system model. For example, one might devise a micro-system model for a specific domain within the macro-system or for a specific process within a domain. These models show how the various entities/agents in the micro-system interact. The level of detail represented in a micro-model depends on the purpose for which it is used.

Figure 3 depicts a micro-system model for medication management in ambulatory settings. It shows activities in the office, pharmacy, home, laboratory, imaging/radiology facility, and third

party payer and the interactions within and between these. Each interaction is shown as an arrow. Errors or safety problems can originate at any one point or at multiple points in the system.

The macro-system and micro-system diagrams are computerized and contain “hyperlinks” that facilitate hierarchical linkage between models and can be used for dynamic data links within databases. For example, any point on the micro-system model can be linked electronically to a table containing relevant data about errors that are known to occur at that point in the system,

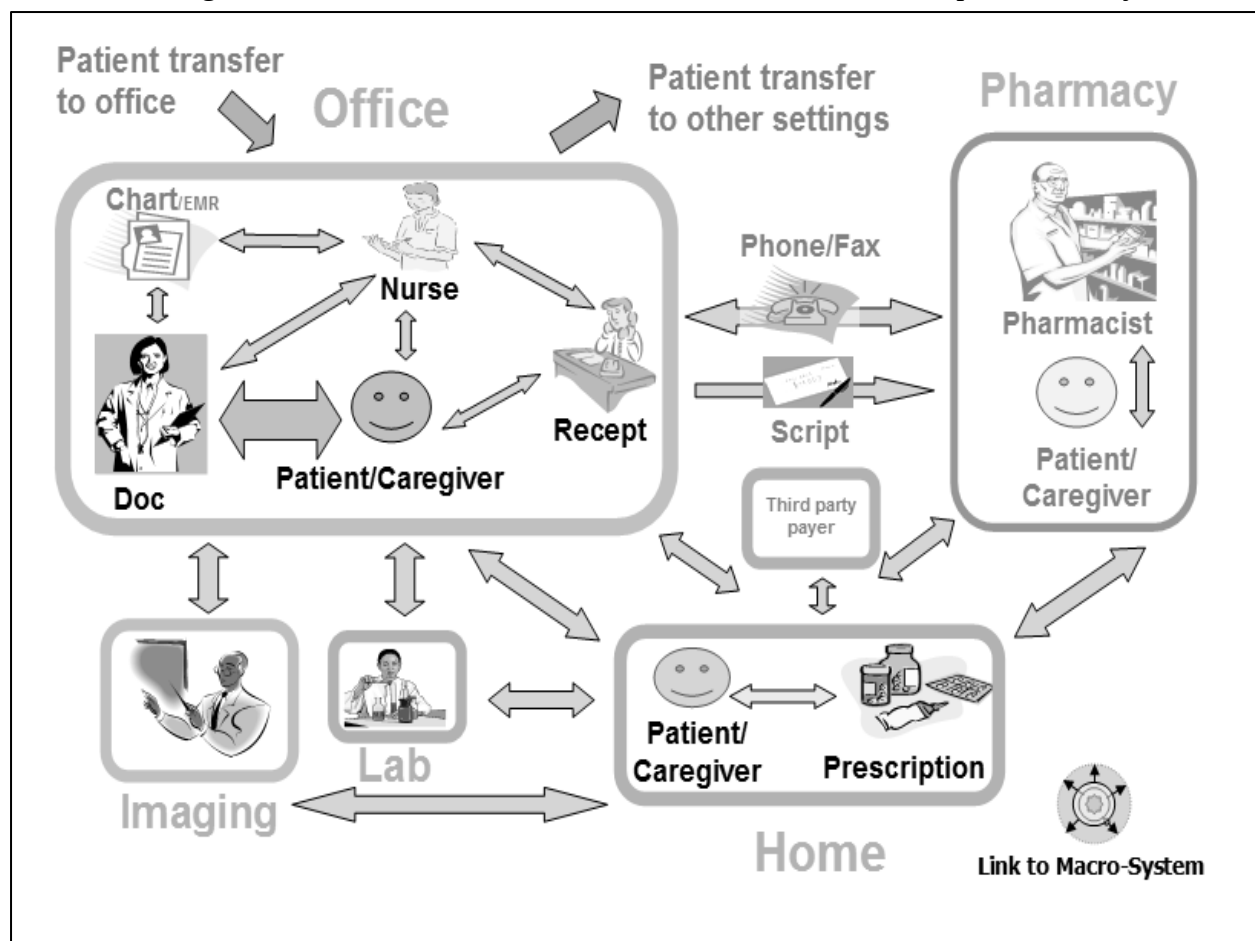


Figure 3. Micro-system model of medication management.

with details of frequency and consequences of these errors and corrective action recommended or used. These macro- and micro-system models can also provide various other functions that we have described elsewhere.¹⁷

A Visual Error Reporting Tool

Figure 4 is an example of how a visual reporting tool could be used, based on the same micro-system model shown in Figure 3. To report an error, the user would first describe the patient's demographic details and enter other information deemed appropriate, such as their job designation, circumstances in which they discovered the error, etc. Then they would commence entering details of the error using the visual interface.

In this case, the error is that the primary doctor (who is reporting this error) refilled the wrong dose of a blood pressure medication by phone. The patient is a 76-year-old female with type 2 diabetes mellitus, hypertension, and coronary artery disease (CAD). She sees her primary doctor every 3 months and is on various appropriate medications, including quinapril 10 mg daily for hypertension. She also sees a cardiologist annually for CAD followup and management. At today's visit to the primary doctor's office, the doctor notices that her blood pressure is above goal at 147/90, while it had been well controlled at previous visits (including the most recent visit 3 months ago). Therefore, he/she inquires as to the patient's compliance with the medication, to which the patient replies "my pressure's probably up because you cut down my medication dose last time." The doctor reviews the chart and finds no documented change in any blood pressure medication. He/she inquires further and discovers that at the patient's previous visit to the cardiologist (8 months earlier), the cardiologist had noted elevated blood pressure and increased the dose of quinapril from 10 mg to 20 mg daily and also prescribed a 6-month supply. Then, 2 months ago, when the patient was running out of quinapril, she called her primary doctor's office for a refill. The doctor reviewed the chart and instructed the nurse to phone in a prescription for quinapril 10 mg daily, since this was the dose documented in the patient's chart. There was no consult letter in the chart from her cardiologist. The patient had seen the primary doctor twice since the cardiology visit but apparently had not mentioned the dose change.

Panel 1 of Figure 4 shows how the doctor would indicate the location of the error, which in this case is in the communication (via telephone) between the doctor's office and the pharmacy. Next, in Panel 2, when presented with a list of possible errors in this step, the reporter picks the relevant item from the list, which in this case was "Wrong dose." Next, the user chooses to describe the contributing factors. As mentioned earlier, one of these was that the chart did not contain any information from the cardiologist regarding the dose change. The user therefore clicks on the chart and chooses the appropriate item from the list, as shown in Panels 3 and 4. Another contributor was that the patient did not inform the primary doctor about the dosage adjustment; this can be entered in the same fashion.

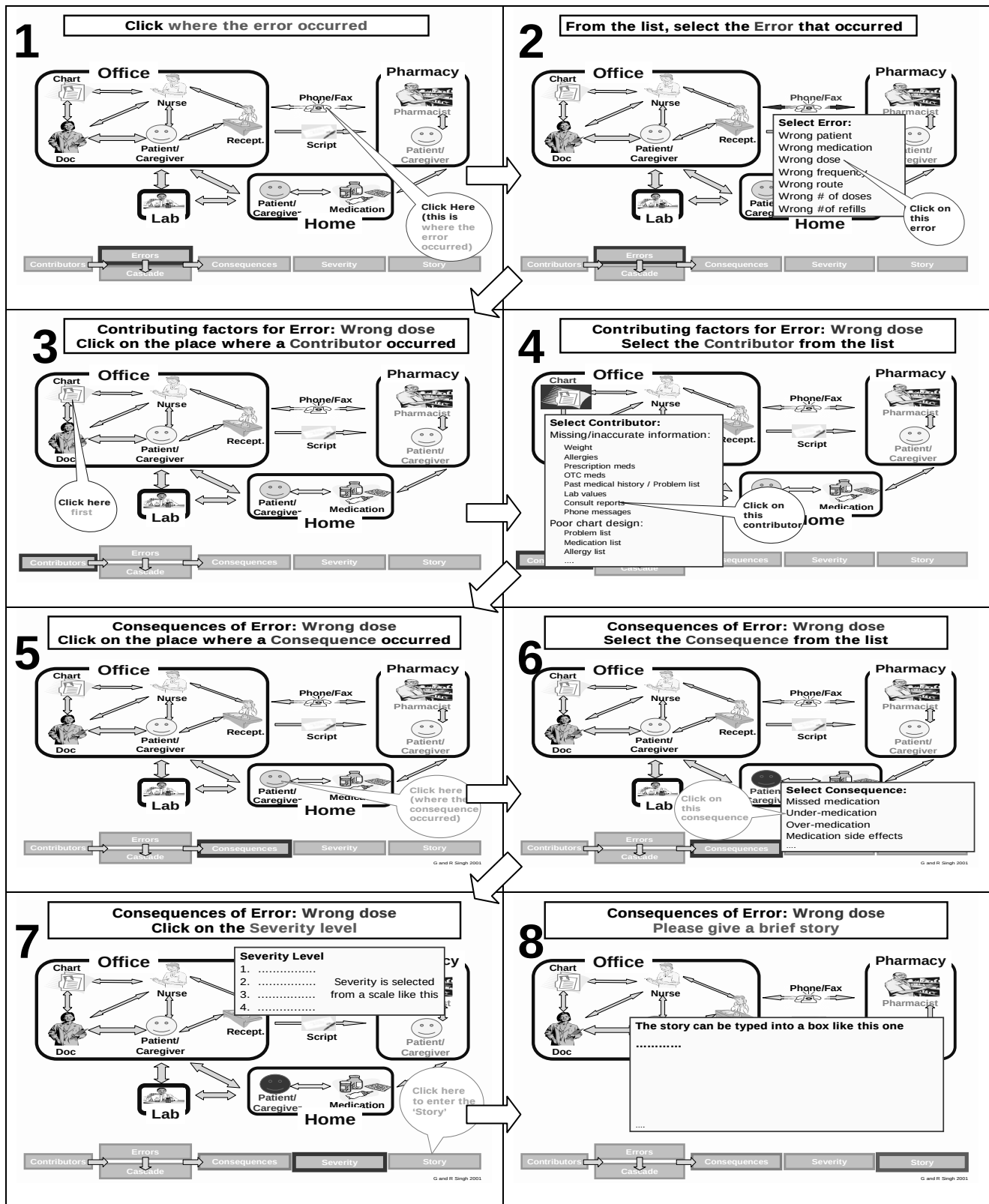


Figure 4. Example of interactive error reporting.

Similarly, the user is prompted to indicate the location and nature of any consequences. In this case (Panels 5 and 6), the patient was under-medicated. Finally, the severity of the error can be elicited, usually on a scale, as indicated in Panel 7, and the user types a brief narrative description of the event to add any other details and help to eliminate any ambiguities (Panel 8).

The various lists, hyperlinked to the entities and their interactions, are designed to help reduce emotive and cognitive biases in perceptions and reporting.

Discussion

We have proposed a novel approach, based on computerized visual models of the health care system, to facilitate the reporting, summarizing, and dissemination of information about medical errors in primary care. The purpose is to make information about medical errors useful both at the practice level and at the policymaking level.

The ability to view a macro- or micro-system diagram together with error frequency information can be valuable in helping decisionmakers at various levels in the health care system identify and prioritize areas for system improvement. Similarly, the ability to summarize a single event—including errors, contributing factors, and consequences—in a clear visual format would appear to provide some advantages when compared to a list of codes. It should be noted that in any reporting system, reports are submitted by human beings who have their own unique viewpoints and past experiences that color their perception of incidents. For example, perceptions of contributing factors will likely vary among reporters for the same incident.

Our hypothesis (as yet untested) is that a visual format could help overcome this issue because the process of reporting involves looking at and interacting with system models. These remind the reporter of the processes that are in place, his/her role in them, the problems that can occur, contributors that might be present, and consequences that can occur, thereby improving situational awareness,¹⁸ as well as aiding narration of the “story.” In other words, the visual models and associated drop-down lists have the potential to help create a common vision of the system. Furthermore, we suggest that a visual format can facilitate information sharing with team members and other stakeholders (including patients and families) and has the potential to enhance the understanding of events, thus facilitating the development of appropriate preventive strategies.

Error reporting using a visual format would require appropriate staff training, probably more so than for a simple paper-based reporting tool. Staff would need to be familiarized with the visual models and the interface. However, some of the potential benefits outlined above might justify such an up-front effort.

Another benefit, important from a practical perspective, is the fact that this visual reporting approach allows the user to code the error while reporting it. This contrasts with conventional reporting systems using existing taxonomies, which require considerable time and effort to dissect written error reports and code them. Individual practices wishing to collect and understand local error data generally cannot afford the time and effort required to manually code errors using alpha-numeric taxonomies, nor are they likely to have the expertise to do so.

Further work is needed to fully operationalize the concepts described here and to evaluate the usability of the visual interface and its potential benefits. In order for the process to be used across health care settings and internationally, it would be necessary to create visual diagrams of other systems. We are beginning to create standardized icons for the whole range of entities in the various settings of the health care system. These would enable interactive creation of micro-system models (potentially by end-users) for any setting.

Figure 5 shows two examples of micro-system models developed for falls and postoperative pain management in a hospital setting. In addition, to facilitate use in a wide variety of settings, this kind of reporting tool should be accessible directly from within electronic medical record systems and should be able to import patient data directly from these records. A recent study¹⁹ in the domain of operating theaters demonstrated that integration of an incident reporting system into an electronic patient record significantly increased the number of incidents reported.

While tracking rates of errors over time or comparing rates among different institutions or regions are commonly perceived aims of error reporting systems, caution is needed in interpreting such data because of the problem of underreporting. According to IOM estimates, only about 5 percent of known errors are reported.² Therefore, differences in rates of errors reported over time or among institutions do not necessarily reflect true differences in rates of errors but may merely represent differences in reporting behavior.

Similarly, and perhaps even more importantly, those errors that are reported most frequently are not necessarily the errors that occur most frequently. They are merely the ones that reporters feel more comfortable reporting.²⁰ It is hoped that creating more user-friendly and intuitive reporting tools, such as the one described here, will help increase reporting rates and so, provide more opportunities to learn. However, this needs to be done in concert with changes in organizational culture²¹ that encourage reporting and learning from errors and discourage blame and punishment for errors that are due to systemic problems. In other words, a shift from the prevailing culture of blame to a culture of safety is called for.

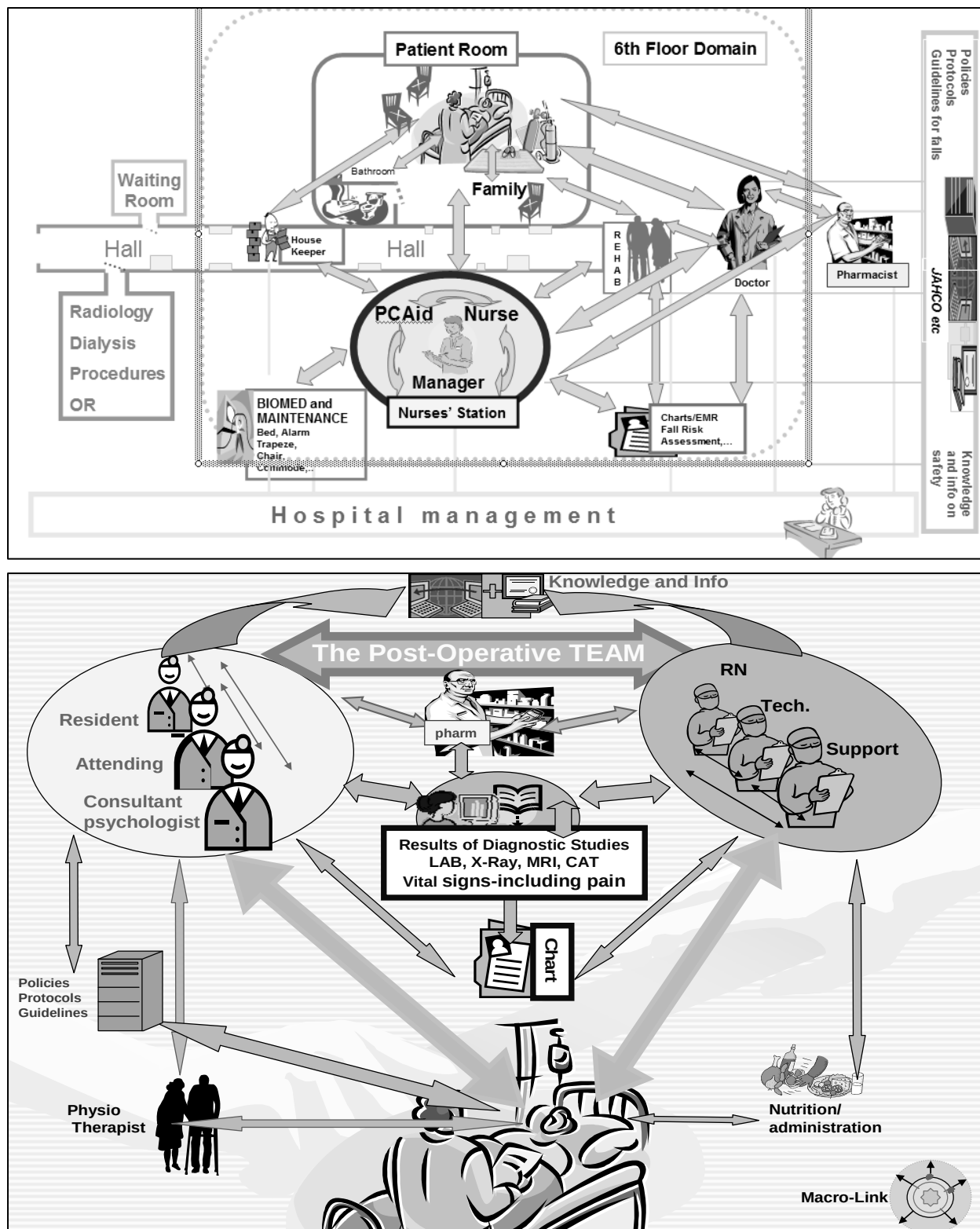


Figure 5. Examples of micro-system models for inpatient falls (top) and for postoperative pain management (bottom). Adapted from Singh R, Naughton B, Anderson D, et al. Building self-empowered teams for improving safety in postoperative pain management. In press.

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References

1. McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. *N Engl J Med* 2003; 348: 2635-2645.
2. Kohn LT, Corrigan J, Donaldson MS, eds. *To err is human: Building a safer health system*. Washington, DC: National Academies Press; 2000.
3. Joseph GM, Stee L, Marian TM, et al. Journal reporting of medical errors: The wisdom of Solomon, the bravery of Achilles, and the foolishness of Pan. *Chest* 2007; 131: 890-896.
4. Billings CE. *Incident reporting systems in medicine and experience with the Aviation Safety Reporting System. A tale of two stories: Contrasting views of patient safety*. Chicago: National Patient Safety Foundation at the AMA; 1998.
5. Leape LL, Arbookire S. *WHO draft guidelines for adverse event reporting and learning systems*. Geneva, Switzerland: World Alliance for Patient Safety; 2005.
6. Patient Safety and Quality Act, United States Public Law 109-41, 2005. Available at: <http://www.mihealthandsafety.org/pdfs/pub-3-scheffler.pdf>. Accessed April 4, 2008.
7. Thompson TG, Brailer DJ. *The decade of health information technology: Delivering consumer-centric and information-rich health care: Framework for strategic action*. Washington, DC: Department of Health and Human Services; 2004.
8. Clancy CM. *Evaluating the potential of new technology. Building a better delivery system: A new engineering/health care partnership*. Washington, DC: National Academies Press; 2005.
9. House of Commons Committee of Public Accounts, A safer place for patients: Learning to improve patient safety, HC 831. London: The Stationery Office Limited; 2006.
10. Aspden P, Corrigan JM, Wolcott J, et al, eds. *Patient safety: Achieving a new standard for care*. Washington, DC: Institute of Medicine, Committee on Data Standards for Patient Safety; 2004.
11. Chang A, Schyve PM, Croteau RJ, et al. The JCAHO patient safety event taxonomy: A standardized terminology and classification schema for near misses and adverse events. *Int J Qual Health Care* 2005; 17: 95-105.
12. *International classification for patient safety*. Geneva, Switzerland: World Health Organization. Available at: www.who.int/patientsafety/taxonomy. Accessed April 4, 2008.
13. Chen F, Philips R. NAPCRG leads efforts to distribute ICPC information. *North American primary care research group newsletter*. 2005 February; 33.
14. Weingart SL. Beyond Babel: Prospects for a universal patient safety taxonomy. *Int J Qual Health Care* 2005; 17: 93-94.
15. Singh R, Pace W, Singh S, et al. A concept for a visual computer interface to make error taxonomies useful at the point of primary care. *Informat Prim Care* 2007; 15: 221-229.
16. Buzan T. *The mind map book*. New York: Penguin; 1991.
17. Singh R, Singh A, Fox C, et al. Computer visualization of patient safety in primary care: A systems approach adapted from management science and engineering. *Informat Prim Care*. 2005; 13: 135-144.

18. Craig PA. Controlling pilot error: Situational awareness. New York: McGraw-Hill; 2001.
19. Haller G, Myles PS, Stoelwinder J, et al. Integrating incident reporting into an electronic patient record system. *J Am Med Inform Assoc* 2007; 14: 175-181.
20. Nuckols TK, Bell DS, Liu H, et al. Rates and types of events reported to establish incident reporting systems in two U.S. hospitals. *Qual Saf Health Care* 2007; 16: 164-168.
21. Singh R, Singh A, Taylor JS, et al. Building learning practices with self-empowered teams for improving patient safety. *J Healthc Manag* 2006; 8: 91-118.

Christiana Care Health System: Safety Mentor Program

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Abstract

According to the Institute of Medicine, as many as 98,000 patients die each year because of preventable medical errors. The Christiana Care Health System is committed to eliminating preventable medical errors. A staff survey in 2001 showed that there were opportunities for improvement related to error reporting. Staff across the board felt they had responsibility for error prevention but viewed the error-reporting process as less than user friendly. Survey respondents also expressed fear of the consequences of being associated with an error. In 2003, the concept of a Safety Mentor program was first proposed during a focus group discussion. As conceived, the Safety Mentor would be an interdepartmental “ambassador” who could help staff navigate the system of error reporting, safe practices, and infection control. By May 2004, approximately 75 frontline staff had assumed this role. Safety Mentors now represent virtually all areas of the organization, including clinical and support departments. Through the Safety Mentor program’s additional efforts to identify barriers and implement best safety practices, Christiana Care has demonstrated a decrease in reported events with major outcomes and an increase in reported near-miss medication events that were corrected before they reached the patient. These trends reflect our efforts to provide reliable health care by detecting failures before they occur, thus mitigating harm to our patients. This increase in near-miss reporting allows us to place emphasis on learning and implementation of practice changes to improve safety. A Safety Mentor program can be implemented in a diverse range of health systems. It has proven to be effective in engaging frontline staff in patient safety efforts. This innovative program was reviewed by the Agency for Healthcare Research and Quality’s High-Reliability Network learning organization and found to be a promising practice.

Introduction

Background: Medical Errors and Need for Culture of Safety

According to the Institute of Medicine, as many as 98,000 patients die each year because of preventable medical errors, exceeding deaths attributable to motor vehicle accidents, breast cancer, or AIDS.¹ The Christiana Care Health System is committed to eliminating preventable harm to patients. Implementing clinical best practices or improved technologies—such as barcoding for medication administration and electronic medical records—is important to this objective. However, the best technology alone will not eradicate error. Rather, a combination of “best practices” and technology within a culture of patient safety is essential for error prevention.

The formal journey to building a patient safety organization at Christiana Care began in 2000 with the formation of the Patient Safety Committee. At that time, it was perceived that reporting of errors was difficult, and many employees were fearful of disciplinary action or professional liability related to reporting events. The committee sanctioned a Patient Safety Opinion Survey in 2001 to elicit staff perceptions of medical errors occurring in our organization. All categories of respondents, including physicians and residents, felt that physicians were most responsible for preventing errors. Nurses felt largely responsible, and all respondents felt some degree of responsibility for patient safety.

Results of this survey confirmed that fear of disciplinary action and professional liability were the most commonly cited reasons for not reporting errors. Only 55 percent of respondents felt that error reporting was widely encouraged and nonpunitive. Fear of punitive consequences for individuals after they report an error is believed to be a strong incentive to report only those errors that cannot be hidden.² An organization in which errors cannot be reported without fear of retribution is going to have greater difficulty identifying system issues that contribute to errors. When asked in the survey if our organization ever improved patient care in response to medical errors, 53 percent (including 34 percent of senior management) replied, “No.” This health care system was not perceived as a learning organization. Lack of reporting was inhibiting the ability to learn.

Seeking a High-Reliability Approach to Improving Patient Safety

High-reliability organizations (HROs), such as those in the aviation and nuclear power industries, commonly operate in a reliable and safe manner, even during uncommon and hazardous circumstances. While insisting on training and high standards of performance, these organizations recognize that performance expectations alone are insufficient to ensure safety.³ The Institute for Healthcare Improvement identified a three-step model for applying the principles that guide high-reliability organizations: (1) prevent failure, (2) identify and mitigate failure, and (3) redesign processes based on critical failures that have been identified.⁴

Another high-reliability model emphasized a “flattened hierarchy” to encourage two-way communication of divergent opinions at every staff level.⁵ This type of environment fosters open communication. The “Safe Passage Council” model from Clarian Health Partners also provided further understanding of essential program features.⁶ With these models and with information gathered from our 2001 staff survey, Christiana Care continued its journey toward building a culture of safety through improved reporting and error prevention.

Safety Mentor Program Design

The concept of a Safety Mentor program was first proposed in 2003 during a focus group discussion. As conceived, the Safety Mentor would be an interdepartmental “ambassador” who could help staff navigate the systems of error reporting, safe practices, and infection control. By May 2004, the program was launched with the role of the Safety Mentor well defined (Table 1). Approximately 75 frontline staff who had been identified as informal leaders were selected by their managers to assume the mentor role. Safety Mentors currently represent virtually all areas of the organization, including, but not limited to, all disciplines of nursing, respiratory therapy, laboratory, home care services, environmental services, pharmacy, radiation oncology, dialysis center, laundry, materials management, maintenance, occupational safety, and employee health.

Table 1. Safety mentors: Role description and meeting structure

Role description	Safety mentor
Responsibilities	<i>The patient/employee safety mentor serves as an interdepartmental ambassador for safety and infection control. The mentor:</i> • Serves as a support to staff throughout the system to heighten everyone's awareness of and responsibility for developing a culture of safety. • Assists staff to identify and report key patient/employee safety and infection control issues to the Patient Safety Committee via designated contact. • Fosters communication of patient/employee safety practices to staff, e.g., National Patient Safety Goals. • Functions as a resource to staff and mentors staff in patient/employee safety and infection control behaviors. • Facilitates patient/employee safety activities within their unit or department, e.g., Unit Level Practice PI committee activities, implementation of patient safety activities. • Serves as a focus group member for the Patient Safety Committee and work teams. • Facilitates learning to develop a culture of safety. • Participates in monitoring/surveillance activities as needed.
Requirements	<i>The safety mentor shall possess the following skills and abilities:</i> • A minimum of 6 months' experience working on unit/department. • Desire or interest in learning. • Knowledge of unit/departmental PI and patient/employee safety activities. • Skilled in oral and written communications. • Ability to collaborate with staff and clinicians. • Ability to gain confidence and establish support.
Meetings	• Safety mentors will collectively meet every other month or more frequently as needed.
Meeting composition	<i>Membership will include representatives from the departments listed below and be facilitated by the Patient Safety Program Manager in collaboration with the Corporate Director, Patient Safety and Accreditation and the Patient Safety Officer:</i> • Respiratory therapy. • Radiology technician. • Laboratory phlebotomist. • Unit level nursing practice PI committees chairpersons (includes Riverside). • Primary care representative. • Home Care Services (VNA) representative.

Table 1. Safety mentors: Role description and meeting structure (continued)

Role description	Safety Mentor
Meeting composition (continued)	• Home infusion. • Satellite office representative (Foulk Road). • Environmental services/escort representatives/laundry. • Pharmacy. • Physician representative. • Radiation oncology/Cancer center representative. • Materials department. • Maintenance department. • Occupational safety. • Employee health. • Dialysis unit.
Meeting purpose	<i>To utilize principles of dialogue for communicating safety activities, to serve as a barometer of the organization's culture of patient/employee safety, and to develop strategies to promote and strengthen a culture of patient safety. To accomplish this, mentors will:</i> • Learn about culture and how to identify the difference between a safe and an unsafe culture. • Receive regular contact, communication, and tools from the designee from the Patient Safety Committee and its work teams. • Define patient safety behaviors. • Support safe behaviors through the development of a recognition of staff for preventing adverse events. • Assist with measuring effectiveness of safety practices.

PI = performance improvement; VNA = Visiting Nurse Association

Role of the Safety Mentor

After a department manager selects a Safety Mentor representative, a letter of appointment is provided, and a Safety Mentor Information Guide is shared. The guide includes an overview of the patient safety movement, specific Safety Mentor roles and responsibilities, safe practice tools used in our organization to facilitate patient safety, National Patient Safety Goal educational PowerPoint® presentations reviewing implementation expectations for Christiana Care, and contact information for internal Patient Safety teams and unit based Medical Directors. The Information Guide also serves as a unit resource for staff to assist in understanding and operationalizing safe practice tools and strategies. The Information Guide is formatted in a three-ring binder, so that new information can be easily added and obsolete information removed. A tab for agendas and minutes of each meeting is included to prevent over-reliance on memory and to promote wider sharing of important information. Detailed information on the use of our Safety

First Learning Report (formerly, event report) is also included to facilitate appropriate use in reporting errors and near misses.

The Safety Mentor attends the bimonthly Safety Mentor meetings. These meetings are facilitated by the Patient Safety program manager in collaboration with the Corporate Director of Patient Safety and Accreditation and the Chief Medical Officer (Patient Safety Officer). At each meeting, data are reviewed from Christiana Care's safe practice behavior monitoring "report card" to assess how well the safety practices are being operationalized.

The Patient Safety program manager and invited presenters then share stories and discuss lessons learned from sentinel events or other adverse outcomes/near misses and address concerns about error reporting. Presentations are viewed as an opportunity to learn, and a blameless environment is encouraged. In addition, efforts to engage patients in their own care by encouraging two-way communication between patients and caregivers are evaluated.

The meetings also provide the Safety Mentors with an opportunity to share patient safety challenges that they face on a daily basis. Barriers to safe practice are readily identified by frontline staff. Safety Mentors represent their unit-based staff and their own experiences, and they know their comments are valued and will lead to change. By incorporating each of these strategies, the patient safety leaders can also determine whether the program is succeeding at fostering trust, encouraging collegiality, and improved teamwork among disciplines and departments.

Communicating, learning, identifying problems, measuring progress, and providing advocacy and enthusiasm for adopting new processes are important roles that Safety Mentors fulfill for their departments. They interact not only with their peers and management but also with multiple disciplines. Safety Mentors are instrumental in providing a channel of communication among frontline staff and the unit-based and system-wide quality and safety councils and committees. Information and expectations about safe practice behaviors are shared with staff, while concerns from staff are heard in a system-wide forum. The following description of Safety Mentor roles provides an overview of specific mentor activities.

Adopt best practices. Consistent with national initiatives, Safety Mentors facilitate patient and employee safety activities within each department. Initiatives include the Joint Commission's National Patient Safety Goals, which are promoted through organizational safety teams. Each Safety Mentor serves as liaison between his/her unit and the Safety Teams to build workable solutions to patient safety issues.

In this role, Safety Mentors have succeeded in the creation of learning tools, such as an educational video depicting "read back" processes for confirming telephone orders and "job aids" such as SBAR (Situation, Background, Assessment, Request) and DATAS (Demographics, Assessment, Tests, Alerts, Status) (Figure 1) communication tool pocket cards that are used at the departmental level to reinforce "best practices." In addition, informal sharing of patient stories at Safety Mentor meetings ultimately led to a system-wide formal storytelling forum, "No Harm Intended: Lessons Learned in Patient Safety."

DATAS Report

Use to report patient condition during hand-offs, i.e., shift-to-shift, unit-to-unit.

D Demographics	Diagnosis/Diet
A Assessment	Allergies Assessment: • Vital Signs • IV /Invasive Lines / • Pain Level - Other Devices • Systems Review • New Medication Orders
T Tests	Test Performed • Results Telemetry • Rhythm
A Alerts	Activity Level Alerts: • DNR Status • Additional Patient/ • Precautions - Family Concerns • Fall Risk • Anticipated Changes
S Status	Status of: • Plan of Care • Current Treatment • Discharge

SBAR Report

Use to report findings to a physician or other members of the health care team about a patient's condition.

Prior to calling the physician, review the last 24 hours of progress notes and always assess the patient.

S Situation	I am calling about: <i>Patient name and location</i> The problem I am calling about is: <i>State what the problem is, when it happened, when it started, how severe it is.</i> The most recent vital signs are: BP: _____, Pulse _____, RR _____, Temperature _____. I have just assessed the patient and I am concerned about: <i>State what you are concerned about.</i>
B Background	State pertinent background information related to the situation. It may include: diagnosis, medications, allergies, labs, code status, interventions and other pertinent clinical information.
A Assessment	What is your assessment of the situation? <i>State what you think the problem is.</i> State if the patient is unstable or appears to be getting worse.
R Request	If you have a specific request related to the problem you are reporting: <i>State the request.</i> Remember to read back all verbal and telephone orders. Request a read back when reporting critical test results.



Figure 1. SBAR and DATAS communication tool pocket cards, which are used at the departmental level to reinforce “best practice.”

Facilitate learning. The mentor guides staff to a better understanding of expectations surrounding safe practice behaviors. When unit-specific barriers and work-arounds are identified, the mentor can “bring home” organizational policies and give them context within the unit’s day-to-day operations. When the mentors identify barriers such as the unit’s environment, excess workload, staffing shortages, or other resource shortfalls, they are empowered to advance strategies to enhance a safe environment for patients and staff. This includes chain-of-command reporting and direct access to the organization’s Patient Safety Officer.

Awareness. Data and information on safe practice behaviors related to safety measures are shared with department staff. Each Safety Mentor receives a monthly report of progress in our measurement of safe practice behaviors. The Safety Mentor is also involved in communicating Safety First Alerts, which are concise notices describing a particular safety concern with safe practices to be implemented (Figure 2). These alerts cover a variety of safety issues such as errors in verbal communication of critical test results and key bounces on electronic IV pumps potentially causing wrong dose infusions. Alerts are prescribed to be shared with all staff affected within a timeframe based on a risk score.

Identify potential failures. The mentor guides staff in identifying key patient/employee safety and infection control issues. Serving as a focus group member for patient safety teams, the mentor identifies safety issues in the unit/department and communicates them to the staff for learning or developing change in practice. In 2005, the work of one safety team led to significant changes in the electronic event reporting system. Electronic reporting is now less time consuming (with fewer questions) and more user friendly (with prompts and pre-filled



CHRISTIANA CARE

Safety First Alert: Potential for errors in verbal communication of orders and critical test results.

Date: March 9, 2006

Safety Concern: Communication has been identified as a major root cause in sentinel events. Errors occur because communication can be incomplete, unclear, misunderstood, or confusing.

“Read back” of all verbal orders, telephone orders, and critical test results is required whenever possible. In an emergency, the information may be repeated back.

The **“read back”** process requires that information be written down and read back as a means of verification.

Areas Affected: All staff taking verbal orders, telephone orders and critical test results reported verbally or by telephone.

Safe Practices:

☒ Expect the receiver of the order or test result to read back the information.

☒ Ask for a “read back” if the receiver has not asked to have the information read back.

☒ Verify that the information that is read back is correct.

Contact Person:

Department: Performance Improvement

Telephone:

Thank you for implementing these safe practices to enhance patient safety.

Figure 2. Sample Safety First Alert. Each is a concise notice describing a particular safety concern with safe practices to be implemented.

demographic information from the hospital information system). Additionally, the mentor facilitates the department's use of the Performance Improvement Safety Hotline. The Safety Hotline is used for proactively communicating near-misses, "good catches," and potential safety hazards that may need review or investigation but not rise to the level of a required event report. The hotline is also used for staff to ask safety questions or request clarification of a regulatory concern. By advocating the use of these reporting tools, the mentor's preoccupation with identifying and reporting ensures that everyone receives the information needed to learn from errors and near misses.

Peer-to-peer feedback. Safety Mentors facilitate peer-to-peer monitoring and feedback of safe practices at the point of care. The Safe Practice Behavior Monitoring Program was developed to assist mentors in assessing their department's progress and to identify peers who exemplify safe behaviors. Conversely, peers who need assistance with safe practices are identified and mentored. Monthly results expose weaknesses and strengths to help the mentor lead improvement of expected behaviors with frontline staff. Individual departments are rewarded when goals are achieved. In addition to a departmental focus on our safe practices, the measurement program is organized uniformly across the system. This allows for specific population and aggregate system level reporting. At Safety Mentor bimonthly meetings, communication about organizational level goals becomes more meaningful as we review results for units and departments and compare these to the system level report.

These defined roles provide a path for communication to flow from the front line up and from the top down. The Safety Mentor program is a model designed to engage frontline staff in fulfilling organizational goals. The model will be shaped over time to meet the diverse needs of our staff as they fulfill the mission of Christiana Care Health Services.

Results

Improved Reporting of Errors

Data from our Safety First Learning Report (event reporting system) show evidence of improved safety awareness and

empowerment among the staff. From 2004 to 2006, the data reflect increased reporting of medication near misses (Table 2, Figure 3). The proportion of reported medication near misses to total reported events also increased. Whether the number of near misses doubled or the number reported was simply better, the improved reporting is

Table 2. Improved near miss reporting

Year	Total reported events (N)	Medication near misses ^a (N)	<u>Near misses</u> Total events (%)
2003	7,321	46	0.6
2004	7,047	46	0.7
2005	6,897	56	0.8
2006	6,464	85	1.3

a Corrected before reaching patient.

providing us with valuable information to learn and make system changes that will be effective in preventing harm to our patients.

Reduced Severity of Errors

In addition to increases in reported near misses, the rate of events with major outcomes also decreased (Figure 4). Between 2003 and 2006, inpatient volume increased 10 percent, while the count of events with major outcomes did not increase proportionately. The net result was a decrease in the rate of events with major outcomes from 1.21 to 1.12 per 1,000 patients – a reduction of 8 percent.

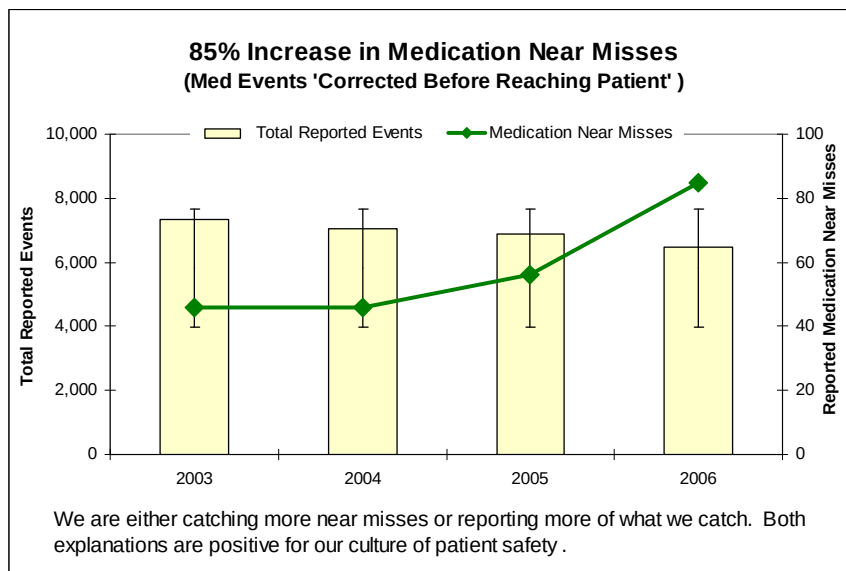


Figure 3. Improved near-miss reporting at Christiana Care Health System.

Safety Culture Changes

Since 2006, Christiana Care has participated in the Hospital Survey on Patient Safety Culture (HSOPSC), which was developed by the Agency for Healthcare Research and Quality (AHRQ).⁷ The prior 2001 survey showed that 76 percent of staff feared disciplinary action if caught making a mistake. By 2006, the AHRQ survey results showed that only 28 percent of respondents felt their “mistakes were held against them.”

The Safety Mentors have been utilized as a focus group to identify the issues of nonpunitive error

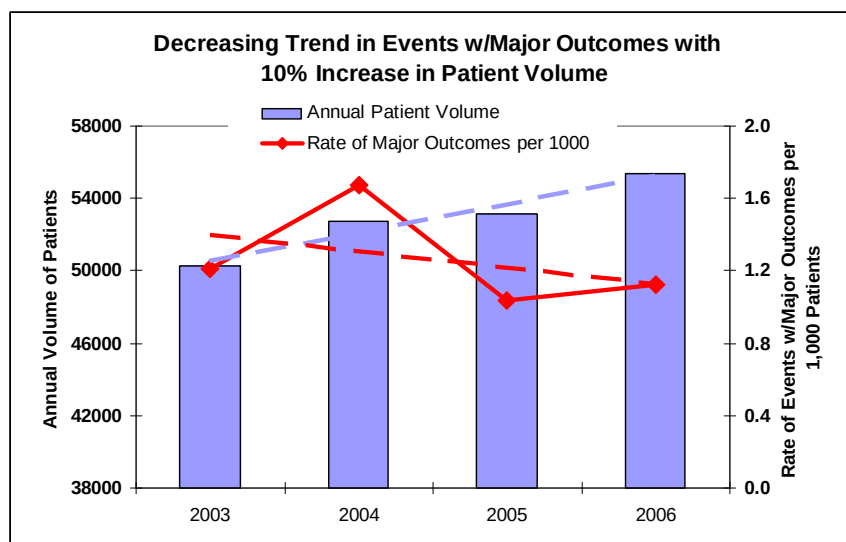


Figure 4. Decreasing trend in events with major outcomes at Christiana Care Health System.

reporting so that concrete action plans can be developed. This group identified a lack of standardization in event analysis and response by management. As a result, an interdisciplinary team has been formed to develop a standardized approach to event analysis and response with integration of “just culture” principles.

The AHRQ HSOPSC provides reliable measures with more detail than prior surveys and includes national benchmark comparisons with 382 hospitals. When assessing strengths and opportunities from the 2006 survey, one of our top strengths was “Organizational Learning – Continuous Improvement.” In addition, compared to national comparative data, learning was also found to be a strength. Frontline staff confirm they are learning from information being shared about errors, and they perceive that positive process changes have occurred because these errors are being identified. Despite these strengths, nonpunitive response, feedback, and communication about errors continue as a focus in our Safety Mentor Program and throughout the Christiana Care system.

Discussion

Instituting the Safety Mentor program, coupled with efforts to implement “best safety practices,” has resulted in a demonstrated decrease in reported events with major outcomes and an increase in reported near-miss medication events that were corrected before they reached the patient. These trends reflect Christiana Care’s efforts to provide reliable health care by detecting failures before they occur, thus mitigating harm to our patients. This increase in near-miss reporting allows emphasis on learning and implementation of practice changes to improve safety. In turn, it is expected that awareness and communication of these successes will lead to an increase in Safety First Learning (event) reporting.

Conclusion

In order to promote consistency and visibility of the Safety Mentor role, formal recognition, appointment, orientation, and education processes were integrated to assist with role development. Formalizing the relationship between the Safety Mentors and unit-based medical directors (physicians) is the next step in improving the program’s effectiveness. Involving physicians as members of the team is likely to maximize the impact of the work of the Safety Mentor group.

Implementing a Safety Mentor program has allowed patient safety strategies to reach frontline staff in a highly personalized, meaningful, and less bureaucratic manner. Communication in any large health care organization can be challenging; the closed-loop communication from frontline Safety Mentor staff to the Patient Safety Officer and back has improved dialogue and generated a rich focus group, which has facilitated quick “wins” in our patient safety program. Providing Safety Mentors with the Information Guide resource helps promote increased awareness of existing teams. It may also facilitate their connection with unit- or department-level initiatives, and it makes educational resources readily available, minimizing unnecessary duplication of efforts.

As confirmed in Safety Mentor meetings, storytelling can be a powerful tool for patient safety. As mentioned earlier, this insight led to development of a system-wide storytelling forum called “*No Harm Intended: Lessons Learned in Patient Safety*.” These sessions are intended to promote open discussion and sharing of lessons learned from near misses or actual events. These sessions are open to all interested staff, with a particular emphasis on frontline health care providers. Some of these sessions are now being scheduled to coincide with Safety Mentor meetings, so that Mentors can attend more easily. When frontline staff see that processes have actually been changed to reduce error potential based on their feedback, this is extremely powerful in generating a nonpunitive learning environment surrounding error reporting.

Safety Mentor programs can be implemented in a diverse range of hospitals and health care systems and have proven effective in engaging frontline staff in patient safety efforts. This program was reviewed by the Agency for Healthcare Research and Quality’s High-Reliability Network learning organization and found to be a promising practice (see HRO guide at www.ahrq.gov/qual/hroadvice/hroadviceapf.htm).

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References

1. Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: Building a safer health system. Washington, DC: National Academies Press; 1999.
2. Leape L. “Concerning patient safety and medical errors.” Testimony before U.S. Senate Subcommittee on Labor, Health and Human Services, and Education, January 25, 2000.
3. Leape L, Berwick D. Five years after to err is human: What have we learned? JAMA 2005; 293: 2384-2390.
4. Nolan T, Resar R, Haraden C, et al. Improving the reliability of health care. IHI Innovation Series white paper. Boston: Institute for Healthcare Improvement; 2004. Available at: www.ihl.org/IHI/Results/WhitePapers/ImprovingtheReliabilityofHealthCare.htm. Accessed March 30, 2008.
5. Weick K, Sutcliff K. Managing the unexpected: Assuring high performance in an age of complexity. Hoboken, NJ: Jossey-Bass; 2001.
6. Rapala K. Mentoring staff members as patient safety leaders: The Clarian Safe Passage Program. Crit Care Nurs Clin North Am 2005; 17: 121-126.
7. Sorra JS, Nieva VF. Hospital survey on patient safety culture. (Prepared by Westat under Contract 290-96-0004). Rockville, MD: Agency for Healthcare Research and Quality; 2004. AHRQ Publication No. 04-0041. Available at: www.ahrq.gov/qual/hospculture/hospcult.pdf. Accessed March 30, 2008.

News Media and Health Care Providers at the Crossroads of Medical Adverse Events

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Abstract

In 2005, Indiana Governor Mitch Daniels issued an executive order that mandated Indiana health and medical professionals to report adverse event data. Although the mandate was designed to improve patient safety, the long-term success of mandatory reporting systems depends on maximizing effective reporting of adverse events and presenting these data in ways that will change the systems causing the medical errors. Perceptions of key constituents play a role in whether reporting is more or less effective in the short term and beneficial to patients in the long term. In this study, we sought to gauge perceptions of two stakeholders integral to the success of this mandated reporting: health care providers, who report adverse events to the State; and the news media, who report results from this government-mandated reporting to the public.

Introduction

Medical adverse events are injuries—fatal or nonfatal—caused by medical management. What are more generally called “medical errors”—preventable adverse events—have been identified as one of the top 10 leading causes of death in the United States, ahead of deaths from motor vehicle accidents, breast cancer, and AIDS.¹ The frequency of medical errors is also recognized by a large proportion of patients as a serious problem; 42 percent of Americans said they had personal knowledge of an error in their own care or in the care of a relative or friend.² Beyond fatality and injury figures, total national costs (lost income, lost household production, disability and health care costs) associated with preventable adverse events have been estimated to range between \$17 and \$29 billion.³

Finding a “cure” for the current system, which allows between 44,000 and 98,000 medical errors per year, is a necessity for patient safety. Nearly a decade ago, the Institute of Medicine (IOM) recommended a mandatory national reporting system for adverse events, overseen at the State level, as “a comprehensive approach to improving patient safety.”¹ Since that time, several States have implemented adverse event reporting systems with different levels of success. To date, most claims of success have been based on the number of events reported by different hospital staff.^{4, 5} While most discussions about medical errors revolve around issues of how to correct certain behaviors thought to increase error likelihood, empirical studies often propose remedies for reducing errors by attempting to remove human error from the medical error equation.^{6, 7, 8}

Although past efforts to address this important issue are noteworthy, we have come to realize that the reporting of adverse events is a complicated issue involving multiple stakeholders; including patients, health care and medical professionals, and the news media. If handled correctly,

medical adverse event reporting has the potential to improve patient safety and promote the open sharing of “best practices” and strategies to avoid future adverse events. However, confusion, fear, and blame may result if adverse event data are misinterpreted or misused. Thus, a systematic study is needed of individual perceptions regarding medical error reporting, mandatory systems of reporting, and the use of data that comes from these reports.

In this study, we explore the issues of medical adverse event reporting in the State of Indiana. Given the recent implementation of adverse event reporting, Indiana provides a useful context to study key perceptual issues that might help explain the potential success or failure of different aspects of one recently developed and implemented mandatory reporting system. Specifically, our study sought to assess the perceptions of two important stakeholders: health care providers and news media reporters.

Understanding the attitudes of these two groups should provide important guidance to identify barriers to the regulation of medical adverse event reporting, conceptualize solutions to those barriers, and develop strategies for the public dissemination of data to improve patient safety. To frame the research questions of central concern for our study, the following section provides a brief overview of adverse event reporting. The methods and data collected from Indiana news media professionals and health care providers are then detailed, followed by a discussion that includes prescriptions that ultimately should affect patient safety.

Overview of Adverse Event Reporting

The realization that medical adverse events are a leading negative contributor to health care quality in the United States led to the formation of a Quality Interagency Coordination Task Force to coordinate quality improvement activities in Federal health care programs. Until the IOM’s 1999 publication of *To Err is Human*,¹ a widely-disseminated indictment of the prevalence of medical adverse events in U.S. health care, adverse event reporting was largely ignored. As of December 2006, 27 States had passed legislation, regulations, or executive orders related to adverse event reporting by hospitals.⁹

The Agency for Healthcare Research and Quality (AHRQ) defines “adverse event” as an injury or death resulting from a medical intervention, something that is not due to the underlying condition of the patient.³ Preventable adverse events reflect two types of failure: either the correct action did not proceed as intended (e.g., an error of execution) or the original intended action was not correct (e.g., an error of planning). Errors can be diagnostic (e.g., misdiagnosis, leading to an incorrect choice of therapy, or a misinterpretation of test results); equipment-related (e.g., defibrillators with dead batteries or intravenous pumps with valves that are easily dislodged or bumped); infection-related (e.g., postsurgical wound infections); transfusion-related (e.g., giving a patient the incorrect type of blood); or misinterpretation of medical orders (e.g., failing to give a patient a particular meal ordered by a physician).³

The National Quality Forum’s (NQF)¹⁰ report lists 27 types of major adverse events.¹¹ These include surgical events (e.g., surgery performed on the wrong body part); product or device events (e.g., patient death or injury associated with the use of contaminated drugs or devices); patient protection events (e.g., infant discharged to the wrong person); care management events (e.g., maternal death or serious disability associated with labor or delivery in a low-risk

pregnancy); environmental events (e.g., death or serious disability associated with an electric shock); and criminal events (e.g., abduction of a patient of any age), to name just a few.

Given the specificity in types of adverse events and variations in the usage of the term, implementing a universal reporting system is challenging. State agencies have been the main proponents of reporting, with particular systems tailored to the needs of medical facilities in each individual State. This study examines Indiana's implementation of a mandatory reporting system in early 2005. The following section outlines the Indiana system, its purported benefits, and perceptions that may lead to questionable success.

Reporting in Indiana: The Current Context

In January 2005, Indiana Governor Mitch Daniels issued an executive order directing Indiana health care and medical professionals to report adverse event data to the Indiana State Department of Health (ISDH).¹² In January 2006, Indiana health care and medical professionals began reporting 27 different types of serious preventable medical adverse events to the ISDH.⁹

The focus of the Indiana regulation is preventable medical adverse events, or adverse events attributable to error.¹ For example, if a patient dies from pneumonia acquired postoperatively, it is an adverse event (e.g., a serious injury or death resulting from medical management, not the underlying condition of the patient). If analysis reveals that the patient contracted pneumonia because of poor hand washing or instrument cleaning techniques by the staff, the adverse event was preventable (e.g., attributable to an error of execution). This latter example is most closely aligned with the lay notion of medical error.

According to the ISDH, the purposes of error reporting include:¹²

- Increasing awareness of medical errors.
- Collecting and analyzing data on medical errors to determine whether there are areas where mistakes could be reduced.
- Assisting health care providers in reducing medical errors.
- Providing information to patients so that they understand their role in helping to prevent errors.
- Promoting the sharing of successful solutions and improvements among health care providers.
- Instituting a culture of open discussion.
- Developing "best practices" aimed at reducing medical errors.
- Reducing health care costs through elimination of errors and duplication.

Perceptions About Reporting

Although perceptions among the general public are important with regard to mandatory medical error reporting systems, the perspective of health care leaders is crucial. The general public seems concerned primarily with errors that occur in their own care or in the care of family members. Whether reporting is mandatory is unlikely to alter these perceptions. However, for health care leaders, the nature of medical error reporting (mandatory vs. voluntary) is likely to affect perceptions of reporting.

Physicians in the United States tend to agree with patients about the importance of disclosure. In a recent survey, 77 percent of physicians felt that they should be required to tell patients when errors are made in their care.¹³ Additionally, they believe the nurse and hospital have significantly less responsibility for the disclosure. This suggests that disclosure is a voluntary act on the part of the physician, who has an ethical (and personal) responsibility to report errors to patients and their families.

Despite a positive perception of error reporting to patients and families, some medical leaders nevertheless question the need and effectiveness of a mandatory reporting system. One potential reason for this resistance is that some leaders may feel they have already built a culture of openness, where medical and health care professionals do not hesitate to report medical adverse events. However, adding a layer of public error reporting could lead to a culture of fear, lessening the likelihood that errors will be reported.

Research has shown that this positive perception of physician disclosure is not always reflected in the actions of medical workers. For example, when physician trainees were queried about the most significant medical mistake they made in the last year, 24 percent reported discussing the error with the patient or family; a later study of physicians found a similar rate, 21 percent.¹⁴ However, according to another study, physicians said that an error need not be disclosed if the harm was trivial or if the patient was unaware of the error.¹³

Health care providers often list fear of litigation as a significant reason for not disclosing medical adverse events. Another potential reason for nondisclosure is that health care professionals may fear how the news media might frame adverse events. Media reports, such as those that surfaced following the release of *To Err is Human*, tend to highlight shocking statistics and pin the blame on individuals rather than scrutinizing loopholes in the system.^{1, 15, 16} Media misjudgments often lead the public to draw false or simplistic conclusions about a multifaceted problem.¹⁷ Because of this tendency, the IOM has been critical of how the news media, including *The New York Times* and *The Washington Post*, have exclusively reported the upper end of death figures attributable to adverse events (i.e., 98,000). Only a handful of news stories explained that IOM's estimates were based on extrapolations from studies from Colorado and Utah, and from New York, at least one of which was 15 years old.¹⁷ Nevertheless, the news media still play a key role in affecting how citizens understand and use information about health care and medical needs.¹⁶

Research Questions

In light of the research reviewed above, we examined how Indiana health care leaders and news media professionals perceive medical adverse events and the recent regulations. Specifically, the project aimed to (1) identify barriers to reporting, including solutions to those barriers; and (2) determine how data are best communicated to the public in order to improve patient safety.

The research presented in this article was conducted after the announcement of the reporting mandate but before the information was released to the public. The *Final Report of the Indiana Medical Error Reporting System*¹⁸ was released subsequent to our data collection efforts. In line with suggestions from our investigation, this document included medical adverse events reported by Indiana hospitals, ambulatory surgery centers, abortion clinics, and birthing centers. The first population of interest was health care professionals. The success of the reporting system will ultimately be decided by those instructed to come forward with medical error information; this is

why the perceptions of health care professionals are important. Our study addressed the following research questions (RQs).

RQ 1: How do Indiana medical and health care professionals perceive the adverse event reporting system? An additional question was posed to address barriers that might limit the effectiveness of the reporting system. To the extent that barriers can be identified, more accurate information can be gained to gauge how the barriers might affect the reporting of adverse events.

RQ 2: What barriers do Indiana medical and health care professionals perceive would affect the reporting of adverse events to the State of Indiana?

RQ 3: What are the suggested solutions to barriers to reporting adverse events as perceived by Indiana medical and health care professionals?

It is also important to understand media perceptions of the reporting system and of medical errors in general, in order to learn how to best communicate data to them. The news media's interpretation of medical adverse events affect how they portray the issue for the public, a crucial aspect of past media releases.

RQ 4: What do Indiana news media professionals understand about medical adverse events reporting?

It is also important to identify perceptions of medical adverse events by Indiana news media professionals, since media perceptions (whether accurate or inaccurate) influence public perceptions.

RQ 5: What do Indiana news media professionals perceive as the possible causes of medical adverse events?

RQ 6: What do Indiana news media professionals perceive as the solution to adverse events?

To understand health care leaders' perceptions of medical adverse events reporting, we conducted a series of focus groups. E-mail surveys targeting Indiana news journalists were also used to gauge their perceptions of medical adverse events. In this article, we discuss each population of interest separately for ease of reading. We then present a general discussion of the studies as a cohesive unit of information with final recommendations regarding patient safety.

Perceptions of Health Care Providers

Methods

The focus group method is an effective approach for understanding how people think and feel about an issue and for identifying lay beliefs among Indiana's health care and medical providers.¹⁹ A total of 32 adult health care professionals and/or medical providers participated in one of five focus groups, with 3 to 11 participants per group. Nurses, quality professionals, hospital executives, physicians, and public relations and marketing professionals were recruited through the Indiana Hospital and Health Association (IH&HA). Work experience among

participants in their current positions ranged from 6 months to 36 years. Participants held degrees, including BA/BS, MA/MS, RN, PhD, and MD. Informed consent was obtained, and focus groups were audiotaped for transcription purposes.

Two women and three men conducted the focus groups. The focus group moderator's guide was divided into six main topic areas. The topic areas were selected based on an informal review of existing literature in the field of adverse events and include: (1) introduction, (2) perceptions of medical adverse events and their regulation, (3) overall impact, (4) communication of data, (5) barriers to adverse event reporting, and (6) solutions to barriers. Researchers solicited input from the ISDH on questions and approval of the final moderator's guide.

The audiotapes of the focus groups were transcribed verbatim. Two coders analyzed data, and the coding scheme was cross-checked by inductive analysis where research begins with the data.¹⁹ Data were coded and categorized into six overall categories, based on open coding, axial coding, and selective coding.²⁰ Initial data analysis involved open coding to identify discrete themes that were compared and grouped within broader categories.

Results: Health Care Providers

Focus group findings addressed the perceptions of health care professionals with regard to three main aspects of medical adverse event reporting: perceptions of the reporting system in Indiana (RQ1), barriers to reporting (RQ2), and solutions to those barriers (RQ3). Themes common to all stakeholder groups are addressed below. The reader is referred to Whitten, et al.,²¹ for a more detailed description of themes from individual constituent groups and complete quotations for their support.

Perceptions of the Reporting System

Anxiety over public reporting. Participants were generally concerned with the media focusing on negative aspects of medical adverse events. One respondent explained, "Nothing is worse for the news media than to have a slow news day. So, they will love this because it gives them something for that week. And it's done under the guise of public service. I don't know whether they have that much of an investment in the game. For them it's like a great story to tell."

Health care providers fear the news media will sensationalize the issue of medical adverse events, shifting the focus away from the intention of the regulation. Health care professionals also fear the public might not be highly medically literate, thus reducing the likelihood that they would correctly interpret the information. This has the potential to lead to a culture of fear among health care providers, while hindering the future reporting of preventable medical adverse events. One health care provider explained, "You get concerned about people publicly sharing because they may get afraid. We have to be careful and go back to not reporting events."

Confidentiality. Instead of reporting errors to the general public, health care and medical professionals suggested error reporting information be shared only among health care organizations to improve the system. One provider said that things would be better if adverse events data were employed within the circle of health care providers: "Let's just not report this to

the public, but let's use this information in a confidential forum between health [care] systems and hospitals." The health care providers were concerned about public perception and litigation regarding public reporting of adverse events data.

Errors as an individual-level phenomenon. Many of the participants in each group focused primarily on the individual's role in any given medical error. Although this focus at the individual level is not completely without merit, it is the system that a mandatory reporting effort attempts to correct. Thus, the perception of the system is one of individual rather than system correction. Providers are cognizant that most adverse events occur because of a problem within a larger health care system. However, they are concerned that a mandatory data reporting system would limit attention paid to root causes of adverse events. Furthermore, they are concerned about how these data would be employed by State or news organizations.

Barriers to the Reporting System

Reporting as punitive. The reporting system was perceived as a punitive measure by a large portion of the participants. One respondent was very clear in stating, "There is nothing here that has anything to do with improving safety. It is just reporting events; there is not a method of sharing of solutions so the State would be better off; this is punitive reporting mechanics." This was associated with confidentiality insofar as participants viewed the mandatory nature of the system as its biggest downfall. Many participants raised concerns about the mandatory system by stating that their particular facility had been reporting errors for quite some time. These current systems are seen as more confidential, less punitive, and less intrusive to a culture of open dialogue.

Solutions

Explanation and education of the goals of the reporting system. Participants across groups highlighted the importance of education and information campaigns, which underscores the system-level nature of the issue. The majority of group members preferred instituting a system that allowed the sharing of adverse events for educational purposes. One respondent explained, "If we are not sharing, we are not learning. We can learn from each other's events." Moreover, getting out the message that reporting is a system-wide phenomenon that is nonpunitive, especially toward individuals, is likely to reduce anxiety associated with the public reporting of these events.

Many participants suggested that instead of simply reporting the number of events, preventive information should also be communicated. Most participants hoped to share information among medical institutions along with the data. One health provider explained, "If you are looking at things, and then you can see what you have done, even if there are near misses or an error, you can go in there and see what others have done or see the processes they have done and hopefully prevent an error from happening."

Summary: Health Care Providers

Health care providers acknowledge the benefits of reporting adverse medical events. They are particularly enthusiastic about the potential of employing adverse event data in instructive ways that can prevent future errors and improve patient safety. However, these same health care

providers have limited confidence that State agencies will employ and report these adverse events in constructive ways. Furthermore, there is a perception that news and other media outlets will misreport the data.

Indiana News Media Perceptions

Methods

Due to their convenience and affordability, we chose to collect data from the news media using e-mail surveys.²² An e-mail survey was sent to one representative from each Indiana radio and television station and each daily and weekly newspaper. The *Editor & Publisher International Yearbook* lists 68 daily and 96 paid weekly Indiana newspapers.²³ A total of 14 television news stations from five major markets (Indianapolis, Fort Wayne, Terre Haute, Evansville, and South Bend) received the questionnaire, based on the Nielson Media's television market list.²⁴ Since few Indiana radio stations focus on news as their primary product, only one radio news station was invited to participate in the e-mail survey.

The survey targeted people who covered health news. The health beat reporter was identified through the news organization's Web site. When news organizations employed general assignment reporters instead of health/medical beat reporters (as is the case for most media organizations in Indiana²⁵),

the e-mail survey was addressed to a newsroom editor or director. The e-mail survey took place from November 17, 2006 to February 17, 2007.

Completed questionnaires were received from 52 participants from the 179 Indiana news organizations, a response rate of 29 percent. The demographic composition of the sample is presented in Table 1 and is reflective of typical newsroom employees.²⁵

Most news employees rated their understanding of health or medical issues as good (54 percent) or fair (40 percent), and they felt somewhat confident (84 percent) about covering health issues.

Table 1. Demographic characteristics of media professionals sample

Demographics		%
Race	Caucasian	92
	Other	8
Education	College degree	52
	Some college	26
Annual income	<\$50,000	40
	\$50,000 - \$74,999	14
Sex	Male	48
	Female	52
Professional task	Editor	50
	News director	12
	Nonhealth/nonmedical beat reporter	16
	Health/medical beat reporter	14

Results: News Media Perceptions

The majority (77 percent) of Indiana journalists were familiar with the term “medical error.” They typically viewed a medical error as a mistake or misdiagnosis that occurred under the care of a hospital, employee, physician, or facility that could either injure a patient or risk the patient’s life. Most journalists learned about the issue of medical errors from the news media (48 percent) or from experience with a friend or a family member (21 percent).

Journalists predominantly believed that preventable adverse events occurred “somewhat often” (39 percent) or “not too often” (39 percent). They believed overwhelmingly (65 percent) that both individuals and the health care system could be responsible for a medical error. However, most journalists (52 percent) felt that they did not know how many Americans were affected annually. They speculated that around 5,000 people were affected annually. Answers varied regarding the proportion of medical errors that were preventable: all (14 percent), three-quarters (25 percent), half (31 percent), one-quarter (2 percent) and “don’t know” (29 percent). The majority of journalists believed that reporting medical error data should be required (98 percent), with slightly fewer journalists stating that data should be released to the public (66 percent).

Perceived Causes of Medical Errors

News media professionals in Indiana believed that medical errors involved multiple contributing factors, including communication barriers (76 percent); heavy patient loads (74 percent); overwork, stress or fatigue of providers (56 percent); and too few nurses (44 percent). They were less likely to indicate poor training of health care professionals (18 percent), increased use of computerized medical records (18 percent), and the fragmented nature of health facilities (20 percent) as causes.

Perceived Solutions

A majority of journalists thought more support was needed for individual health care providers to prevent adverse events. News media professionals indicated that “very effective” solutions to preventing medical errors included requiring hospitals to implement systems to avoid medical errors (86 percent), recording of corrective and preventive procedures (80 percent), allowing more time with patients (68 percent), increasing the number of nurses (52 percent), and reducing the number of hours doctors worked to alleviate fatigue and stress (52 percent).

Summary: News Media

In summary, Indiana news media survey respondents demonstrated an awareness of the problem of medical adverse events, but more sophisticated comprehension was not evident. Even though they did not display extensive knowledge of adverse event reporting, they overwhelmingly felt this should be mandatory, and they viewed the media as being responsible for reporting adverse events to the public. Ironically, they often learned about the concept of adverse events from other media outlets.

It is worth noting that due to the specialized nature of the stakeholder group being targeted for this study, our sample size was rather small. Future research might benefit from a larger-scale, national level analysis of perceptions of media professionals reporting health care-related issues.

Discussion: Putting These Perceptions in Context

Empirical evidence suggests that medical errors are not often disclosed, despite the fact that patients, physicians, and the public support disclosure.^{14, 26} This situation may be due to a lack of disclosure guidelines for practitioners or communication from leadership implementing the change.^{14, 27} Health care providers opined that medical providers should be encouraged to share and learn from one another to prevent adverse events. Education and continual communications that clearly address the goals and expected benefits of adverse event reporting should be provided by the State. This information is essential to overcome skepticism about the system's purpose. Health care professionals expressed their interest in viewing information on errors, the prescriptive practices used to correct them, and evidence-based changes occurring from their reporting of medical adverse events.

Health care professional focus groups further stated that the system should reflect a culture free of blame and a commitment to protect patients. There is a perceived need to shift the individual-based model to a system-based model, whereby medical errors would be defined as a process issue. The overarching theme propelling this mandatory change is patient safety. This is not just a hospital system issue, but an issue that involves local government officials and the public as well. The success of Indiana's mandatory reporting system depends upon communication among all three entities.

The news media play a key role in molding public perception about medical errors, and many health care organizations look to the media to communicate to the public on their behalf. Good relationships among the media, health care organizations, and the State are vital to achieving statewide patient safety improvements.

Descriptive data demonstrated that most reporters (86 percent) were general assignment reporters, editors, or news directors, which means they did not regularly cover health or medical issues. It is important, therefore, to have educational material available to the news media. Results reveal the importance of making the process and procedures of the medical error reporting systems transparent to the media, regardless of their health care background or knowledge. The goal of communication is to provide patients with information, so they can understand their medical care. The majority of the news media believed adverse events should be reported to the State, and that errors and corrective practices should also be shared with the public. Background knowledge of a statewide communication system might encourage the news media to focus less on numbers and more on how the State works to ensure a safer medical environment.²⁸

The ultimate goal is to enhance patient safety using adverse event data. The challenge is to backtrack to the act of health care providers reporting adverse events and to the media communicating these errors to the public (and other media). In order to create a State-level

adverse event reporting infrastructure that meets its long-term goal of enhancing patient safety, a host of key activities must be implemented.

- The State should provide education and continual communication that clearly addresses the goals and expected benefits of medical error reporting. This information is essential to overcome skepticism about the system's purpose. To optimize effectiveness, the format, presentation style, and message strategy should be tailored for multiple audiences.
- The medical adverse event reporting system should be standardized across the State. Health care providers want to work together, but they fear that the lack of a standardized system would be a barrier to the system.
- The system should reflect a no-blame culture, and a commitment to protect patient safety should be clear in all public communications. Defining adverse events as a process issue is a necessary but delicate undertaking. Statements about medical adverse events could cause more fear than calm among the public, even if the "blame" is shifted from individuals to process. Statements should highlight the commitment of hospitals and their staff to protect patient safety in every feasible way.
- To reduce public confusion and fear, help should be provided for hospitals, so that a consistent message regarding medical errors can be presented. This could include creating media templates to assist medical organizations in responding to medical errors and providing public relations assistance for media and hospital professionals through a statewide public relations contact.
- Make the process and procedures of the medical error reporting system transparent to the media, and establish a communication sharing system before the release of any reports. Knowledge of a statewide communication sharing system would encourage the news media to focus less on numbers and more on how the State is working to ensure safer medical environments, which would be particularly important to members of the public who have been affected by a medical error.
- Provide extensive background information on medical errors and associated regulations on a continual basis. This could include the availability of a Web site that could provide in-depth information that is available in all forms for the public and the news media.
- The news media need to be educated on how medical professionals take action once a medical error has occurred. This includes educating the media on how to help the public use the data to make informed health care decisions.

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References

1. To err is human: Building a safer health system. Institute of Medicine. Washington, DC: National Academies Press; 1999. Available at: www.iom.edu/Object.File/Master/4/117/ToErr-8pager.pdf. Accessed April 8, 2008.
2. Stark K, Smith F, Simms P, et al. Covering the quality of healthcare. A resource guide for journalists. Association of Health Care Journalists; 2002.
3. Medical errors: The scope of the problem. AHRQ Pub. 00-P037. Rockville, MD: Agency for Healthcare Research and Quality; 2000. Available at: <http://www.ahrq.gov/qual/errback.htm>. Accessed April 9, 2008.
4. Milch CE, Salem DN, Pauker SG, et al. Voluntary electronic reporting of medical errors and adverse events: An analysis of 92,547 reports from 26 acute care hospitals. *J Gen Intern Med* 2006; 21: 165-170.
5. Leape LL, Bates DW, Cullen J, et al. Systems analysis of adverse drug events. *JAMA* 1995; 274: 35-43.
6. Koppel R, Metlay JP, Cohen A, et al. Role of computerized physician order entry systems in facilitating medication errors. *JAMA* 2001; 293: 1197-1203.
7. Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA* 2003; 289: 1107-1116.
8. Miller LK, Nelson MS, Spurlock BW. A compendium of suggested practices for preventing and reducing medication errors. Roseville, CA: California Institute for Health System Performance; 2001.
9. Patient safety toolbox for states. Portland, ME: National Academy State Health Policy. Available at: www.pstoolbox.org/. Accessed April 8, 2008.
10. About us. Washington, DC: National Quality Forum; 2006. Available at: www.qualityforum.org/about/. Accessed April 8, 2008.
11. National Quality Forum updates endorsement of serious reportable events in healthcare [press release]. Washington, DC: National Quality Forum; 2006. Available at: www.qualityforum.org/pdf/news/prSeriousReportableEvents10-15-06.pdf. Accessed April 8, 2008.
12. Hospital data release result of governor's order ISMA e-reports. Indiana State Medical Association; 2007 March 5. Available at: www.ismanet.org/news/e-reports/2007_Reports/3-5-07/hospitaldata.htm. Accessed April 8, 2008.
13. Gallagher TH, Waterman AD, Ebers AG, et al. Patients' and physicians' attitudes regarding the disclosure of medical adverse events. *JAMA* 2003; 289: 1001-1007.
14. Mazor KK, Simon SR, Gurwitz JH. Communicating with patients about medical adverse events. *Arch Intern Med* 2004; 164: 1690-1697.
15. Jackson T, Harper A. Blunders will never cease: How the media report medical errors – A risky business. *Br Med J* 2001; 322(7285): 562.
16. Walsh-Childers K. Newspaper influence on health policy development. *News Res J* 1994; 15: 89-101.
17. Dentzer S. Media mistakes in coverage of the Institute of Medicine's error report. *Eff Clin Pract* 2000; 3: 305-208.
18. Whitson T, Garten B, Azbill M. Indiana medical error reporting system: Final report for 2006. Indianapolis, IN: Indiana State Department of Health; 2007. Available at: <http://www.in.gov/isdh/regsvcs/mers/pdf/FinalReport2006.pdf>. Accessed April 9, 2008.
19. Krueger RA, Casey MA. Focus groups: A practical guide for applied research. 3rd ed. Thousand Oaks, CA: Sage Publishing; 2000.
20. Shoemaker PJ, Tankard JW, Lasorsa DL. How to build social science theories. Thousand Oaks, CA: Sage Publishing; 2004.
21. Whitten P, Dutta MJ, Carpenter S, et al. Reporting adverse medical events in Indiana: News media and health provider perceptions and expectations. West Lafayette, IN: Regenstrief Center for Healthcare Engineering Publications; 2007.
22. Dillman DA. Mail and internet surveys. The tailored design method. 2nd ed. Hoboken, NJ: John Wiley & Sons, Inc; 2007.
23. Editor & Publisher international year book. Northbrook, IL: Editor & Publisher; 2006.
24. Nielsen media research. Designated market areas, 2005. New York, NY: The Nielsen Company; 2008. See: www.nielsenmedia.com/nc/portal/site/Public/. Accessed June 5, 2008.
25. Weaver DH, Beam RA, Brownlee BJ, et al. The American journalist in the 21st century. U.S. news people at the dawn of a new millennium. Mahwah, NJ: Lawrence Erlbaum Associates; 2007.
26. Blendon R, DesRoches CM, Brodie M. Views of practicing physicians and the public on medical adverse events. *N Engl J Med* 2002; 347: 1933-1940.

27. Rosenthal J, Riley T. Patient safety and medical adverse event: A roadmap for state action. Portland, ME. National Academy for State Health Policy; 2001.
28. Charmaz KC. Constructing grounded theory: A practical guide through qualitative analysis. Thousand Oaks, CA: Sage Publishing; 2006.

Risk Assessment

Risk-Based Patient Safety Metrics

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Abstract

Patient safety programs require meaningful metrics. Dominant frameworks are based on two safety metrics: one that seeks to identify, measure, and eliminate error and one that seeks to identify, measure, and eliminate injuries. However, non-health care safety programs suggest a third framework, hazard- or risk-based measurement. Error measurement has many limitations, including the issues of error identification, hindsight bias, outcome-based judgment, and reinforcement of blame. Although injury-based metrics might aid the prevention of harm, limitations include poor discrimination of preventability, resulting in misdirected interventions, missed opportunities, and disregard for the systems-based nature of unsafe health care. In contrast, work in safety science allows for a third framework: risk-based patient safety metrics that are consistent with systems thinking in health care. These metrics focus on identifying the underlying hazards or risks in the system that ultimately lead to errors and injuries. In this article we explore the strengths and limitations of these frameworks and describe a practical application of risk-based patient safety metrics.

Introduction

A valid, reliable, and usable system of metrics is integral to any patient safety program. Data related to patient safety can be used for a range of purposes, including the selection of improvement initiatives, measurement of the success of safety improvement efforts, enhanced transparency by public reporting, organizational accreditation, and even contracting and reimbursement. With the increase in patient safety data applications, the importance of the data has increased commensurately.

Several data attributes should be considered in the context of patient safety metrics. First, are the data feasible to collect? Are the collected data reliable and valid? Do the data support their intended use? What is the rationale for using a given patient safety metric? It is the rationale for using a given patient safety metric that underlies the focus of this article. The mere creation or use of patient safety measures does not assure that they will be useful for improving safety and reducing harm. Even worse, invalid measures can lead to poor decisionmaking, whereas measures that do not lead to safety improvements can be viewed as lost opportunity costs.

The two dominant frameworks for patient safety metrics focus on measurement of errors and measurement of injuries.^{1, 2} While arguably there is a role for including both of these frameworks, a third model—i.e., metrics focused on hazards or risks—is based on safety science and human factors engineering.³

The following discussion explores the strengths and limitations of these frameworks with practical suggestions for the range of patient safety data consumers.

Error-Based Patient Safety Metrics

The work of James Reason and others has clearly identified the role of errors in preventable harm to patients. In the context of patient safety, errors are defined as a failure of a planned action to be completed as intended—i.e., an error of execution—or the use of a wrong plan to achieve an aim —i.e., an error of planning.^{4, 5, 6} These definitions are based on the premise that the goal of health care is to successfully execute the correct plan of care for any given patient. Thus, error-based metrics seek to identify deviations from this health care goal.

The measurement of errors in health care might appear like a reasonable means of assessing safety. First, errors in the delivery of health care are common. Studies of both pediatric and adult populations reveal that medication errors occur in 3.0 to 6.9 percent of inpatients.^{7, 8, 9, 10, 11, 12} The relatively high frequency of errors leads to a second potential advantage of measuring errors in health care: errors seem easy to identify and measure. Finally, errors can guide improvements. If errors are the source of unsafe health care, then one needs to prevent the errors.

There are, however, significant limitations inherent in efforts to measure errors. One of the important limitations is the inability to create a meaningful metric or rate. To have a rate that is valid, reliable, and ultimately meaningful, both a numerator and denominator are necessary. In the context of errors, denominators are not necessarily problematic. Medication error rates might utilize denominators of patient days, number of medications dispensed, or number of patient admissions. However, it is entirely possible that an appropriate denominator might not be readily available for calculating an error rate. For instance, any attempt to measure the error rate in infusion pump programming requires a choice between potential denominators, including number of medications infused, number of pumps programmed, number of programmers involved, number of steps in programming process, or even the number of key punches involved in programming.

A greater limitation of error rates in patient safety is the inability to identify a valid and reliable numerator. If an error rate is:

Identified errors
Potential opportunities for that error to occur

then, the numerator is only as valid and reliable as the means of identification. Unfortunately, there is no valid and reliable means for identifying all errors.

Voluntarily reported events provide one means of identifying errors as a potential numerator. Yet, reported events, by definition, reflect only those events that individuals recognized as an error and then reported. Errors could go unrecognized, particularly by the person committing the error.^{13, 14, 15} Reporting itself depends on the ease of use of a reporting system, the organizational culture and its attitude toward reporting of errors (including any consequences of reporting), and the competing demands on a potential reporter.¹⁶ For example, nurses with multiple patient care demands might not realistically have time to report, independent of her/his belief in the importance of reporting.

Cultural issues are also critical to reporting rates. The fear of reprisal or legal action might lead to underreporting.^{17, 18} Subsequently, any error metric that used reported events as a numerator would therefore be a rate of reporting and not a true rate of medical error occurrence.¹⁶

Two other means of identifying errors in health care have been described in the health care setting, although typically, these methods are limited to detecting medication errors and not other types of health care delivery errors: chart review and direct observation of the provision of care in different settings. Chart review has been used in a number of studies to identify errors as a numerator. In order for chart review to identify all errors, the following sequence of events must occur:

Error occurs

- Every error is recognized by a health care provider.
- Every error is documented by the provider.
- Chart in which errors were documented is reviewed.
- Reviewer recognizes each documented event during review.
- Error is attributed correctly.

The need for each of these additional steps to occur perfectly makes it less likely that chart review would provide a true numerator to establish an error rate.

Error identification by means of direct observation of health care workers has been reported as successful.¹⁹ Similar to error identification through chart review, correct determination of a numerator of error rates through direct observation is contingent on another sequence of events:

Error occurs

- Every error occurrence during the observation period is witnessed by an observer.
- All errors are recognized by the observer as errors.
- Observer correctly attributes event as error.

The limited likelihood of absolute ascertainment of errors through direct observation suggests this method is also incapable of establishing a true numerator for error rates.

Two important findings have been made when reporting events and chart reviews, and direct observations of the medication process have been compared. First, the different techniques seemed to yield different results based on the phase of the medication process that was being measured.^{20, 21, 22} Second, the events found by reporting, chart review, and direct observation appeared to be complementary, rather than redundant.

Ultimately, no valid or reliable method for establishing error rates is available in most health care settings. Therefore, patient safety programs that leverage error rates as their principal safety metric are operating on flawed data that could lead to incorrect prioritization of safety improvement efforts.

Multiple issues are associated with error-based metrics. “Hindsight bias” leads to simplified attributions of the cause of errors.^{23, 24} Furthermore, incorrect or inadequate attribution of causality may create the potential for misguided actions to “solve” the wrong problem, resulting in more complicated and less safe systems.²⁵ This might result in what Cook has called the

“cycle of error,” or the medical equivalent of the arcade game “whack-a-mole”——events occur, inadequate evaluation leads to incorrect actions, which gives the misperception of fixing a problem until a new event, potentially created by the actions, pops up in a new setting.²³

Steps can be taken to minimize hindsight bias, and there are positive benefits of this phenomenon in adaptive learning.²⁴ However, the use of retrospective analyses colored by hindsight could inadvertently increase a system’s complexity. As a result, “improvements” intended to decrease the risk of patient harm might only prevent the same adverse event from recurring, rather than improving overall system safety.

Another limitation of error-based metrics is “judgment based on the outcome of the events.” The perception of a sequence of events associated with the administration of anesthesia can be significantly influenced by the outcome of the case, regardless of the actual actions and judgments of the provider.²⁶ The fact that knowledge of an outcome might influence evaluations of the quality of a decision has very real implications for identifying errors as potential metrics.²⁴

Another major limitation of error-based metrics is the emphasis on the performance of individuals without consideration of the larger system in which care is provided. As illustrated by the Systems Engineering Initiative in Patient Safety (SEIPS) model for systems in health care, providers are merely one of five systems elements.²⁷ Providers (1) attempt to perform tasks (2) using tools and technology (3) in a given environment (4) within the larger context of an organization (5). Any system outcome, whether it is an error or safe care, results from the performance of and interaction between the five system elements, and not solely the performance of the provider. Although an error may be proximally associated with an individual clinician, organizational factors create the circumstances in which the failure occurred.²⁵ These organizational factors have been identified as latent errors that foster an environment in which an active error is more likely to occur.^{28, 29}

Error-based metrics can also be influenced by the psychological concept of attribution theory.³⁰ Well known biases, such as the self serving bias and fundamental attribution error, make it more likely that those in power are likely to blame the clinician on the “sharp end” when patient harm or an error occurs. At the same time, the clinician on the “sharp end” tends to blame the situation or circumstances surrounding the event.³¹ Despite any disclaimer that unsafe health care is a “systems problem” of care delivery, the tendency to blame people for errors underscores a final reason why patient safety programs should move beyond a pure focus on error-based metrics.³

Finally, any discussion of error-based metrics would be incomplete without recognizing that the concept of “human error” is socially constructed and, therefore, may not be meaningful in many circumstances.³² Indeed, people attribute causes of unwanted outcomes to “human error,” and people make such attributions with all of their biases and under different kinds of pressures. Therefore, calling something “human error” or “error” might not be factually meaningful. Full exploration of this perspective is beyond the scope of this article, but interestingly, it has led some safety scholars to call for “ditching human error.”^{33, 34}

Despite these limitations, the identification of errors does hold value for a patient safety program. Identified errors can serve several important roles. First, trends in reported events, while not valid as rates of event occurrence, are a potential reflection of an organization’s patient safety

culture. Second, identified errors are learning opportunities that might allow for intervention prior to future harm to patients. It should be noted that even if a given hospital chooses to focus on error-based metrics in the face of the discussed limitations, the National Coordinating Council for Medication Error Reporting and Prevention issued a formal statement that there is no value in using error rates to compare hospitals and health care organizations.³⁵

Injury-Based Patient Safety Metrics

The second major framework for patient safety metrics focuses on patient injuries. It has been argued that because errors and harm are often unrelated in a cause-effect manner, a patient safety program should focus on the elimination of harm.¹

Several organizations have proposed indicators that are intended to identify injuries. Following administrative database analysis, the Agency for Healthcare Research and Quality (AHRQ) put forth a set of potential in-hospital complications that might represent patient safety events.³⁶ Similarly, the Institute for Healthcare Improvement's *100K Lives Campaign* focused specifically on strategies to reduce the incidence of specific patient injuries, including in-hospital cardiac arrest, acute myocardial infarction, adverse drug events, surgical site infection, central venous line infection, and ventilator-associated pneumonia.³⁷

The goal of eliminating patient injuries makes injury-based metrics very attractive to a patient safety program. However, injury-based patient safety measures are not without shortcomings. By definition, identification, measurement, and analysis of injuries are reactive, taking place after an injury occurs. Consequently, they are subject to the same limitations as error-based patient safety metrics, including hindsight bias, incorrect attribution, blaming, and failure to consider the complexities of systems.

Additionally, not all patient harm is preventable. Unless a tool for identifying injuries is highly predictive for preventable events, resources might be spent identifying, analyzing, and trying to eliminate unpreventable injuries. There is scant literature on the positive predictive value of widely used injury-based measures, such as the AHRQ Patient Safety Indicators (PSIs). Study of these measures in a pediatric population led to AHRQ eliminating several measures from use in children and modifying other of the remaining measures.³⁸ These shortcomings illustrate an unintended consequence of injury-based metrics, which include events that are not preventable and thus not affected by improvement. In light of the pay-for-performance movement, evaluating hospitals by injury-based metrics—which include false-positive events—may cost the hospitals reimbursement dollars and lead them to misdirect improvement efforts, resulting in lost opportunity costs. For instance, if an injury-based metric identifies a falsely high rate of decubitus ulcers at a hospital, planned changes to Medicare reimbursement would have direct negative influence through incorrectly lowered payments.³⁹

The risk to health care providers resulting from the use of injury-based metrics and pay-for-performance reinforces the problem of incorrect attribution of causation. The identification of many of these events depends on documentation and hospital coding in administrative data sets. Therefore, a hospital might admit a patient, preventable harm might occur, and then the patient might be discharged without accurate documentation and coding to reflect the harm event. If this patient were either transferred or admitted to a second hospital that correctly identified the event,

it would be this second hospital that would receive “credit” for causing harm. This limitation of incorrect attribution may disappear since Medicare has implemented a new billing form, the UB-04, to replace the prior UB-92 form and, with this change, a “Present on Admission” indicator has been added.⁴⁰ However, until this change in coding practices is fully implemented, hospitals that accept patients from other care facilities are at risk for having harm to patients incorrectly attributed to them.

These issues of false-positive/false-negative identification and incorrect attribution of causality potentially undermines the value of using injuries as a patient safety metric. Ideally, a patient safety program would use injury-based metrics to calculate an injury rate that could be trended. That rate would be:

$$\frac{\text{Identified injuries}}{\text{Potential opportunities for those injuries to occur}}$$

As with error measures, correct identification of injuries as a numerator may be inherently problematic. Similarly, defining potential opportunities as a reliable denominator may be challenging. Thus, changes in the rate might reflect true changes in the rate of injury occurrence or simply changes in the way the numerator or denominator are collected. The potential lost opportunity costs and inappropriately lower reimbursement under a pay-for-performance system illustrate very practical concerns about the value of injury-based metrics to a patient safety program.

The final criticism of measuring patient harm as a primary metric for patient safety efforts might be viewed as philosophical in nature. By design, the measurement of injuries requires that before anything can be measured and improved, a patient must first be injured. Medical injury is very much a reality in health care, but it is worth raising the question as to whether health care metrics should be based on waiting for harm to occur, rather than attempting to proactively prevent patient injury.

Despite the numerous limitations, the desire to eliminate preventable harm to patients reinforces the need to understand the limitations of injury-based metrics while still learning from injuries. A strategy that couples the improvement opportunities identified by error-based metrics with those identified with injury-based metrics might outweigh the limitations inherent to either method.

Hazard- or Risk-Based Patient Safety Metrics

The term “risk” is used widely in health care. When obtaining informed consent for a procedure, risks may be presented as the chance of undesirable outcomes during the procedure. Risk ratios are used in epidemiology and medical literature to represent the likelihood of a disease or event occurring relative to an exposure. For instance, the risk of a central venous line-associated infection can be presented relative to whether sterile procedure was used during placement. Risk management is an intrinsic part of hospitals and health care organizations, although traditionally its focus has been on protecting organizations from financial loss.^{41, 42} However, with a few notable exceptions, the concept of risk and risk-based metrics as understood by human factors engineers and safety scientists remains relatively unexplored in the specific context of patient safety.^{3, 43, 44}

The lack of explicit recognition of risk in the context of patient safety does not mean examples are not available. One example that has been identified in both the medical and popular literature relates to central venous line-associated bloodstream infections (CVL BSI).^{45, 46} These infections are costly, common, and result in significant harm, lending themselves to a potential injury metric. Historically, CVL BSIs were viewed as largely unpreventable, although a handful of interventions were known to decrease the risk of infection. By treating failure of compliance with these interventions as a risk factor for infections and by implementing a checklist to drive compliance with this “central line bundle,” significant reduction of CVL BSIs has been achieved.^{46, 47}

Many other known patient safety errors and injuries can be reframed similarly in terms of risks. Other hospital-acquired infections result from lack of proper hand hygiene. Thus, poor hand hygiene is a patient safety risk factor that can be reduced with a resultant decrease in infections. Wrong site surgeries are known to be preventable through use of the universal protocol.⁴⁸ Failure to comply with this protocol is a recognizable yet preventable risk; compliance, on the other hand, can reduce or prevent harm.

Outside of health care, safety risk factors are called hazards^{49, 50} or the causes of, or circumstances leading to, unwanted outcomes, not the unwanted outcomes themselves (e.g., error or injury). The hazard identification and control approach is the preferred safety approach in non-health care safety programs, with injury surveillance as an important and complementary component. Although not typically viewed from this perspective, health care situations readily lend themselves to a similar risk identification and control approach.

Hazard identification and control is the basis for safety planning procedures for manufacturing. These procedures state, “The design phase of the proposed ISO (1991) safety strategy includes: (1) specification of the limits of parameters of the system, (2) application of a safety strategy, (3) identifications of hazards, (4) assessment of the associated risk, and (5) removal of the hazards or limitations of the risk, as much as practicable.”⁵¹

According to the U.S. Occupational Safety and Health Administration (OSHA), which enforces employee health and safety regulations for all industries, including health care, a successful safety program has four components: (1) management leadership and employee involvement, (2) worksite analysis, (3) hazard prevention and control, and (4) safety and health training. Regarding hazard prevention and control, OSHA states, “Management must provide the resources and authority so all personnel can find the hazards in the worksite and, once found, to eliminate or to control those hazards.”⁵² Applying these approaches to a health care context, it follows that systematic efforts to identify risk of harm, assess these risks and, whenever possible, eliminate or reduce these risks are a necessary activity for patient safety programs.

As previously mentioned, the concept of identifying risks in health care with subsequent design or redesign is not new to the patient safety literature. Prior publications have focused on the need to leverage these concepts of hazard and risk to achieve sustainable safety improvements.^{3, 53} To fully understand these concepts, it is helpful to frame errors, injuries, and risks in the context of health care systems (Figure 1). Both errors and injuries are possible outcomes of the performance of, and interactions between, the five aforementioned systems elements. That is, while a provider attempts to perform a task using tools and technology in a given health care environment within

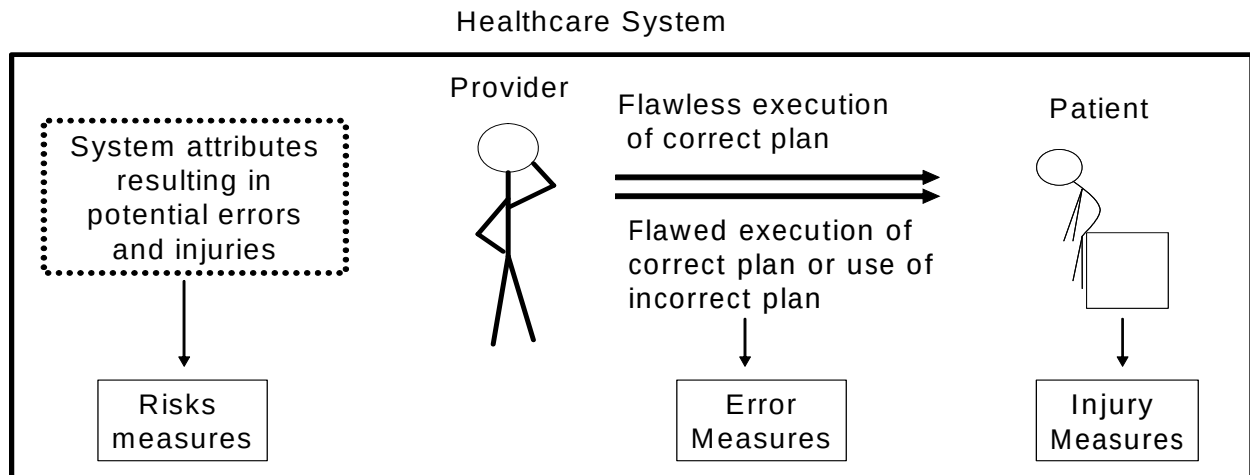


Figure 1. Error, injury, and risk measures in the context of health care systems.

the larger context of an organization, the provider might commit an error that, in some circumstances, causes an injury to a patient.

Another clinical example that illustrates the relationship between systems, risks, errors, and injuries is the use of concentrated potassium on patient care units (Figure 2). A nurse might be directed to administer a diuretic to a patient who is in congestive heart failure on a medical unit. While attempting to obtain the dose of diuretic, the nurse might inadvertently obtain a dose of potassium chloride. Administration of this potentially lethal electrolyte could lead to a life threatening cardiac arrhythmia and cardiac arrest. In this scenario, a specific error might be measured—i.e., incorrectly obtaining and administering potassium chloride rather than a diuretic. Additionally, an injury occurred that might be measured—i.e., the cardiac arrest. However,

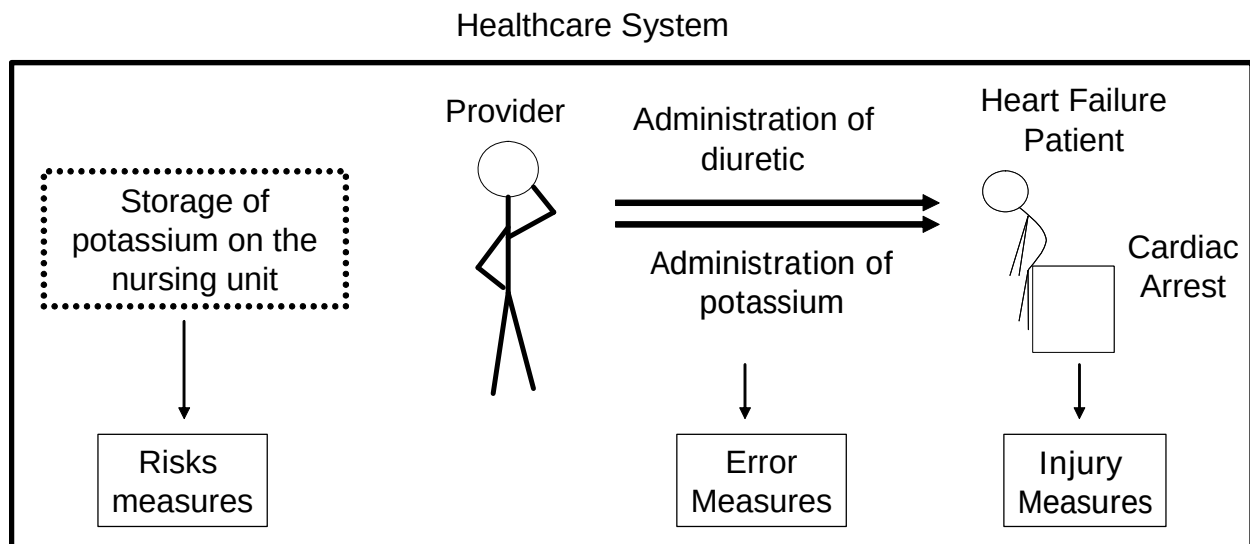


Figure 2. Clinical illustration of systems, errors, injuries, and risks.

patients with congestive heart failure may experience a cardiac arrest independent of medication dosing, and thus, the injury might not ever be correctly associated with the preceding error. Similarly, not every administered dose of potassium chloride will necessarily lead to an arrest. Thus, the error might occur and go undiscovered and unmeasured.

Central to this clinical scenario is the fact that the storage of concentrated potassium on patient care units presents a potential danger to patients, independent of whether a given hospital experiences and identifies a medication error of this nature and the resultant patient injury. That is, the design of a system of health care delivery that results in the storage of potassium on patient care units creates a potentially preventable risk that could be identified, analyzed, and eliminated, regardless of whether a hospital ever experienced either potassium-related errors or injuries.

A shift “upstream” from injuries and errors to safety risk factors (i.e., hazards) provides an alternative rate to the error and injury rates described previously. The risk-based metrics become:

$$\frac{\text{Assessed risks}}{\text{Identified risks}} \quad \text{and} \quad \frac{\text{Eliminated risks}}{\text{Assessed risks}} \quad \text{resulting in} \quad \frac{\text{Eliminated risks}}{\text{Identified risks}}$$

In the first statement, the denominator is limited only by identification of risks that are relevant to that organization. The numerator is clearer relative to those in error and injury rates. Either a risk has been assessed or not. In the second statement, all assessed risks become the denominator, with a numerator consisting of those assessed risks that have been eliminated. For the sake of simplicity, the first two statements can be combined to create the simple metric of eliminated risks over identified risks at a given health care organization.

Consistent with the limitations of error and injury rates, the denominators in these risk relationships are subject to the limitations of any discovery process used by a patient safety program and, therefore, will never represent all potential risks. The intent of this metric is different from those of errors or injuries. In the case of errors and injuries, the previously discussed metrics are attempts to reflect all errors or harm in a hospital. In the case of the proposed risk metric, the fact that the denominator is “identified risks” clearly suggests that there are other unknown risks. Rather than attempting to represent all risks, this measure instead emphasizes the need to first understand and then eliminate risks in a proactive manner.

Multiple potential implications are involved in adopting such a risk-based metric. First, in keeping with OSHA safety guidelines, organizations are charged with identifying and assessing potential risks. The identification of risks can be accomplished by use of a wide range of data sources. Errors—whether identified by report, chart review, and/or observation—can provide information on potential organizational risks. This is particularly true of “near-miss” and “no-harm” errors, which do not cause harm and yet might herald significant potential harm to patients. Identified injuries also become a source of risk identification, regardless of whether or not the injury is preventable. In using errors and injuries as sources for identifying risk, the rates of errors and injuries are irrelevant. Instead, in keeping with the work of Woods and Cook,⁴³ the stories behind errors and injuries can be explored with the intent of finding underlying risks.

Other potential sources of risk identification include the published literature, alerts of sentinel events, medical device recalls, and even anecdotal reports from colleagues. One potential source heavily leveraged in non-health care industries is the safety inspection by a safety expert.^{49, 50} In other industries, safety and human factors engineers are routinely employed, and part of their job is to conduct periodic and formal hazard inspections, in which the goal is to identify hazards or risk factors for error and injury (e.g., potassium chloride on the unit or a difficult-to-navigate barcoded medication administration system). Health care delivery organizations have yet to embrace such a model.

Risk-based patient safety metrics also have other implications. Adoption of a risk-based metric shifts the focus from reactively evaluating errors and injuries (with all their associated limitations) to proactively seeking out and evaluating risks that might exist. Another implication is the potential value of involving frontline staff who could become part of the process for proactively looking for potential risks.⁵⁴ This strategy requires no education of employees of error taxonomies or classification systems of injury severity. At the level of senior management and leadership, using risk-based metrics has a potential psychological benefit. By their nature, the risk-based metrics have a positive connotation; the numerator represents positive acts that have ideally resulted in enhanced safety through the elimination of risk. In contrast, both error- and injury-based metrics essentially provide a count of organizational failures. It is not a great leap to imagine leaders who might value a metric emphasizing and reinforcing improvement over one that provides a reminder of system failures. In turn, shifting any culture of blame to one more consistent with high-reliability organizations has at least a hypothetical benefit.⁵⁵

In each case, an organization can assess each identified potential risk for its relevance to their institution. This assessment might require additional data collection to verify whether the risk exists in the health care delivery setting, as in the case of determining whether a national infusion pump recall is a viable risk to their organization. Additionally, this assessment would likely require the involvement of clinical content experts. In the case of public reports of a type of bacterial infection outbreak in newborn nurseries, the clinical content experts might include infectious disease experts, neonatologists, and infection control specialists. In the case of a medication recall, the content experts might be the ambulatory clinic manager and clinic staff charged with tracking medication samples. Without the involvement of the clinical content experts, an organization might incorrectly determine that a specific risk was present. If a risk did not exist, the organization would have no further action to take beyond periodic surveillance to assure that the risk is not introduced later.

When a risk has been identified and assessed to be relevant to a health care organization, then the next step is elimination of the risk. The science of safety improvement is beyond the scope of this discussion. However, the human factors literature clearly indicates the need to design solutions into the care delivery system to achieve sustained elimination of risks.^{3, 53} Although redesigning health care delivery systems is no small undertaking, a patient safety program that incorporated a risk-based approach to measuring and improving safety would be consistent with the existing safety science used in non-health care industries.

A risk-based framework might be nearly universal outside health care, but evidence that it has been attempted in health care is limited. As a result, the conventional wisdom of focusing on errors and/or injuries might win out over what could be viewed as a theoretical argument for

broadening the approach to address risks. However, one illustration of the benefit of systematically focusing on hazards or risk has been published.⁵⁴ In this study, the use of a traditional incident reporting system over 5 years yielded a total of 200 reported events, all of which came from nursing. In contrast, a system of identifying hazards (safety risk factors) on the same study units resulted in 359 reports in 12 weeks. At the same time, the range of types of problems reported using the hazard-based system increased significantly, with much greater physician involvement: zero physician reports of incidents during the 5-year period, compared with 29 percent physician reports when the system was changed to a hazard-reporting system. Although generating more reports was not the goal *per se*, the incorporation of a risk-based framework led to greater proactive identification of problems in their hospitals, which in turn, by preventing future harm, allowed for a positive effect.

Additional Applications of Risk-Based Patient Safety Metrics

The proposal of using risk-based patient safety metrics is entirely consistent with learning from identified errors and focusing on the elimination of injuries. As described, a patient safety program that adopts a risk-based approach is also consistent with the science of human factors. However, there are additional potential applications for an organization that adopts a patient safety framework centered on the identification, assessment, and reduction of risk.

One practical application of adopting a risk-based framework is the refocusing of all patient safety activities. Specifically, the primary functions of a patient safety program then become:

1. Identifying risks.
2. Assessing risk through analysis and clinical interpretation.
3. Reducing and eliminating risk through a range of efforts.

Any activity undertaken by the patient safety program can be evaluated in light of these three functions. Education of staff and patients is entirely consistent with risk identification and reduction. Noncompliance with accreditation requirements, such as the Joint Commission's National Patient Safety Goals or the Leapfrog criteria, is also an organizational risk. Thus, assessment of a hospital's performance relative to these goals and steps to correct any deficiencies are entirely consistent with the risk-based framework.

A second practical application of the risk-based approach to a patient safety program is the implementation of patient safety competencies among hospital staff and physicians. A set of patient safety competencies that has been introduced at multiple organizations reinforces the risk-based framework (Personal communication, Nancy Kimmel, PharmD, March 2004). The competencies include: (1) report what you find; (2) fix what you can; and (3) communicate to your supervisor those things you cannot fix.

Essentially, health care staff are encouraged to actively seek out potential risks, even though those risks might not have led as yet to an error or injury; communicate the risks; and eliminate them whenever possible. The competencies can be readily evaluated as part of employee performance review, simply through statements such as, "Tell me about something you reported in the last 3 months"; or "Tell me about a time when you fixed a risk to patients, families, or employees." The continual reinforcement of this process of risk identification, assessment, and

reduction at the individual employee level arguably is consistent with high-reliability organizations.

A final application or benefit of risk-based metrics is reinforcing the alignment between patient safety, risk management, and quality activities at an organization. The coordination of safety, risk management, and quality activities might be unclear within any given health care organization.⁵⁶ A patient safety program built around identifying, assessing, and eliminating risks is consistent with existing models of quality improvement and might result in more efficient use of organizational resources.

Conclusion

The practice of patient safety improvement has evolved significantly over the last decade. This evolution reflects both primary patient safety research in the health care setting and a growing appreciation for safety science developed in non-health care settings. In turn, the health care community has applied safety research findings from health care and non-health care settings through changes in care delivery and the introduction of patient safety-oriented technologies. Arguably, sufficient evidence is available to merit similar advancements in the practice of patient safety metrics, with a move beyond reactive measures of systems outcomes (i.e., errors and injuries) to measures of systems risks that ultimately cause the undesirable systems outcomes.

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References

1. Layde PM, Cortes LM, Teret SP, et al. Patient safety efforts should focus on medical injuries. *JAMA* 2002; 287: 1993-1997.
2. McNutt RA, Abrams R, Aron DC. Patient safety efforts should focus on medical errors. *JAMA* 2002; 287: 1997-2001.
3. Karsh B, Holden RJ, Alper SJ, et al. A human factors engineering paradigm for patient safety – designing to support the performance of the health care professional. *Qual Saf Health Care* 2006; 15(Suppl 1): i59-i65.
4. Reason J. *Human error*. New York: Cambridge University Press; 1990.
5. Reason J. Human error: Models and management. *Br Med J* 2000; 320: 768-770.

6. Reason J. Beyond the organisational accident: The need for "error wisdom" on the frontline. *Qual Saf Health Care* 2004; 13: 28-33.
7. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. *N Engl J Med* 1991; 324: 370-376.
8. Dean BD, Allan EL, Barber ND, et al. Comparison of medication errors in an American and British hospital. *Am J Hosp Pharm* 1995; 52: 2543-2549.
9. Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. *JAMA* 1997; 277: 312-317.
10. Bates DW, Boyle DL, Vander VM, et al. Incidence of adverse drug events and potential adverse drug events: Implications for prevention. *JAMA* 1995; 274: 29-34.
11. Nelson KM, Talbert RL. Drug-related hospital admissions. *Pharmacotherapy* 1996; 16: 701-707.
12. Folli HL, Poole RL, Benitz WE, et al. Medication error prevention by clinical pharmacists in two children's hospitals. *Pediatrics* 1987; 79: 718-722.
13. Blavier A, Rouy E, Nyssen A-S, et al. Prospective issues for error detection. *Ergonomics* 2005; 48: 758-781.
14. Kanse L, Van der Schaaf TW, Vrijland ND et al. Error recovery in a hospital pharmacy. *Ergonomics* 2006; 49: 503-516.
15. Kontogiannis T. User strategies in recovering from error in man-machine systems. *Safety Sci* 1999; 32: 49-68.
16. Holden RJ, Karsh B. A review of medical error reporting system design considerations and a proposed cross-level system research framework. *Hum Factors* 2007; 49: 257-276.
17. Wu AW, Folkman S, McPhee SJ, et al. Do house officers learn from their mistakes? *JAMA* 1991; 265: 2089-2094.
18. Hobgood C, Weiner B, Tamayo-Sarver JH. Medical error identification, disclosure, and reporting: Do emergency medicine provider groups differ? *Acad Emerg Med* 2006; 13: 443-451.
19. Barker KN, Flynn EA, Pepper GA, et al. Medication errors observed in 36 health care facilities. *Arch Intern Med* 2002; 163: 1897-1903.
20. Barker KN, McConnel WE. The problems of detecting medication errors in hospitals. *Am J Hosp Pharm* 1962; 19: 360-369.
21. Shannon RC, De Muth JE. Comparison of medication error detection methods in the long term care facility. *Consult Pharm* 1987; 2:148-151.
22. Flynn EA, Barker KN, Pepper GA, et al. Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *Am J Health Syst Pharm* 2002; 59: 436-446.
23. Cook RI. A brief look at the new look at complex system failure, error, safety, and resilience. Chicago, IL: Cognitive Technologies Laboratory; 2005. Available at ctlab.org/documents/BriefLookAtTheNewLookVerA.doc.pdf. Accessed March 25, 2008.
24. Henriksen K, Kaplan H. Hindsight bias, outcome knowledge and adaptive learning. *Qual Saf Health Care* 2003; 12: 46-50.
25. Karsh B, Brown R. The impact of organizational hierarchies on the design and analysis of medical error research. *Proceedings of Human Factors in Organizational Design and Management-VIII*; Santa Monica, CA: IEA Press; 2005. p. 293-298.
26. Caplan RA, Posner KL, Cheney FW. Effect of outcome on physician judgments of appropriateness of care. *JAMA* 1991; 265: 1957-1960.
27. Carayon P, Hundt AS, Karsh B, et al. Work system design for patient safety: The SEIPS model. *Qual Saf Health Care* 2006; 15(Suppl I): i50-i58.
28. Reason J. Understanding adverse events: Human factors. *Qual Health Care* 1995; 4: 80-89.
29. Reason J. Safety in the operating theatre - Part 2: Human error and organisational failure. *Qual Saf Health Care* 2005; 14: 56-60.
30. Kelley HH, Michela JL. Attribution theory and research. *Ann Rev Psych* 1980; 31: 457-501.
31. DeJoy DM. Managing safety in the workplace: An attribution theory analysis and model. *J Safety Res* 1994; 25: 3-17.
32. Hollnagel E. Why "human error" is a meaningless concept. Position paper for NATO Conference on Human Error; Bellagio, Italy; 1983. Available at www.ida.liu.se/~eriho/Bellagio_M.htm. Accessed March 25, 2008.
33. Kohn LT, Corrigan JM, Donaldson MS. To err is human: Building a safer health System. Washington, DC: National Academies Press; 2000.
34. Hollnagel E. Human reliability assessment in context. *Nuc Eng Tech* 2005; 37: 159-166.
35. Council recommendations: Statement from NCCMERP - Use of medication error rates to compare health care organizations is of no value. National Coordinating Council for Medication Error Reporting and Prevention; 2002. Available at www.nccmerp.org/council/council2002-06-11.html. Accessed March 25, 2008.

36. Patient safety indicators overview. AHRQ quality indicators. Rockville, MD: Agency for Healthcare Research and Quality; 2006. Available at: www.qualityindicators.ahrq.gov/psi_overview.htm. Accessed March 25, 2008.
37. The 5 Million Lives Campaign. Cambridge, MA: Institute for Healthcare Improvement. Available at www.ihl.org/IHI/Programs/Campaign/. Accessed March 25, 2008.
38. Scanlon MC, Miller M, Harris JM, et al. Targeted chart review of pediatric patient safety events identified by the AHRQ PSI methodology. *J Patient Saf* 2006; 2: 191-197.
39. CMS announces payment reforms for inpatient hospital services in 2008. Baltimore, MD: Center for Medicare & Medicaid Services. [Press release]. www.cms.hhs.gov/apps/media/press/release.asp?Counter=2335&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date. Accessed March 25, 2008.
40. Are You Ready for the UB – 04? Chicago, IL: Health Information and Management Systems Society. Available at: www.himss.org/content/files/200612_UB-04_FAQs.pdf. Accessed March 25, 2008.
41. Bryant JM, Hagg-Rickert S. Development of a risk management program. In: Carroll R, ed. *Risk management handbook for health care organizations*, 3rd edition. San Francisco, CA: Jossey-Bass; 2001. p. 46.
42. Vincent C. Introduction. In: Vincent C, editor. *Clinical risk management*. 2nd edition. London, UK: Br Med J Books; 2001. p. 1.
43. Woods D, Cook RI. Nine steps to move forward from error. *Cognition Tech Work* 2002; 4: 137-144.
44. Cook RI, Woods D, Miller C. A tale of two stories: Contrasting views of patient safety. National Health Care Safety Council of the National Patient Safety Foundation at the AMA; 1998. p.1-86. Available at www.ctlab.org/documents/A%20Tale%20of%20Two%20Stories.pdf. Accessed March 25, 2008.
45. Gawande A. The checklist. *The New Yorker*; 2007 Dec 10; 1-8. Available at www.newyorker.com/reporting/2007/12/10/071210fa_fact_gawande. Accessed March 25, 2008.
46. Pronovost P, Needham D, Berenholtz S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med* 2006; 355: 2725-2732.
47. Berenholtz SM, Pronovost PJ, Lipsett PA, et al. Eliminating catheter-related bloodstream infections in the intensive care unit. *Crit Care Med* 2004; 32: 2014-2020.
48. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery. Oakbrook Terrace, IL: The Joint Commission; 2003. Available at www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf. Accessed March 25, 2008.
49. Smith MJ, Carayon P, Karsh B. Design for occupational health and safety. In: Salvendy G, ed. *Handbook of industrial engineering: Technology and operations management* 3rd ed. New York: John Wiley and Sons; 2001. p. 1156-1191.
50. Smith MJ, Karsh B, Carayon P, et al. Controlling occupational safety and health hazards. In: Quick JC, Tetrick LE, editors. *Handbook of occupational health psychology*. Washington, DC: American Psychological Association; 2003. p. 35-68.
51. Karwowski W, Warnecke HJ, Hueser M, et al. Human factors in manufacturing. In: Salvendy G, ed. *Handbook of human factors and ergonomics*, 2nd ed. New York: John Wiley and Sons; 1997. p. 1899-1900.
52. Safety and health management systems e-tool. Overview of system components. U.S. Department of Labor, Occupational Safety & Health Administration Available at: www.osha.gov/SLTC/etools/safetyhealth/components.html. Accessed March 25, 2008.
53. Battles JB, Lilford RJ. Organizing patient safety research to identify risks and hazards. *Qual Saf Health Care* 2003; 12: 2-7.
54. Morag I, Gopher D. A reporting system of difficulties and hazards in hospital wards as a guide for improving human factors and safety. Paper presented at the Human Factors and Ergonomics Annual Meeting. San Francisco, CA; 2006.
55. Weick KE, Sutcliffe KM. *Managing the unexpected*. San Francisco, CA: Jossey-Bass; 2001.
56. Institute of Medicine. *Crossing the quality chasm*. Washington, DC: National Academies Press; 2001.

Leveraging Existing Assessments of Risk Now (LEARN) Safety Analysis: A Method for Extending Patient Safety Learning

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Abstract

Prospective risk assessments are being conducted at health care institutions across the country in response to the Joint Commission requirement. However, an opportunity is being missed to combine these risk assessments to identify generic risks and risk contributors across institutions. The U.S. Department of Energy (DOE) applies a successful methodology, known as “risk binning,” to analyze a group of risk assessments to identify generic risks and risk contributors. Establishing high-priority targets and identifying effective interventions for health care are essential to improve patient safety. This article describes how the Leveraging Existing Assessments of Risk Now (LEARN) Safety Analysis method can be used to analyze a group of risk assessments through the application of “risk binning” methodology to existing risk assessments from multiple institutions.

Background

Risk assessments, such as failure modes and effects analysis (FMEA), have been shown to be effective for identifying, assessing, and addressing risks in many life-critical industries that must function with high reliability, including medicine.^{1, 2} The process of conducting a thorough FMEA in medicine is time and resource intensive, yet the results of these detailed assessments are rarely shared.

The U.S. Department of Energy (DOE) has developed a successful standardized methodology using “risk binning,” which enables the analysis of a group of risk assessments across institutions to identify generic risks and risk contributors from processes and systems.³ In this article, we use a group of risk assessments to illustrate the application of this methodology in medicine.

Although prospective risk assessments are being conducted at health care institutions across the country in response to the Joint Commission’s requirement, an important opportunity is being missed—i.e., using these risk assessments to identify generic risks and risk contributors to improve the understanding of similar processes across institutions. By adapting methods from other high-risk industries, risk assessments from multiple institutions can be analyzed to improve our understanding of the significant risks and risk contributors of health care processes across

institutions. This approach could result in medicine achieving greater success in reducing errors and risks similar to the success achieved by the field of energy.

This article presents a detailed example of the application of the adapted DOE methods to leverage existing knowledge via an analysis of a group of existing health care risk assessments (e.g., FMEAs), much like a meta-analysis. These methods can be useful in health care contexts to advance the knowledge of potential risks in the systems and processes in health care. The identification of generic risks and risk contributors can then be used to shape the design of safety interventions and controls to improve patient safety.

DOE Safety Analysis Methods

DOE uses a “Safety Analysis” process to develop controls (safety interventions) for non-reactor nuclear facilities. Briefly, this Safety Analysis method includes four basic steps that involve several substeps:

1. Identifying hazards by the participating institutions prior to the grouping of risk assessments.
2. Performing hazard evaluations using failure events from existing risk assessments.
3. Selecting candidate accidents by:
 - a. “Binning” failure events into accident categories and according to other relevant criteria.
 - b. Selecting representative cases (emblematic case scenarios representing a particular contour of risk) to further evaluate and identify risks and risk contributors.
4. Identifying safety controls or interventions to reduce risk.

Adapting the Method to Health Care

Terminology, contexts, and processes in health care differ from other high-risk industries, and these differences must be accommodated for effective application of the Leveraging Existing Assessments of Risk Now (LEARN) Safety Analysis method to health care. The following sections describe the initial modifications of the process and criteria necessary for this method to be applied effectively to health care.

To be clear, this LEARN Safety Analysis method is not intended to provide an epidemiology of types of events. The LEARN Safety Analysis method is more akin to a meta-analysis of risk assessment data to glean and combine the results of many studies. These types of data qualitatively analyze existing risks inherent in medical care processes and cannot adequately generate rates of events.

FMEA prospective risk assessments are intended to specify the particular way that processes fail. Risk assessments are conducted on processes thought to need improvement. The results of these risk assessments are failure modes—i.e., how the system fails. The risks related to these fail points, common to a number of institutions’ risk assessments (generic risks), are identified as generic risks. The contributors to these risks that are common to a number of institutions’ risk assessments are generic risk contributors and are identified and described. The processes and criteria described here will be further modified iteratively through use.

The DOE method has been adapted from evidence-based criteria found in the available patient safety literature related to performance-shaping factors and child-specific risk factors by

applying different accident category/event types appropriate for health care. The extent of an increase or decrease in the frequency of risk and resulting consequence(s) are considered based on these criteria.

Step 1: Identify Hazards

The hazards are identified in the risk assessments that are subsequently grouped.

Step 2: Hazard Evaluations

This step is also completed during the risk assessments (i.e., FMEA, root cause analysis [RCA], probabilistic risk assessment [PRA]). The following questions are typically asked (Table 5):

- “What can go wrong?” — to identify fail points.
- “How likely is it?” — to identify frequency.
- “What are the consequences?” — to identify harm.

Table 1 provides an example the types of information received in the risk assessments for analysis.⁴

Step 3: Selecting a Candidate Accident

Selecting the candidate accident requires multiple substeps. The fail points are categorized according to the type of event, using the categories, performance-shaping factors, and patient characteristics (e.g., child-specific risk factors) described below and underlying thematic similarities (i.e. handoffs, verification of task completion). This set of categories, developed through a review of patient safety events, is appropriate for health care. The categories are effective for designating medical care processes in both hospital-based and ambulatory medical care.⁵

Step 3.1: Accident categories/event types (Table 2).

Step 3.2: Criteria – Performance-shaping factors. The fail points are categorized by performance-shaping factors (Table 3). The performance-shaping factors follow the framework presented by Charles Vincent as “factors that influence clinical practice.”⁶

Table 1. Example FMECA worksheet for correct blood transfusion

Step ID	Step	Success criteria	Failure mode	Cause	Category			Comment	Risk
					Freq.	Cons.	Safe-guard		
5.10	Document results in computer or downtime log	Correct crossmatch	Enter incorrect information into computer or into log	Human error interruptions	F1	CP4	S5	Computer or log entry triggers blood issuance.	High
5.11	Print or handwrite crossmatch results on blood unit tag in lab	Document correct patient and blood type	Incorrect or illegible handwritten label	Human error	F2	CP1	S2	Make handwritten labels only during computer downtime (<1% of time). If info is wrong, the Fenwal armband on patient will catch the error.	Low
5.12	Attach printed (or handwritten) blood unit tag to donor blood and Fenwal # sticker	Correct tag on correct unit	Put wrong tag on unit	Processing multiple specimens at one time	F2	CP3	S2	Later, the Red Cross label will be checked against the unit tag.	Med

FMECA = failure modes, effects, and criticality analysis

Table 2. Accident categories/event types

-
1. Preventive medicine (immunization and preventive screening).
 2. Diagnostics (medical history and physical examination, diagnostic testing, reading, recording, and interpreting results).
 3. Treatment
 - Medications, blood products, fluid, diet (ordering, transcribing, dispensing, and administration).
 - Surgical and nonsurgical procedures (preparation, performance of the procedure, and post-procedural care).
 - Appointment scheduling, referral, and followup communications.
 - Other medical treatments (psychiatric, social services, and discharge planning).
 4. Patient monitoring (monitoring of patient status).
 5. Patient communication (communication, education, consent, and confidentiality for preventive care diagnostics, medications, non-surgical procedures and surgical care, post-surgical care, and other medical treatments).
 6. Patient identification.
 7. Equipment-related (equipment malfunction, equipment availability, and use of equipment).
 8. Administrative (medical records and other clinically significant administrative processes).
-

Step 3.3: Criteria – Child-specific risk factors. There is growing evidence that the epidemiology of errors and patient safety risk differs in pediatrics from that of adult medical care.^{7, 8, 9} Specific characteristics of children—“child-specific risk factors”—have been shown to lead to patient safety risk.^{5, 9, 10} Nevertheless, the literature establishing high-priority targets and effective interventions for pediatric patient safety is relatively limited.^{11, 12} Further study is needed to improve the safety of children’s medical care. Most inpatient and emergency medical care for children is delivered in institutions that primarily treat adults and may have only a small pediatric service.

These institutions are unlikely to have a pediatric emergency medicine physician on staff, and they may lack basic pediatric equipment and skills.^{12, 13} They are also unlikely to conduct proactive risk assessments that focus on children’s medical care and might not have the requisite personnel or expertise to conduct such an analysis. Research on pediatric patient safety has established “child-specific risk factors” (Table 4) and has demonstrated how these factors contribute to patient safety risk. Studies are emerging that demonstrate the need for pediatric customization of safety interventions to prevent increases in morbidity and mortality when safety interventions are implemented.^{14, 15} The application of these factors can add one step to a risk assessment to specify particular risks to child patients from the results of a general risk assessment.

Table 3. Performance-shaping factors in health care

1. Institutional context (economic and regulatory context).
2. Organizational and management factors (financial resources, policy standards and goals, and safety culture priorities).
3. Work environment (staffing levels and skills mix; workload and shift patterns; design, availability, and maintenance of equipment; and administrative and managerial support).
4. Team factors (verbal communication, written communication, supervision and help seeking, and team structure).
5. Individual staff factors (knowledge and skill, motivation, physical and mental health).
6. Task factors (task design and clarity of structure and availability and use of protocols).

For example, the context of pediatric medication ordering requires the consideration of two child-specific factors: (1) physical characteristics (e.g., variable size) and (2) physiologic development (e.g., limited or variable physiologic development). Medication dosage must be customized based on weight and physiologic state (e.g., kidney function). These additional steps in the medication ordering process can result in increased risk of error. What might seem to be a relatively minor misplacement of a decimal point in calculating the medication dose can result in a 10-fold error, often with serious consequences for pediatric patients. Additional criteria could be applied for other subpopulations of patients. Figure 1 shows further classification based on child-specific factors.

Table 4. Child-specific risk factor categories**Physical characteristics**

- Small size, weight, and morphology
- Varied physical characteristics including significant variation in size, weight, and morphology

Physiological development

- Developing physiologic systems
- Varied signs and symptoms
- The impact of growth

Cognitive-social-emotional development

- Developing nature of understanding
- Communication capability
- Behavioral regulation

Minor/legal status

- Parental responsibility for medical management
- Decisionmaking and consent
- Confidentiality
- Supervision

In applying the method to medicine, a representative case of this type of failure would be further assessed to identify the potential impact of the performance-shaping factors of emergency medicine. For example, the influence of performance-shaping factors, such as frequent interruptions and time pressures on medication ordering, would be assessed to estimate the frequency of risk and determine the risk bin.

Through the application of these child-specific risk factor criteria, an additional analysis could be conducted to further specify particular risks specific to children's health care to inform safety improvement of the subpopulation of pediatric patients. Additional criteria could be applied for

other subpopulation of patients. Figure 1 show further classification based on child-specific factors.

Step 3A. Risk-binning analysis protocol to identify significant risks. The categories of frequency and consequence of each fail point are used in combination to identify the significant (relatively higher) risks through a process called “risk binning.” Table 5 illustrates a matrix for the application of these sets of criteria. In this schema, risks assessed in Risk Bin IV are low to moderate consequence and extremely unlikely to beyond extremely unlikely. The highest risks with the highest consequence are in Risk Bin I, the next highest in Risk Bin II, and so forth. Failure events in Risk Bins I and II become the focus for targeted attention.

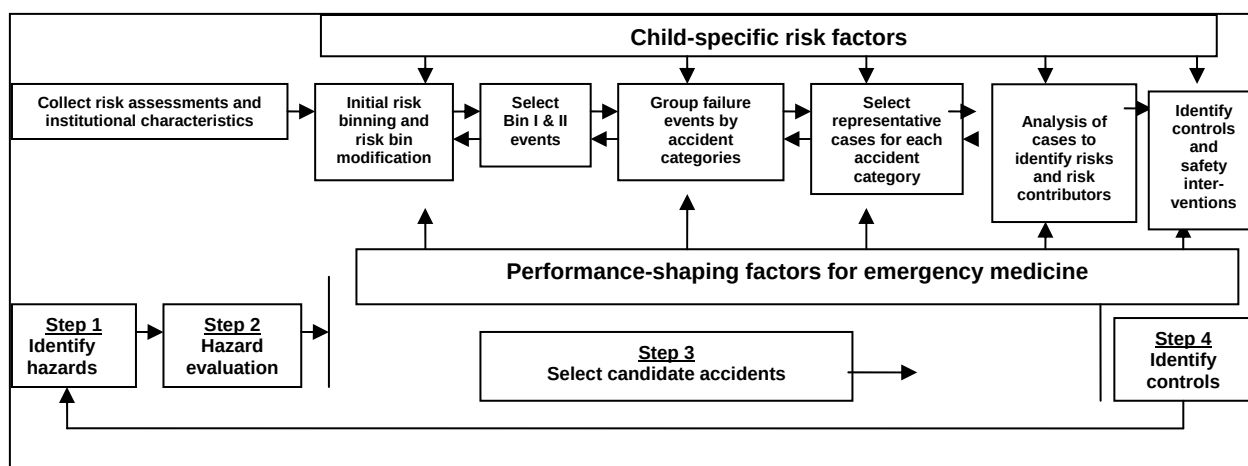


Figure 1. Additional analysis using child-specific risk factors.

Table 5. Risk bin categories

Consequence level	Beyond extremely unlikely	Extremely unlikely	Unlikely	Anticipated
High	III	II	I	I
Moderate	IV	III	II	I
Low	IV	IV	III	III

Identified failure events in the assessed processes are reviewed for frequency of occurrence, the resulting consequence, and the safeguard effectiveness (Table 6) based on the results of the risk assessment. They are then modified iteratively through the review of a dedicated risk assessment team, according to the child-specific risk factors and “medicine performance-shaping factors,” to evaluate the potential need for adjustment to increase or decrease the assessment of frequency, and consequence. The combination of frequency and consequence categories are used to calculate a level of patient risk that is defined as High, Medium, or Low. Safeguard effectiveness is dropped out of this analysis as safeguards usually refer to institution specific safety features. A separate analysis of safeguards can generate particularly effective safeguards that may warrant broader adoption.

Table 6. Frequency and consequence of failure mode categories and safeguard effectiveness categories

Category	Frequency	Description
F1	Remote	Possible, no known data (happens once in 10 years)
F2	Uncommon	Documented but infrequent (happens once a year)
F3	Occasional	Documented and frequent (happens once a month)
F4	Very frequent	Documented, occurs routinely (happens more than once a month)
Category	Consequence	Description
CP0	None	No impact on the chance of failure mode
CP1	Little	Little impact on the chance of failure mode
CP2	Some	Some impact on the chance of failure mode
CP3	Significant	Significant impact on the chance of failure mode
CP4	Certain	Almost certain chance of failure mode
Category	Safeguard Type	Description
S1	Multiple checks	Hospital procedure has a formal built-in check and other safeguards
S2	Formal check	Hospital procedure includes a formal built-in check
S3	Standard practice	Standard practice includes a check
S4	Noticeable	Worker notices and responds
S5	Nondetectable	The failure is not detectable

Step 3B. Selection of representative cases. In the adapted LEARN Safety Analysis methodology, after “risk binning” the failures, representative cases are selected for each represented accident category that falls into Risk Bins I or II, the highest risk categories. Representative cases are those that are emblematic of the risk scenarios identified. For example, the selection of representative cases in the nuclear industry is based primarily on grouping failure events by causes, physical characteristics, and the potential for severity of consequences for particular relevant phenomena, such as fire. In this study, these groups are called “failure categories.” Representative cases are then selected from the failure categories.

Typically, in the DOE Safety Analysis process for important topics—such as facility handling or processing of nuclear material—the types of representative cases would include such cases as fires, leaks, and load drops. Representative cases provide an embedded context of risk that enables exploration of the complexity of the context.

Selection of representative cases for this adapted methodology uses the child-specific factors (e.g., medication ordering, accident category, variable size and weight, and immature physiology of a young child), the performance-shaping factors (e.g., distractions and noise, verbal communication of orders, and lack of staff with pediatric training), and the underlying thematic

failure similarities as categories. The cases themselves determine the need for refinement. This categorization results in generic themes of risks and specific contributors to these risks and the selection of potential risk-reducing interventions.

Step 4: Identify Risk Contributors

Examination of representative cases identifies generic risks and risk contributors. Through iterative analysis, these risks and risk contributors should be listed and grouped to consolidate and direct attention toward high-impact contexts of risk. Risk assessments can be reviewed to examine specific risks found, based on specific organizational or process features called “institutional artifacts,” risks or safeguards due to the specific method, process, or a specific organizational structure present. Potential examples of institutional artifacts we may encounter include computerized physician order entry (CPOE) or inclusion of a pediatric pharmacist in rounds on a particular service.

Step 5: Design of Safety Interventions and Controls

In the analysis of representative cases, the hierarchy of safety improvement strategies can be applied toward development of potential safety interventions aimed at mitigating the generic risks and risk contributors. We present here a modified hierarchy of interventions based initially on that developed by Vaida and The Institute for Safe Medication Practices.¹⁶ The design of potential safety interventions can be informed by the error preventing or mitigating strength of the intervention. The modified hierarchy of interventions includes:

1. Forcing functions.
2. Automation, computerization, and technology.
3. Standardization and protocols.
4. Staffing organization.
5. Policies, rules, and expectations.
6. Checklists & double-checks.
7. Risk assessment and communication errors.
8. Education and information.
9. Personal initiative – vigilance.

It is important to remember that the resulting safety interventions require further testing before they can contribute new or additional fail-points. This LEARN Safety Analysis method can then become another method for prospective assessment of implementation of safety interventions across institutions.

Conclusion

The LEARN Safety Analysis method can provide several methods for assessment: (1) a catalogue of risks across institutions, (2) identification of underlying generic risks, (3) an additional step that can supplement and customize the risk results for special populations and

specialized medical care contexts, and (4) an analysis of the relative safety or risk of specific institutional artifacts.

This method may have particular advantages for health care organizations that include multiple institutions. The LEARN Safety Analysis method can be applied to risk assessment information grouped across the institutions to inform broader organizational patient safety needs and goals.

Hospital associations and patient safety organizations could bring together institutions interested in improving the safety of a specific context of medicine and “drilling down” to specific risks and risk contributors that exist across institutions, as well as underlying generic risks that may exist across a variety of safety topics. The findings from such applications could then be used to develop safety interventions that could then be tested and supported through “Learning Collaboratives.”

Finally, this method can be used by oversight or regulatory organizations to provide an overview of generic risks and risk contributors and to serve as a basis for moving the entire U.S. health care system to higher and safer standards of care.

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References

1. Joint Commission Resources. Failure modes and effects analysis in healthcare. Oakbrook Terrace, IL: Joint Commission; 2005.
2. Engineers study design, hospital cuts falls 50%. Healthcare Risk Manage 2006; 1 Aug. Available at: www.accessmylibrary.com/coms2/summary_0286-17375523_ITM. Accessed March 18, 2008.

3. Preparation guide for U.S. Department of Energy nonreactor nuclear facility documented safety analyses, change notice No. 2; DOE-STD-3009-94. Washington, DC: US Department of Energy; Available at: hss.energy.gov/NuclearSafety/techstds/standard/std3009/doe-std-3009-94_cn3_3-30-06.pdf. Accessed March 18, 2008.
4. Coles G, Young J. Use of failure modes effects and criticality analyses to improve inpatient safety. Safety Analysis and Risk Assessment Division of the ASME International Congress and Exposition; 2002 Nov 17-22; New Orleans, LA.
5. Woods DM, Thomas EJ, Holl JL, et al. Adverse events and preventable adverse events in children. *Pediatrics* 2005; 115: 155-160.
6. Vincent C. Framework for analyzing risk and safety in clinical medicine. *Br Med J* 1998; 316: 1154-1157.
7. Miller MR, Elixhauser A, Zhan C. Patient safety events during pediatric hospitalization. *Pediatrics* 2003; 111: 1358-1366.
8. Woods DM, Bhatia MM, Ogata E, et al. Child-specific risk factors and patient safety. *J Patient Saf* 2005; 1: 17-22.
9. Slonim AD, LaFleur BJ, Ahmed W, et al. Hospital reported medical errors in children. *Pediatrics* 2003; 111: 617-621.
10. Mohr JJ, Lannon CM, Thoma KA, et al. Learning from errors in ambulatory pediatrics (LEAP). *Advances in patient safety: From research to implementation*. Vol. 1, Research findings. AHRQ Pub. 05-0021-1. Rockville, MD: Agency for Healthcare Quality and Research; 2005. Available at: <http://www.ahrq.gov/downloads/pub/advances/vol1/Mohr.pdf>. Accessed March 18, 2008.
11. Miller MR, Pronovost PJ, Burstin HR. Pediatric patient safety in the ambulatory setting. *Ambul Pediatr* 2004; 4: 47-54.
12. Warden GL, Sundwall DN, eds. Institute of Medicine report – Emergency care for children: Growing pains. Washington, DC: National Academies Press; 2006.
13. Gaushe-Hill M, Lewis R, Schmitz C. Pediatric preparedness of U.S. emergency departments: A 2003 survey. *Pediatrics* 2007; 120: 1229-1237.
14. Han YY, Carcillo JA, Venkataraman ST, et al. Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system. *Pediatrics* 2005; 116: 1506-1512.
15. Woods DM, Mohr JJ, Mehra M, et al. Anatomy of a patient safety event. A taxonomy for pediatric patient safety. *Qual Safe Health Care* 2005; 14: 422-427.
16. Institute for Safe Medication Practices. Medication error prevention “toolbox.” Medication safety alert. June 2, 1999. Available at: www.ismp.org/msaarticles/toolbox.html. Accessed May 30, 2008.

A Model of Care Delivery to Reduce Falls in a Major Cancer Center

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Abstract

Falls are a leading cause of injuries sustained by hospitalized patients. Injuries sustained as result of patient falls in a cancer hospital are often severe, due to the nature of the underlying medical condition. A case-control study was conducted within a major cancer center to determine risk factors for falls, and a new falls risk assessment instrument was developed. A demonstration project was initiated and consisted of implementing a new model of care delivery to reduce patient falls. For the quarter (Q) following program implementation (Q2 2007), unassisted falls decreased from 4.90 falls to 2.96 falls/1,000 patient days compared to the previous quarter. Unassisted falls were reported at a rate of 3.73 falls/1,000 patient days in Q3 2007. Educational training is being conducted for new staff and float pool companion staff so that every provider on the unit has been exposed to the program.

Introduction

Patient falls are the most frequently reported adverse event in hospitals and the leading cause of injury deaths in adults aged 65 years and older.^{1, 2} Injuries sustained as result of patient falls in a cancer hospital are often severe because of the nature of the underlying medical condition. These conditions can include a predisposition for fractures due to bony metastases or uncontrollable bleeding from thrombocytopenia or medications used to prevent deep vein thrombosis. Unfortunately, when serious injury (e.g., hip fracture) occurs, surgical repair is necessary, the patient's hospital stay is extended, and the patient may be discharged to a rehabilitation facility instead of home. Not only does this mean a financial cost to the institution, the insurance carrier, and/or patient, but associated quality of life issues affect the patient and family as well.

In 2005, our institution prioritized patient falls as one of the most important safety threats to our patients and initiated a performance improvement falls prevention project with two goals: decreasing patient falls and decreasing fall-related injuries. After development of a new falls risk assessment instrument, we undertook a demonstration project in 2007 to test and evaluate interventions targeted at reducing patient falls.

Instrument Development and Testing

The vast majority of falls risk-assessment instruments have been developed for use in long-term care facilities, and we determined that they are not useful for our acute care population. To facilitate the development of a falls risk-assessment instrument within a major cancer center, we

conducted a case-control study to determine risk factors. Each of the 73 patients who fell in the first quarter of 2005 was matched with two patients of a similar age from his/her unit (indicating a similar diagnosis). In total, the charts of 219 patients (73 cases, 146 controls) were reviewed. The initial list of variables was developed from factors commonly named in the literature, as well as those identified in clinical practice. These variables included:

- Sex (M/F).
- Number of secondary diagnoses (0/1-2/3+).
- Hearing loss (Y/N).
- Cognitive impairment (Y/N).
- Cognitive impairment within 48 hours of fall (Y/N).
- Motor deficits (Y/N).
- Procedure within 48 hours of fall (Y/N).
- Use of assistive devices (Y/N).
- History of falls (Y/N).
- Intravenous fluid (Y/N).
- High volume hydration with 48 hours of fall (Y/N).
- Patient-controlled analgesic (Y/N).
- Number of pieces of patient equipment (IV pole, chest tube, etc.; 0/1-2/3+).
- Number of medications (0/1-3/4-6/7+).
- Presence of psychotropic, antihypertensive, anticonvulsant, diuretic/cathartic, and/or analgesic medication (Y/N for each).

Significant results from this initial case-control study were used to formulate the pilot instrument. Not only were the patients screened according to these variables, they also were screened with an additional assessment using the Katz Index of Independence in Activities of Daily Living. On the Katz Index, six activities of daily living (bathing, dressing, toileting, transferring, continence, and feeding) are assessed by assigning one point for independent completion.³ Patients with higher Katz scores are considered to be more independent and thus, it is hypothesized, less likely to fall.

The pilot instrument was tested from February to June 2006 on four units (neurology/orthopedics, leukemia/lymphoma, gastrointestinal surgery, head and neck). Inter-rater reliability of the pilot instrument was 87 percent. If a patient fell anywhere in the hospital during the pilot period, a team responded to review the patient's risk score, if applicable, and additional variables present at the time of the fall, such as environmental (e.g., spills, furniture), equipment (e.g., IV tubing, IV poles), and patient (e.g., dizziness, confusion) variables.

The visit by the falls team was not punitive in nature; the intent was to investigate the circumstances leading to the fall. The time and location of the fall, patient diagnosis, age, pertinent lab results, medications received the day of the fall, falls risk score (as applicable), and Katz score (as applicable) were recorded, as were the responses to the following Yes/No questions:

- Was the fall related to toileting?
- Was the patient told to call for help prior to getting out of bed?
- Did the patient call for help prior to the fall?
- Was there a companion assigned to the patient?
- Were family members or visitors present at the time of the fall?
- Did the patient undergo a procedure during the previous shift?

The falls team was on call during normal business hours, and the night nursing supervisor recorded the data during nights and weekends.

A second prospective case control study was conducted during the pilot, and statistically significant variables from the first case control study were reconfirmed and used in the development of the final instrument (Table 1). Data were collected from 62 cases and 124 controls over a 4-month period. Using chi-square testing, fall history was significant at $P < 0.01$ level; psychotropic and anticonvulsant medications were significant at $P < 0.001$ level. From the Katz Index, the variables “Needs assistance with toileting” and “Needs assistance with transferring” both had $P < 0.05$.

During the second case-control study, we also examined patient falls by time of day and location of the fall. The results showed that 62 percent of patient falls occurred between 8:00 p.m. and 8:00 a.m., which was not surprising, since the night shift has fewer care providers; 67 percent of patient falls occurred in relation to toileting (i.e., ambulating to and from the bathroom, or transferring to the bedside commode).

Table 1. Newly developed MSKCC^a patient falls risk assessment instrument

Falls Risk Assessment	
<i>Check the box next to each factor present. One or more checks make a patient at high risk for falling.</i>	
Patient Factors	
History of falls	☐
Needs help transferring to commode or toilet	☐
Needs help moving from bed to chair, or requires a complete transfer	☐
Sensory Deficits	
Visual/auditory impairment affecting mobility	☐
Peripheral neuropathy	☐
Motor Deficits	
Gait imbalance	☐
R or L side weakness	☐
Lower extremity weakness	☐
Medications	
Psychotropics (e.g., sleep medications, hypnotics, sedatives, anxiolytics) or anticonvulsants	☐

^a Memorial Sloan-Kettering Cancer Center

The newly developed instrument is not scored or summed. Intuitively, it did not make sense to try to assign points to each of the risk factors and calculate a cut score to determine risk for falling if the results suggested that each variable increased the patient's risk of falling.

The positive predictive value (PPV) of the new instrument is 91 percent, whereas the PPV of the previous instrument was 66 percent. The previous instrument was a home-grown tool that included the following variables: history of a previous fall, age >65 years, sensory deficits, cognitive changes, impaired mobility, generalized weakness, and medications. There was no assessment regarding the ability of the patient to actually get up and move independently or transfer from one point to another. A high risk for falling was determined by having more than one risk variable present, as

in the new instrument. In contrast to the old instrument, though, where patients were assessed only at the time of admission, patients are assessed twice daily with the new instrument.

The new instrument was an improvement in identifying patients at risk for falls, but this alone was not going to help reduce falls; for that purpose, targeted interventions for specific risk variables were needed. The nursing care plan for the patient at high risk for falling was thus revised. Standard safety interventions were designated for all patients and grouped into categories: environmental safety, patient safety, and daily routines (Table 2).

Specific interventions were added for high risk patients according to the risk factors category from the new instrument (Table 3). The new risk assessment

Table 2. Standard safety interventions for all patients admitted to the hospital

Environmental safety

1. Remove excess equipment/supplies/furniture from room.
2. Secure excess electrical and telephone wires.
3. Clean all spills in patient room or hallway immediately. Place sign to indicate wet floor hazard.
4. Secure locks on beds, stretchers, and wheelchairs.
5. Keep floors clutter/obstacle free (with attention to path between bed and bathroom/commode).
6. Place call light and frequently used objects within patient reach.
7. Assure adequate lighting, especially at night.

Patient safety

1. Orient patients to surroundings, including bathroom, use of bed, and location of call light.
2. Encourage patients/families to call for assistance when needed.
3. Use properly fitting nonskid footwear.
4. Assure ambulation as ordered.
5. Evaluate patient's ability to interpret information.
6. Evaluate potential medication side effects.
7. Keep assistive devices at bedside within reach.

Assess and assist patient in the following daily routine (schedule)

1. Assess mobility and gait as necessary.
2. Assess mental status, cognition, ability to perform ADLs.
3. Assess medications daily.

instrument and falls prevention interventions were adopted across all inpatient units in January 2007. Subsequently, a demonstration project targeting the neurology/orthopedics unit was initiated in March 2007. The aim of this project was to provide intensive training regarding patient safety. Program content included the design and implementation of a new model of care delivery to reduce patient falls and falls with injury.

Project Development

The neurology/orthopedic unit was chosen as the demonstration unit, since it consistently had the highest quarterly falls rate of all inpatient areas, due to the high-risk nature of the patient population. Prevalence of the risk factors on the new falls instrument supported choosing this unit (Table 4).

Departmental nursing leadership identified six individuals from the unit—including registered nurses, nursing assistive personnel and unit assistants—with an interest in patient safety to compose a team to lead the initiative. The unit-based nurse leader, nurse

Table 3. Interventions for patients assessed as high risk for falling

Standard interventions for high fall-risk patients 1. Implement standard interventions and any specific interventions indicated by assessment. 2. Assess the need to move patient to room with best visual access to nursing station. 3. Institute flagging system: red arm band, red star on primary board, red dot on patient floor card outside patient room. 4. Remain with patient while toileting; do not turn lights off at night. 5. Assist with bedside sitting, personal hygiene, and toileting. 6. Observe/round every hour. 7. Reorient confused patients as necessary. 8. Establish elimination schedule, including use of bedside commode, if appropriate. 9. Notify receiving areas of high fall risk, e.g., radiology. 10. Collaborate with nurse leader, clinical nurse specialist, or nursing supervisor to determine the need for a companion, e.g., sitter. 11. Reinforce activity limits/safety precautions with patient/family. Additional interventions Physical limitations or motor deficits 1. Assist with transfer or ambulation PRN. 2. Assess for nocturia, urgency, and implement toileting schedule. 3. Supervise and/or assist with toileting. 4. Obtain and use bedside commode PRN. 5. Reorient confused patients as necessary. 6. Consider PT evaluation if new deficits arise. 7. Instruct patient to use assistive devices, as appropriate, e.g., cane, walker. 8. Use assistive devices as necessary, e.g., cane, walker. Medications 1. Assess for medication side effects and consult pharmacist/physician when appropriate. 2. Educate patient/family about possible side effects, e.g., sleep aids, diuretics, narcotics, anticonvulsants. 3. Evaluate schedule/type of medication, e.g., diuretics/laxatives. 4. If taking anticoagulants, educate patient/family regarding increased risk of bleeding with injury. Sensory deficits 1. Ensure the patient wears personal glasses and/or hearing aids. 2. Assess for numbness and decreased sensation in extremities. 3. Assist with ambulation as needed.

educator, and clinical nurse specialist were also involved. The Director of Evidence-Based Practice and Research and the Director of Acute Care Services served as mentors and facilitators for development and rollout of the project.

The group met weekly, starting 2 months prior to project rollout. They immediately realized that if they wanted a realistic chance of reducing falls and injuries associated with falls, they needed to start to change the unit safety

culture from one of “The patient fell; it happens” to one of “Why did the patient fall, and what could have been done to prevent it?” Instead of a strictly lecture-driven format for the training, a didactic and interactive teaching format was proposed. The consensus was that this project was of such importance that a day-long training program, not just a brief inservice, was needed to educate the entire staff. With a total of 88 staff members, the unit leadership devised a work schedule so that the training could be conducted on 3 different days within 1 week in order to include all staff members.

Program Agenda

The overriding goal of the program was to identify the staff’s responsibilities in ensuring patient safety. The four objectives that drove the agenda were: (1) describing elements of a safe culture and the internal and external forces that influence patient safety; (2) discussing latent issues that contribute to unsafe patient conditions; (3) discussing the responsibilities of team members in ensuring patient safety through teamwork, communication, and delegation; and (4) describing changes in practice to improve patient safety.

The team designed a training agenda that included morning didactic presentations with small group activities in the afternoon. Didactic presentations covered the topics of safety and change theory, unit-specific falls and falls with injury data, teamwork, accountability, communication, delegation, and a unit-specific safety model. In the afternoon, the small groups spent time studying patient scenarios to identify safety hazards and developing interventions for the unit-specific patient safety model.

Table 4. Prevalence of falls risk factors on neurology/orthopedic unit

Risk Factor	Prevalence (%)
History of falls	24
Needs help transferring to commode or toilet	68
Needs help moving from bed to chair or requires a complete transfer	72
Visual or auditory impairment	0
Peripheral neuropathy	16
Imbalance	68
Right or left side weakness	60
Lower extremity weakness	68
Psychotropics or anticonvulsants	36

Developing a Culture of Safety

The “Swiss Cheese Model”⁴ has been used since the 1990s in the risk analysis of accident causation, and it has recently gained popularity in aviation safety and health care systems. The Model equates human systems to multiple slices of Swiss cheese, stacked together. When the slices of cheese (representing defensive barriers within the system) shift and the holes in the slices (representing gaps in the defensive barriers) align or change size, conditions become favorable for an accident to occur.⁵ Information presented to the staff equated barriers to prevent patient falls with policy and procedure (e.g., falls risk assessment, existing interventions), environmental safety barriers (e.g., side rails, grab bars in bathroom), and available staff (e.g., nurses and assistive personnel). According to the Swiss Cheese Model, gaps in defensive barriers are caused by active failures and latent conditions. Active failures were identified as high-risk patients left unassisted in the bathroom or a lapse in coverage during breaks or change of shift. Latent conditions were identified as environmental hazards, lack of toileting rounds, and lack of a safety culture on the unit.

The presentation on safety culture culminated in highlighting the requirements for safe practice, including a skilled and knowledgeable workforce, well-maintained equipment, efficient job design and scheduling, and a safe environment. From this presentation, the staff was able to understand that they were responsible for closing the gaps in the defensive barriers and reporting near misses, as well as actual events.

Change Theory

In large or complex institutions, implementing change to the culture can be difficult. For purposes of this training program, change equated to a shift in the patient safety culture on the unit. The lecture on change focused on typical reactions to change, both negative and positive, and strategies for managing change. Negative reactions to change were identified as sadness, fear, withdrawal, anger, and resistance. Positive reactions to change included being excited, motivated, and enthusiastic. Strategies for managing change in the workplace included teaching the staff to evaluate the proposed change, identifying personal gains or losses that occur due to the change, and learning to put the change into perspective. The overall message was “change is inevitable”; it may be difficult, but often it is for the best.

Unit-Specific Falls Data

Unit-specific patient falls and falls-with-injury data were presented to the staff. From the data obtained during the pilot testing of the new falls risk-assessment instrument, we knew that 67 percent of the falls on the unit were associated with toileting activities (either getting from the bed or chair to the bathroom or the commode). The distribution of falls by time of day had two distinct peaks, with the most falls occurring between 0400-0700 and 1200-1500. These periods corresponded primarily with staff breaks, resulting in fewer staff on the unit.

Specific institutional case studies—a 58-year-old woman and a 72-year-old man who fell and sustained hip fractures on the day prior to their scheduled discharge—were presented to illustrate clearly the financial and quality-of-life devastation accompanying a fall with injury. They allowed the staff to understand on a more personal level how a serious injury extends the

patient's hospital stay and negatively affects their quality of life, since both of these patients were discharged to rehabilitation facilities instead of to their homes.

Teamwork, Communication, and Delegation

Although the unit staff knew each other and often worked together on the same shifts, the project development team felt it was important to focus on improving teamwork, communication, and delegation.

Teamwork. The distinction was made between groups vs. teams. Group members work independently, and often they are not working toward the same goal. Team members work interdependently with a common goal and provide mutual support to one another. The presentations reiterated that teams succeed when the members trust each other, commit to the goal, hold themselves accountable, and focus on results.

Communication. Communication was approached from a “left-brain, right-brain” perspective, since brain dominance affects how a person processes information and communicates with others. The team felt it was necessary to emphasize this, as patient handoff and communication of specific information to staff members are critical components of patient care. Verbal cues, including how one conveys information in terms of tone of voice, inflection, and loudness, were highlighted, as well as such nonverbal cues as eye contact, facial expression, and posture. The staff was encouraged to consider their own communication patterns, along with those of their team members. Listening skills were reinforced: acknowledging the person, providing undivided attention, and repeating for clarification. If communication can be improved, whether by content or style, patient information should be more accurately conveyed.

Delegation. Delegation was a worthwhile skill to include because inexperienced nurses often find themselves having to delegate patient care to tenured assistive personnel. With the increasing complexity of cancer treatment and therapies, nursing care demands are high, and nursing assistants need to be available for specific patient needs. The registered nurse delegates tasks depending on the needs and condition of the patient, the complexity of the task, and the abilities of the staff to whom the task is delegated, all within the context of other patient needs.

Unit-Specific Safety Model

The project team developed a unit-specific safety model based on the notion that patient safety begins with each staff member. While each individual has unique responsibilities for patient care, everyone has the same responsibility for patient safety. The team developed the “ABCD Model for Patient Safety” (Figure 1). “A” corresponds to the “area” around the patient; “B” refers to the “bathroom” or toileting considerations; “C” considers the “comfort” of the patient; and “D” relates to any “desire” the patient may have at the time the nurse or assistive personnel is making rounds.

Within each of these categories, staff were instructed that four questions need to be asked each time a patient is assessed or care is planned:

1. What human factors need to be considered?
2. Is the physical environment conducive to patient safety?
3. Are any equipment or patient-related items affecting safety?
4. What system or process is in place to assure safety?

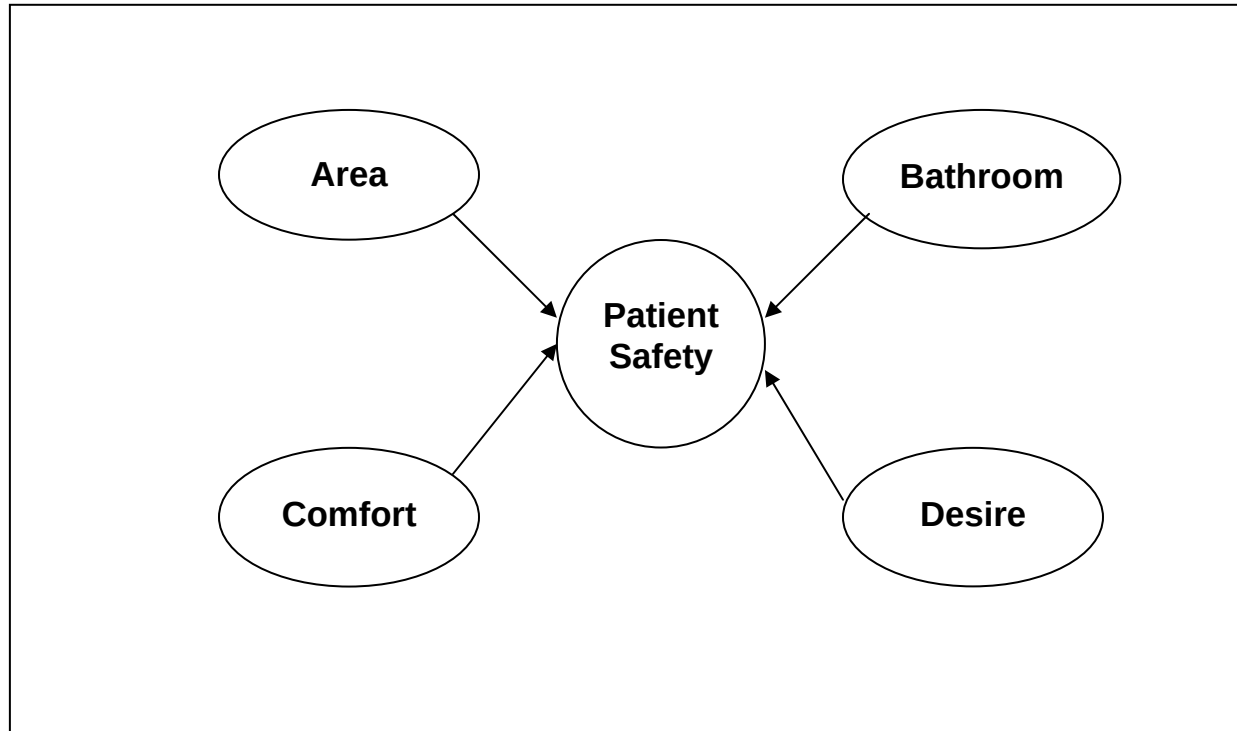


Figure 1. The ABCD model for patient safety.

During the small group sessions, multiple patient scenarios were presented, and each patient was evaluated according to the ABCD model. Emphasis was placed on the importance of maintaining the safety of the patient through careful consideration of individual risk factors that put a patient at high risk for falling.

For example, when considering the “Area” around the patient, a patient assessed with left-sided hemiparesis would be assigned to the bed positioned in the room with the night stand and nurse call system to his/her right side, thereby promoting access to personal items and call for assistance within easy reach.

The staff was instructed to carefully consider what safety measures were in place to assure patient safety in the “Bathroom.” Prior to the training, the staff had traditionally defaulted to patient privacy over patient safety. The previous culture provided for complete privacy while the patient was using the toilet, so that even though a patient was assisted to the toilet or commode he/she would be left alone to toilet, despite the likelihood of tipping, slipping, or falling when left alone. Now, if the patient was assessed as being at high risk for falling, the staff was to remain with the patient during toileting.

Program Evaluation

The program was rated “5” (outstanding) by 90 percent (N = 79) of the participants and “4” (excellent) by 10 percent (N = 9). Individual comments included the following:

“It is obvious how important this program is since two directors were here the whole day.”

“The falls information and case studies made me think about what a big problem this is.”

“Safety is up to everyone.”

“ABCD. It makes sense. It applies to every patient.”

“Thanks for having small group sessions. It helps the teaching make sense.”

“It is worth an entire day off the unit. It shows how important this is.”

Results

The staff safety program was conducted during the last week of March 2007 on one unit, and the ABCD Model for care delivery went live on April 1, 2007. In the quarter following program implementation, the unassisted fall rate dropped from 4.90 falls/1,000 patient days (Q1 2007) to 2.93 falls/1,000 patient days in Q2 and remained lower than the initial level in Q3 (3.73 falls/1,000 patient days). Since program implementation, this unit no longer has the most patient falls in the hospital; at the end of Q3, it ranked third out of 11 inpatient units.

Subsequently, we have started tracking assisted falls on this unit, since assisted falls have not previously counted when calculating the falls rate. An assisted fall occurs when a patient is being accompanied by a care provider and begins to fall, typically due to an identified risk factor, and the provider lowers him/her to the floor. Assisted fall rates suggest that patients are being identified as being at high risk for falls and are being assisted during ambulation or transfer. Patients are not usually harmed because they are lowered to the floor instead of falling to the floor. For Q2, the assisted falls rate was 1.30/1,000 patient days, compared to 1.45/1,000 patient days during Q3.

Discussion

Since the program launch in March 2007, multiple system and process changes have either occurred or commenced. Safety improvements are being made to patient bathrooms, including changing the bathroom fixtures to enhance illumination, strategically placing additional grab bars to allow patients safer access to the toilet, shower, and sink; and purchasing a wider mounted shower chair. Communication at change of shift between all care providers focuses on pertinent safety issues, including high risk for falls, and a plan for hourly rounding is developed as needed. The nursing assistive personnel keep track of patient risk factors and specific needs on a worksheet, and all staff must ensure that patient needs are met during shift report and staff

breaks. Communication between the patients and providers using the nurse call system is facilitated by the unit assistant, who takes the message from the patient, communicates it to the appropriate staff, and then confirms with the patient that the message has been relayed and when to expect a caregiver to respond to the call.

Four full-time equivalents designated for incremental assistive personnel were funded by hospital administration as part of this demonstration project to improve staffing ratios and make more providers available to assist patients. Their schedules cover the 1200-2000 and midnight-0800 timeframes, which correspond to the two peak times of day when fall rates were highest on the unit. Three positions have been filled, with one individual already working on the unit and two others participating in orientation. We anticipate seeing fall rates decline farther as these individuals complete orientation and are indoctrinated in the unit safety culture.

The nurse leader and clinical nurse specialist on the unit review every patient fall according to the ABCD model. The unit-based team participates as investigators to determine what happened to cause the patient to fall. The human element, physical environment, patient-related factors, and system/process issues are evaluated. This review method has produced some noteworthy results that have already led to system change. For example, three of the falls in Q2 occurred while the patient was being attended by staff who had not attended the initial safety training (per diem or travelers). All three patients had been assessed as being at high risk for falls and were left unattended in the bathroom. In Q3 we saw the same thing occur, as 10 new staff were hired and had not completed the safety program. As such, the program was to be repeated in December 2007 to ensure that all new staff received the information related to the ABCD model and the unit approach to patient safety.

The program development team did not disband after the initial training and is still meeting at regular intervals on the unit. They have assumed responsibility for training of new staff and ongoing program evaluation. Continuing data collection in the quarters ahead will show whether this intervention contributes to the downward trend in the unassisted falls rate. Currently, departmental nursing leadership provides hospital and unit-specific data to the team, and in turn, they provide continual feedback regarding information on falls and falls with injury to the staff.

Conclusion

Program rollout is scheduled for five additional nursing units in 2008. Again, interested staff from each area will be identified. Since our institution is divided into nursing units that care for specific types of cancer diagnoses, unit-specific falls data, case studies, and specific risk factors will be incorporated into each unit-based program. The nursing directors have made a commitment to mentor each team and facilitate each rollout to build capacity at the unit level. We believe that if we demonstrate through our actions that patient safety and prevention of patient falls are of paramount importance and choose staff at the unit level who are invested in achieving these goals, the success of the program will be sustainable.

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References

1. Eldridge C. Evidence-based falls prevention: A study guide for nurses. Marblehead, MA: HCPro; 2004.
2. Centers for Disease Control and Prevention. Falls among older adults: An overview. Available at: www.cdc.gov/ncipc/factsheets/adultfalls.htm. Accessed March 3, 2008.
3. Katz S, Ford AB, Moskowitz RW, et al. Studies of illness in the aged. The index of ADL: A standardized measure of biological and psychosocial function. JAMA 1963; 185: 914-919.
4. Reason J. Human error. Cambridge, UK: Cambridge University Press; 1990.
5. Reason J. Human error: Models and management. Brit Med J 2000; 320: 768-770.

Using a Computerized Fall Risk Assessment Process to Tailor Interventions in Acute Care

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Abstract

Patient falls account for a significant portion of injuries in hospitalized patients. The literature on falls and fall-related injury in acute care is extensive but includes primarily expert opinion and quality improvement reports. The evidence on the effect of standardized interventions to reduce falls in acute care settings is inconsistent. This lack of effect may be due to variability in patients' fall risk factors and the fact that interventions may only be effective if tailored to address specific patient needs. This paper describes how the Aurora-Cerner-University of Wisconsin – Milwaukee Knowledge-Based Nursing Initiative[®] framework was used to create an evidence-based, computerized, fall risk decisionmaking process to support nurses in tailoring prevention interventions based on patient need. In addition to supporting nurses in decisionmaking and documentation, clinical information fields were created to facilitate data retrieval for quality improvement and research.

Introduction

In 2001, the Institute of Medicine (IOM) encouraged health care organizations, purchasers, and patients to work together to redesign patient care processes, emphasizing that care should be based on the best available scientific knowledge.¹ However, the gap between knowledge development and subsequent clinical application is well known. The challenge is to bridge the gap by efficiently and effectively providing the best evidence to providers where it is needed most, at the bedside.

Patient falls in acute care hospitals account for a significant number of patient injuries.² Serious injuries (e.g., fractures, sprains, lacerations, or concussions) have been reported to occur in 6 to 10 percent of inpatients who fall, adding significantly to length of stay and cost of care.^{3, 4} The literature on falls and fall injury in acute care is extensive. However, much of it consists of literature reviews, expert opinions, or safety/quality improvement activities that are innovative but largely untested by research. Prevention efforts have been focused on identifying high-risk patients and reducing risk factors.^{2, 5}

To date, consistent evidence on standardized interventions that effectively prevent falls among hospitalized patients is lacking.^{5, 6} This lack of evidence may be related to the fact that patient fall risk factors vary, and that interventions may only be effective if they are based on sound evidence and are tailored to address patient-specific needs.

This paper describes how the Aurora-Cerner-University of Wisconsin – Milwaukee (ACW) Knowledge-Based Nursing Initiative[®] (KBNI) framework was used to create evidence-based practice recommendations to reduce fall risk in hospitalized adults. It describes how recommendations for patient assessment, nursing diagnosis/problem identification, nursing interventions, and nursing-sensitive outcomes are developed and computerized to help nurses tailor prevention interventions⁷ to reduce fall risk, based on patient characteristics and needs. The ACW KBNI project was also designed to ensure that clinical care documentation was coded to a standardized language to facilitate data retrieval for quality improvement and research.

Background

The ACW KBNI is an innovative partnership between a health care system, an informatics vendor, and academia that is designed to facilitate “best practice” by nurses through embedding evidence-based practice recommendations in a clinical information system (CIS) with decision support. The partnership was formed in July 2004 between Aurora Health Care, Cerner Corporation, and the University of Wisconsin-Milwaukee College of Nursing with a vision to accelerate and expand the use of knowledge and evidence in nursing practice through intelligent technology.⁸ Aurora Health Care is an integrated health delivery network in eastern Wisconsin comprising 14 hospitals, over 100 outpatient clinics, and over 7,000 nurses. Cerner Corporation is a leading public, global health care technology company with more than 1,500 clients worldwide. The University of Wisconsin-Milwaukee College of Nursing is the largest nursing school in Wisconsin.

The Knowledge-Based Nursing Initiative (KNBI) Process

The ACW KBNI process is divided into two distinct phases: one, a knowledge generation/utilization phase; and two, a data-mining phase. This paper focuses on describing the knowledge generation/utilization phase, in particular, the topic of “risk for falls” for adults in acute care. This phase is divided into four major steps:

1. Searching and synthesizing the evidence.
2. Making actionable clinical practice recommendations.
3. Embedding these recommendations into the clinical documentation system with decision support.
4. Evaluating the outcome of this work.

To support the delivery of care, clinical practice recommendations are organized into the four parts of the nursing process: assessments, diagnoses, interventions, and outcomes. Reassessments and the revision of diagnoses and interventions are facilitated by embedded decision support to facilitate clinical decisionmaking throughout the hospital stay. The ACW KNBI process is described briefly, followed by details of how it was applied to the phenomenon, risk for falls. It is worth noting that the KBNI process has been used for other topics, such as delirium, activity intolerance, and venous thromboembolism, to name a few.

The KBNI process begins by identifying a “phenomenon” of concern (i.e., a clinical topic in a specific population) about which clinical practice recommendations will be made. The knowledge development team includes:

- The knowledge developer, a nurse with graduate preparation, preferably at the doctoral level.
- A research librarian.
- Doctorally prepared nurses with expertise in knowledge synthesis, coding terminology, and data mining.
- Master’s-prepared advanced practice nurses and clinical nursing staff.

Searching, Evaluating, and Synthesizing Evidence into Recommendations

The knowledge developer, research librarian, and knowledge synthesis expert collaborate to search the literature, looking for relevant research and clinical journal articles, literature reviews, clinical practice guidelines, and other professional reports. Once the initial search is complete, the knowledge developer screens each identified source for relevance (e.g., clinical topic, population, venue of care, outcome) and quality (e.g., appropriate methodology, fatal flaws).

Relevant sources of acceptable quality are read and critiqued using evidence-specific criteria. After the critique, the results and conclusions from relevant, quality sources are abstracted and entered into an evidence table. The ACW KBNI Evidence Table[®] is formatted to facilitate the abstraction of descriptive source information (e.g., question/topic, methodology, sample), findings, and author conclusions that warrant consideration when assessment, diagnosis, intervention, and outcome recommendations are made. Knowledge developers also gather information about background and problem significance and may code information to facilitate subsequent analysis. Results from relevant findings are noted, whether statistically significant or not.

To prepare for synthesizing practice recommendations, the knowledge developer reviews the evidence for quantity, quality, and consistency.⁹ Each source is evaluated and assigned an evidence type (e.g., systematic review, randomized clinical trial, observational [cohort or case-control] study, descriptive or qualitative research, clinical article). Eventually, the relevant credible evidence is synthesized into practice recommendations, and each recommendation is assigned a rating for the strength of evidence supporting it based on a rating system¹⁰ modified from the evidence rating system proposed by Melnyk and Fineout-Overholt.¹¹ Modifications are done to account for types of evidence not specified in the original rating system (e.g., psychometric research).

Making Actionable, Evidence-Based Recommendations

The goal of the ACW KBNI process is to make clear, concise, actionable recommendations based on evidence using several strategies:

- First, as the recommendations are drafted, a corresponding flow diagram is created to ensure that recommendations flow logically with appropriate follow-through (e.g., recommended assessments are used in clinical decisionmaking and never “dead end,” causing nurses to gather data that are not clinically useful).
- Second, each recommendation is written to specify “For whom? Do what?” This ensures that recommendations are concrete and applied to appropriate patient population(s) based on the evidence. To facilitate bedside use, the knowledge developer identifies notes to be embedded into the information system as referential text or decision support.
- Third, standardized terminology is used in the recommendations whenever possible, to facilitate consistent patient care documentation, coding, and subsequent data retrieval.
- Fourth, recommendations are reviewed for clarity and relevance by ACW project experts and practicing nurses.

The finished ACW KBNI referential product includes four parts:

1. A phenomenon overview.
2. The synthesis of clinical practice recommendations, strength of supporting evidence ratings, rationale, and notes for embedding.
3. A reference list, including types of evidence.
4. A flow chart of the recommendations.

The final product is made available to the personnel who embed the computerized care plans and decision-support mechanisms into the clinical information system and, as a reference document, to clients of the informatics vendor.

Embedding the Recommendations and Promoting Adoption of Practice Changes

After the referential synthesis is complete, the KBNI knowledge-development team works closely with the informatics and clinical partners to embed the recommendations into the clinical information systems, closely adhering to the evidence-based recommendations.

Evaluating Outcomes

Once the recommendations are embedded into the clinical information system, important data become available in the clinical repository. During the KBNI data-mining phase, data can be extracted using quality improvement or research methods to determine the extent to which the processes of care and targeted interventions specified in the recommendations were used and to evaluate patient outcomes.

Applying the Process to Fall Prevention in Acute Care

Synthesizing the Evidence for the Phenomenon: Risk for Falls

A “patient fall” is defined as “an unplanned descent to the floor (or an extension of the floor; e.g., trash can or other equipment) during the course of a patient’s hospital stay with or without

injury to the patient.”¹² The diagnosis of “risk for falls,” the focus of this paper, is defined as the state in which an individual has “increased susceptibility to falling that may cause physical harm.”¹³

Searching the Literature

An extensive review of the literature was conducted with an initial focus on evidence published between 1996 and 2005 on nursing assessments, diagnoses, interventions, and outcomes related to risk for falling for adults in acute care. (Note: Postfall management was investigated as a separate ACW KBNI topic).

This search was supplemented with topic-specific searches and updated with new papers released during the review. The databases searched included PubMed, Cumulative Index to Nursing & Allied Health Literature[®] (CINAHL), Cochrane Database of Systematic Reviews, Web of Science, PsycINFO[®], and National Guideline Clearinghouse. Additional evidence was accessed from professional and accrediting organizations and governmental agencies (e.g., the Joint Commission,^{2, 12} the Veterans Health Administration (VHA),¹⁴ the Agency for Healthcare Research and Quality (AHRQ),¹⁵ and others).

Search terms and phrases included: falls, accidental falls, risk assessment, risk factors, risk management, and falls assessment. These were searched alone and in combination with other terms, including fall intervention, inpatient accidents, potential for injury, impaired physical mobility, accidental injuries, patient safety, safety management, injury control, safety promotion, and accident prevention, to name a few.

The search yielded a large number of citations. After preliminary screening for relevance and quality, more than 200 sources were entered into the “Risk for Falls” evidence table. A total of 30 fall risk-scoring tools were reviewed for reliability, validity, and feasibility for use in the acute care setting. Despite an attempt to strictly limit the review to evidence relevant to the acute care setting, many of the published systematic reviewers (10 percent of the evidence) reported on fall research findings from both community and acute care venues. The majority of available evidence on fall prevention in acute care settings was gleaned from observational (i.e., cohort or case control, 27 percent), descriptive (24 percent), and qualitative (6 percent) research; additional evidence was derived from publications classified as clinical articles, guidelines, and narrative literature reviews (27 percent). Clinical trials (randomized or controlled without randomization) represented only 6 percent of the evidence, a finding that was not surprising, given the nature of the acute care environment and the presence of regulatory requirements that mandate fall risk assessments and interventions to reduce the risk of falls.

Organizing the Evidence to Evaluate Risk Based on Fall Etiology

Morse^{16, 17} has identified three types of falls in the acute care setting:

1. **Anticipated physiological falls.** These are falls that occur in patients who are identified as “fall-prone,” based on identified risk factors (e.g., unstable gait, history of falling). Morse reported that anticipated falls are the most common (78 percent of falls),¹⁷ although a more

recent report suggests that this type of fall only accounts for 34 to 38 percent of falls in hospitalized patients.¹⁸

2. **Unanticipated physiologic falls.** These are falls that are attributed to physiologic causes, but occurrence of the condition could not be predicted (e.g., seizures, fainting).¹⁷
3. **Accidental falls.** Accidental falls are caused by the patient slipping, tripping, or having a mishap. Morse indicated that accidental falls are less common,¹⁷ but a more recent report suggests that accidental falls account for 45 percent of falls in acute care.¹⁸

Therefore, the ACW KNBI recommendations for fall risk assessments, diagnoses, and interventions were designed to be comprehensive and to reduce fall risk across all three etiologies.

Assessing for Risks of Anticipated Physiologic Falling

Almost 75 percent of the citations that met the relevance and quality criteria for inclusion in the review provided evidence that pertained to the assessment of a patient's risk of falling based on factors that can be anticipated. Clinical experts, researchers, and accrediting agencies² agree that patient assessment is important. However, the processes for evaluating patient risk are very diverse.

Fall risk assessment based solely on the clinical judgment of the nurse, without the use of a tool/questionnaire, has been shown to vary with the experience level of the clinician, and overall, it has been shown to have an accuracy of 35 percent.¹⁹ Although the literature contains many fall risk assessment tools, many are "home grown" without established reliability and validity.²⁰ Using a reliable and valid fall risk assessment tool is recommended because it allows nurses to make decisions regarding the patient's potential for falls in a systematic manner, rather than using intuition,²¹ and the process of risk assessment can be done reliably despite changes in personnel and the advance of time.²²

Over 50 sources of evidence dealt with the development, use, and/or validation of fall risk assessment tools that are designed to identify patients with physiologic conditions that allow one to predict that they would be at increased risk of falling. Of the 30 tools reported in the literature, the published report(s) on only 12 of these tools included sufficient psychometric information to allow for adequate review and comparison.

Several tools were developed and tested in acute care settings, where staff members were aware of the study and were allowed to implement interventions to prevent falls from occurring. This reduced the usefulness of reported tests of sensitivity and specificity because these values could be affected if high-risk patients, who are predicted to fall, do not fall because of the interventions that were used.²³

In the synthesis, tools were recommended for use if they had published evidence of acceptable validity and reliability when hospital staff used the tool, and there was at least one replication study with acceptable reliability and validity. After reviewing the available psychometric data, four tools were found to meet the criteria for recommendation. These included: the Morse Fall Scale,¹⁷ the Schmid Fall Risk Assessment Tool,²¹ the Fall Risk Assessment Tool (FRAT),²⁴ and the St. Thomas Risk Assessment Tool in Falling Elderly Patients (STRATIFY).²⁵ However,

it was noted that the FRAT²⁴ and STRATIFY²⁵ tools were developed and tested primarily in acute care geriatric or rehabilitation units and may not be suitable for use on general medical/surgical units.

In reviewing the acute care fall prevention literature and the risk factors evaluated by fall risk tools, a small number of risk factors were consistently identified: prior fall history; impaired mobility; altered mental status; altered elimination; and the use of sedative and hypnotic medication.^{5, 15, 17, 22, 26, 27, 28, 29, 30, 31} These five factors were recommended as screening indicators to identify patients, who should be evaluated more closely for fall risk using a valid and reliable tool (Table 1).

Since researchers have documented that patient risk may change during a hospital stay,^{17, 29} reassessment has been encouraged.¹² The KBNI synthesis recommended that these five screening indicators be built into routine physical assessment screens so that they trigger a fall risk reassessment whenever a change in one of these factors is documented.

Strategies to Prevent Unanticipated Physiologic and Accidental Falls

Fall risk tools are typically designed to predict anticipated physiologic falls, which represent 34 to 78 percent of the falls that occur in acute care.^{17, 18} Patients also fall because of special conditions (e.g., seizures, fainting) or accidents. Both of these fall types are typically unpredictable. In order to assess for and design interventions to prevent these unanticipated or accidental falls, three factors that were identified in the review of the literature were proposed (Table 1).

First, the presence of certain special conditions or diagnoses (e.g., syncope, fainting, seizures, or pathologic hip fracture) has been associated with unanticipated physiologic falls.¹⁷ Evidence about falls related to these conditions in acute care is lacking. However, in community-based populations, syncope is most commonly caused by orthostatic hypotension, vasovagal response, and drugs; serious cardiac-related syncope occurs less often.³² Community-dwelling elders with orthostatic hypotension or unstable blood pressure were reported to have a two-fold increase in risk of falling.³³

In the absence of published studies to address these conditions in hospitalized patients, these community-based reports could be considered as evidence to support a recommendation for increased monitoring and assistance for patients with these conditions. Patients who have syncope, orthostatic hypotension, seizure disorder, or cardiac arrhythmias, as well as patients recovering from physiologic events—such as an adverse drug reaction, a procedure, or surgery—can be anticipated to be at increased risk for unstable blood pressure (hypotension), syncope, and subsequent falling at certain high-risk times (e.g., after the event, during their first time out of bed).

Table 1. Recommendations for fall risk assessment

Screen all patients on admission for probable indicators of FALL RISK.

- History of falls within the past year
- Impaired mobility/gait
- Altered mental status
- Prescribed medications known to be associated with falls (e.g., sedatives, hypnotics)

Strength of the evidence supporting the recommendation = observational research

1. If positive screen, use a reliable/valid tool to evaluate (anticipated) FALL RISK.

Tools with published reliability & validity:

- Morse Fall Scale (1987)^{16,17}
- Schmid Fall Risk Assessment Tool²¹
- Fall Risk Assessment Tool^{24*}
- St. Thomas Risk Assessment Tool In Falling Elderly Patients^{25*}

* Tested only in older populations on units with extended length of stay

Strength of the evidence supporting the recommendation = observational research

2. Assess for FALL-RELATED INJURY RISK factors:

- Metastatic bone disease
- Osteoporosis
- Antiplatelet agents (except low-dose aspirin)
- Anticoagulant therapy
- Elevated coagulation laboratory results
- Decreased platelet count
- Coagulopathy

Strength of the evidence supporting the recommendation = descriptive and observational research

3. Assess for FALL-RELATED SPECIAL CONDITIONS:

- Syncope
- Seizure disorder
- Cardiac arrhythmia
- Adverse drug effect
- Physiologically recovering from procedure or surgery

Strength of the evidence supporting the recommendation = descriptive research/expert opinion

4. Evaluate PATIENT WILLINGNESS or ABILITY to participate in fall prevention

Strength of the evidence supporting recommendation = descriptive research

Table 1. Recommendations for fall risk assessment (continued)

Ongoing Assessment
Monitor all patients for changes in status that warrant a re-evaluation of fall risk:
• New onset of probable indicators of fall risk (refer to screening criteria above) • Occurrence of a fall event • New medication that increases fall risk (e.g., hypnotic, sedative) or risk for injury (anticoagulant, antiplatelet agent, except low-dose aspirin) • New occurrence of a special condition • Planned (daily) re-evaluation for patients with diagnosis of high risk for falls
Strength of the evidence supporting recommendation = observational research

Second, certain patient conditions may increase a patient's risk for injury secondary to a fall.^{27, 34} For example, metastatic bone disease and osteoporosis have both been associated with increased risk of fracture.²⁷ The use of antiplatelet therapy or anticoagulant therapy, increased prothrombin time (PT), increased partial thromboplastin time (PTT), decreased platelet count (thrombocytopenia), and coagulopathy all can increase risk of bleeding. Anticoagulant-treated patients who fall and experience loss of consciousness or intracranial bleeding have a high rate of mortality.^{35, 36} Use of antiplatelet agents, such as aspirin and clopidogrel, in traumatized elderly patients has been associated with a significant increase in risk of mortality related to intracranial bleeding,^{37, 38} although low-dose aspirin by itself does not appear to increase the rate of bleeding.³⁹ While these drugs and conditions do not affect actual fall risk, they do increase injury risk from a fall and warrant assessment and appropriate interventions to monitor for safety and motivate patients to adhere to fall prevention interventions.

Third, and possibly the most important factor that influences fall risk, is the degree to which the patient is willing and able to be involved in the fall-prevention process. Researchers have documented that a high percentage of falls occur when the patient is not in the presence of a caregiver.^{3, 4, 17, 40, 41} Patient understanding and active participation are critical components of all strategies used to prevent falling and fall-related injuries, particularly in preventing accidental and unanticipated falls that occur in the absence of a caregiver.

Using Patient Assessments to Diagnose Fall Risk and Plan Interventions

The KBNI recommendations related to diagnosing risk for falls (Table 1) advises the nurse to utilize information about fall risk, injury risk, special conditions, and patient willingness and ability to participate in prevention to formulate a fall-related diagnosis that will guide the selection of appropriate interventions to prevent falling for patients with any of the three identified etiologies. This process is consistent with the Joint Commission's patient safety recommendations for assessment and creation of a fall-reduction program that includes interventions to reduce patient risk.² A decision-support mechanism was developed (Figure 1) to verify the presence of risk factors and support the nurse in formulating a diagnosis based on patient assessment. Four common patient populations were identified. Note: Other diagnoses are possible, requiring nurses to use clinical judgment to diagnose, plan, and implement appropriate

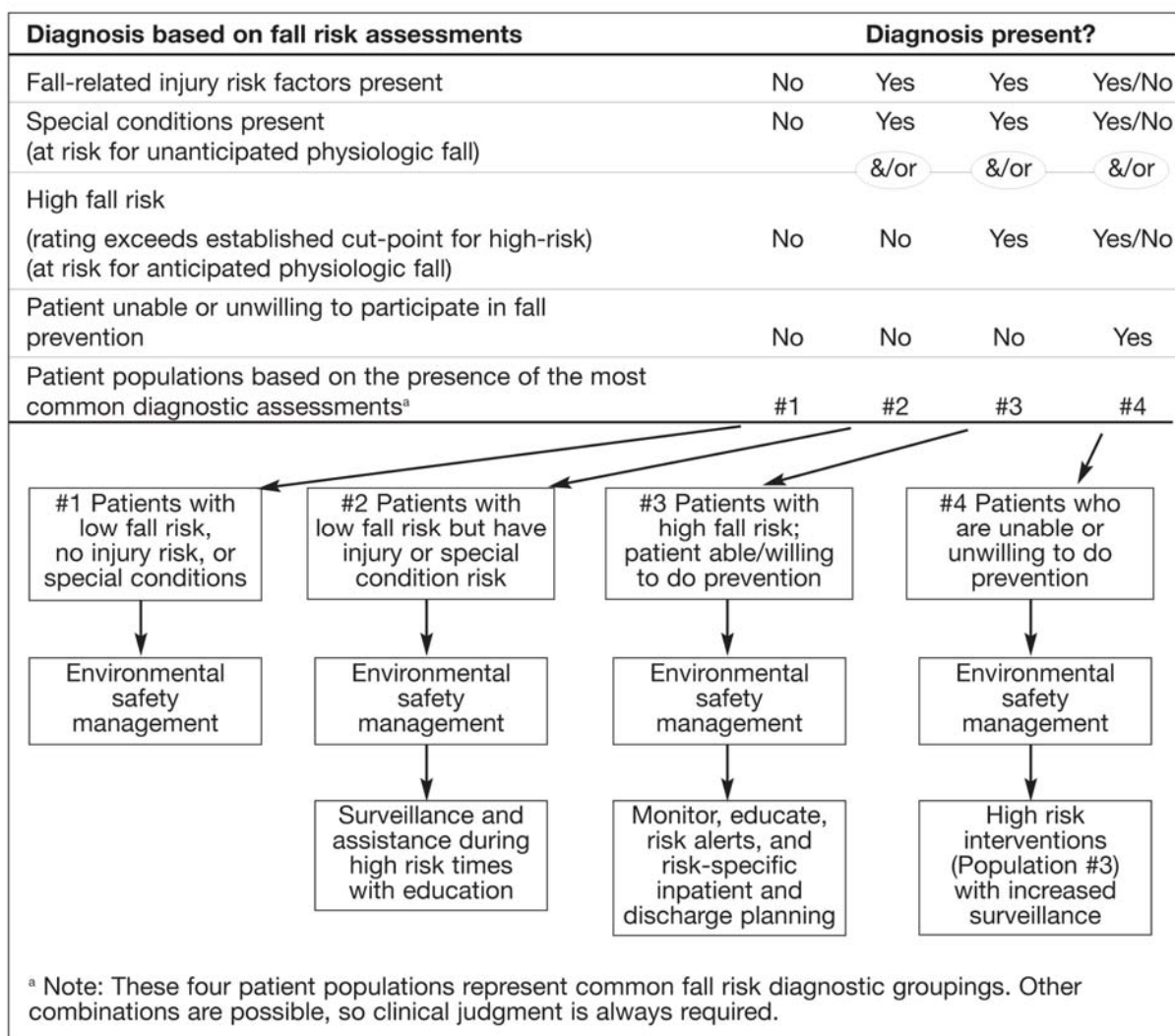


Figure 1. Overview: Using fall risk assessment to diagnose and tailor prevention interventions.

interventions to meet patient needs. An overview of these populations is provided with additional details for evidence-based interventions in the section that follows.

Population #1: Patients with low fall risk and the willingness/ability to participate in prevention. Patients who have none of the identified fall risks (i.e., injury risk, special conditions, or anticipated fall risk) and who are willing and able to participate in fall prevention interventions have the lowest risk for falling. These patients and—in fact—all patients, require environmental safety interventions designed to prevent accidental falling.

Population #2: Patients with low fall risk, willingness/ability to participate in prevention, but have an injury and/or special condition risk. This population has a fall risk score below the cut-off value for being at high risk for anticipated physiologic falling; they are willing and able to participate in prevention; but they have special conditions (or injury risk factors) that increase the likelihood of a fall-related injury. Implementing traditional high-risk fall prevention

strategies for altered mobility, elimination, or mental status requires time and effort and is not likely to be useful, since these patients do not have these risk factors. However, they are at higher risk for injury if an unanticipated or accidental fall occurs, so they are likely to benefit from additional surveillance and assistance during activities/times when these falls are most likely (e.g., first time out of bed after a procedure/medication). Patient education about these risks and safety precautions to reduce risk are essential for these patients.

Population #3: Patients who are at high risk for anticipated falls and are willing/able to participate in prevention. Patients in this category include those who screen positive for one or more of the probable indicators of fall risk (e.g., history of falling, impaired mobility, altered mental status, altered elimination, or use sedatives/hypnotics) and exceed high-risk cut-off values on fall risk tools. Interventions include establishing risk alerts and implementing risk factor-specific plans of care with patient/family education to ensure that patients keep themselves safe when staff is not present.

Population #4: Patients who are unable or unwilling to participate in fall prevention. Patients who are unable or unwilling to participate in fall prevention because of cognitive or mental status impairments pose the greatest challenge. In addition to risk factor-specific plans, human and equipment resources must be appropriately deployed to provide a higher level of surveillance to ensure safety at all times.

Diagnosis-Based Interventions to Reduce Falls and Fall-Related Injury

Recommendations for evidence-based interventions focus on: monitoring all patients for changes in status that increase their fall risk and/or risk of fall-related injury (Table 1), preventing accidental falling for all patients using environmental management strategies, and uniquely tailoring additional interventions to address individual patient needs according to their assessment-based diagnosis (Figure 1). Interventions are recommended for the most common patient populations (Table 2) to achieve improvements in fall and fall-related injury outcomes using standard measures established by the Joint Commission for benchmarked comparison (Table 3).¹² The following summary represents excerpts taken from the ACW KBNI synthesis document, since the comprehensive report is too extensive to include here.

Interventions for Population #1 (and all patients): Environmental safety management. The effectiveness of environmental management strategies to prevent falls in acute care is generally untested. In the absence of research, many organizations have generated their own lists of “standard” environmental management interventions that often include strategies generated in response to adverse events that occurred in their organization. Many different lists of environmental safety interventions to prevent falling have been published with more than 40 different environmental interventions being reported by 17 published sources included in the KBNI review.^{4, 6, 14, 22, 24, 29, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52} During the synthesis process, the diverse list was condensed into a listing of the 10 most frequently reported interventions (Table 2).

Although research on environmental interventions is limited, one study⁵³ evaluated the effects of a nursing staff “rounding protocol,” which involved performing 12 key actions to anticipate needs, reduce call light use, and increase patient satisfaction. Six of the 12 steps in the protocol involved fall prevention-related environmental management strategies, including placing call

Table 2. Recommended interventions for common patient populations based on risk assessment

Interventions for Population #1: Patients with Low Fall Risk (Designed to be used for *all* patients)

Implement Environmental Safety Management

- Orient patient to room/call system
- Put bed in low position with wheels locked
- Encourage use of sensory and ambulatory support items
- Remove clutter and any extra furniture or equipment
- Put personal items within reach
- Put call light within reach; patient demonstrates ability to use
- Encourage use of nonskid slippers/shoes
- Provide adequate/glare-free lighting with night light available
- Encourage use of handrails and bathroom safety bars
- Additional interventions based on individual patient needs

Strength of Evidence Supporting Recommendation: Expert Opinion/Descriptive Research

Interventions for Population #2: Patients with Low Fall Risk, but with Injury or Special Condition Risk

- Increase surveillance and assistance, based on disease/condition-specific factors (e.g., first time out of bed after a surgery or procedure; patient is likely to have an adverse reaction to treatment or medication)
- Inform patient and significant other (SO) of the presence of injury or special condition risk
- Reinforce importance of calling and waiting for assistance before activities that increase fall risk
- Provide patient/SO with disease/condition-specific education to reduce risk of falls (e.g., for seizure management, syncope)
- Help patient identify environmental hazards and personal behaviors that increase risk for accidental falling and to choose interventions that will reduce risks after discharge

Strength of Evidence Supporting Recommendation = Observational Research/Expert Opinion

Table 2. Recommended interventions for common patient populations based on risk assessment (continued)

Interventions for Population #3: Patients with High Fall Risk & Willingness/Ability to Participate in Fall Prevention

- Educate patient/significant other regarding fall risk and prevention
 - o Inform patient /SO of the presence of and fall-related injury risk factor(s)
 - o Reinforce importance of calling and wait for assistance during activities that increase risk of falling during hospitalization
 - o Reinforce use of sensory and ambulation aids at all times; consider use of a gait belt
 - o Appropriate use of side rails for environmental controls and enhanced mobility (not for restraint)
- Implement fall risk alert system (e.g., wrist bands, signage, electronic/written communication)
- Collaborate with physician (early in hospitalization) to address risk factor-specific patient problems, including mobility/gait, medications, elimination, or others, with referrals as appropriate
- For patients on medications that increase fall risk, consult pharmacist/physician

Strength of Evidence Supporting Recommendation = Descriptive/Observational Research

Interventions for Population #4: Patients Who Are Unable/Unwilling to Participate in Fall Prevention

- Implement all appropriate interventions for patients at high risk of falling (see Population #3)
- Increase supervision; intensity based on patient need ranging from moving patient for increased visibility to the use of continuous supervision (e.g., a sitter)
- Provide individualized toileting interventions (based on needs/patterns)
- For patients with altered cognitive/mental status, collaborate with the physician to evaluate and implement appropriate interventions
- Consider bed/chair exit alarms appropriate to the setting and needs of the patient
- Consider use of new bed/safety technologies
- Carefully progress activity in the cognitively impaired patient
- Minimal and appropriate use of restraints
- Develop fall prevention discharge plan

Strength of Evidence Supporting Recommendation = Expert Opinion/Descriptive Research

Table 3. Fall and fall-related injury outcome measures

Measure	Definition
Fall	An unplanned descent to the floor (or extension of the floor; e.g., trash can or other equipment), with or without injury to the patient.
Assisted fall	A fall in which any staff member (whether nursing service employee or not) was with the patient and attempted to minimize the impact of the fall by easing the patient's descent to the floor or, in some manner, attempting to break the patient's fall. "Assisting" the patient back to bed or chair after a fall is not an assisted fall.
Repeat fall	More than one fall by the same patient after admission to a unit.
Fall rate	(Number of falls (with or without injury) by unit type during calendar month x 1,000) Divided by number of patient days by unit type during the calendar month
Fall injury level	The extent of injury experienced by a patient following a fall, with followup at least 24 hours later if injury extent is not known at the time of the initial fall report. None: Patient had no injuries resulting from the fall. Minor: Resulted in application of a dressing, ice, cleaning of a wound, limb elevation, or topical medications. Moderate: Resulted in suturing, application of Steri-Strips™/skin glue, or splinting. Major: Resulted in surgery, casting, traction, or required consultation for neurologic or internal injury. Death: Patient died as a result of injuries sustained from the fall.
Fall injury rate ^a	(Number of falls with an injury level of minor or greater by unit type during calendar month x 1,000) Divided by patient days by unit type during the calendar month

a National standards for injury levels have yet to be established.

Source: The Joint Commission. Implementation guide for NQF-endorsed voluntary consensus standards for nursing-sensitive care performance measures: Patient falls (NSC-3) and falls with injury (NSC-4). Available at www.jointcommission.org.

light, telephone, table, tissue, water, and garbage receptacle within reach. Regular rounding (every 1-2 hours) using the protocol significantly reduced call light use and increased patient satisfaction. Although the study was not designed to evaluate falling as a primary outcome, the researchers reported that patient falls were reduced in the group that received the every-1-hour rounding intervention. The researchers did not report if the sample represented patients who were at risk for falls (no fall risk assessments were reported), and they evaluated fall outcomes based on fall counts by unit over a limited (10-week) time period. These two methodologic issues limit the generalizability of these findings for fall prevention. However, the study does provide some evidence that environmental management may influence the incidence of falling in acute care.

Interventions for Population #2: Patients with low fall risk, but with injury or special condition risk. The primary intervention for preventing unanticipated physiologic falling (e.g., due to dizziness, fainting, etc.) involves teaching or warning the patient.¹⁶ The interventions described for this population (Table 2) are designed to increase staff and patient awareness of several very specific interventions to prevent falling in patients who typically are not identified to be at risk.

Interventions for Population #3: Patients with high fall risk and willing/able to participate in prevention. Systematic reviewers reported that most acute care fall prevention programs were heterogeneous and employed a variety of often labor-intensive strategies, without being designed to determine which treatment components were efficacious.^{6, 40} The most commonly reported approach to fall prevention was the implementation of multiple interventions aimed at identifying high-risk patients and minimizing individual patients' risk of falling. Reviewers reported that research quality varied across most studies, with incomplete reporting about how interventions were selected, implemented, and evaluated.^{6, 22, 41}

Making sure that patients at high risk of falling are readily identifiable by health care personnel was one of the most commonly reported fall prevention interventions. Strategies for patient identification included signs on the patient's door, signs above the patient's bed, interdisciplinary communication, and the use of colored slippers or blankets to indicate level of risk. Research reviewers described several studies, where the use of high-risk patient identification bracelets, signs, stickers, or tags was inexpensive and easy, but none demonstrated that these measures as isolated interventions decreased falls.^{15, 22} Given broad clinical use, ease, and affordability, high-risk patient identification was included as a recommendation, even though research to support its use was limited.

To synthesize the evidence, common fall prevention strategies reported in 19 published sources were gathered, summarized, and used to supplement the recommendations (Table 2). Most authors reported using multiple strategies, including risk assessment, risk identification, use of sensory and ambulatory assist devices, appropriate use of side rails, patient education, and referral (e.g., physical therapy). Most authors reported that interventions were established based on literature review and consensus opinion.^{4, 6, 14, 15, 22, 24, 29, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55}

Interventions for Population #4: Patients with high fall risk who are unable or unwilling to participate in prevention. Patients who screen positive for altered mental status may have symptoms associated with delirium, dementia, or depression. These are diagnoses that require specialized assessments and interventions that are beyond the scope of the current discussion. However, the immediate use of additional fall prevention interventions is warranted in this group of patients who demonstrate an unwillingness or inability to participate in fall prevention (refer to the details in Table 2).

Researchers have reported that a high percentage of falls occur when patients are not in the presence of a caregiver.^{3, 4, 17, 40, 42} Increasing supervision is an essential intervention for patients who are unwilling or unable to participate in prevention. However, research on clinically effective and cost-effective strategies to provide supervision is limited. Several authors^{24, 46, 48, 50, 51, 52, 55} have recommended the use of periodic patient "checks" every 1 to 2 hours, a fairly labor-

intensive strategy. As noted above, a recently published study provided some exploratory evidence (with limited application to fall prevention) suggesting that active “rounding” with the offer of pain medication and toileting as needed and a protocol for environmental management did have an effect on falling when conducted at least hourly but not when done every 2 hours.⁵⁴

Studies have shown that falls happen most frequently during times when patients are active¹⁶ and frequently during elimination and toileting-related activities.^{3, 16, 45, 56, 57} This was particularly true for older patients who were unattended while toileting. These falls were also observed to be frequently associated with injury. Individualized toileting care appears to be an intervention with a high potential to reduce falls and injury in this population.

Among recently discharged medical patients, 15 percent of readmissions during the first month after discharge were found to be due to an injury sustained from a fall. However, the investigators were unable to determine whether the increased fall risk was due to acute illness or hospital-associated processes (bed rest/complications).⁵⁷ Appropriate interventions to maintain patients’ functional status—even as they assure the patient’s safety while in bed, sitting, or ambulating—are recommended.

Special care during mobilization may be needed with cognitively impaired patients. The findings of two randomized controlled trials and one descriptive study suggest that patients with impaired cognition experience balance problems when distracted by conversation or dual task performance.^{58, 59, 60} Early risk factor-specific discharge planning is needed to ensure effective post-hospital care for these patients.⁶¹

Using the Clinical Information System to Evaluate Process and Outcomes

In addition to the creation of screens and a decision-support mechanism, additional fields were created to collect important information about patient characteristics, assessments, interventions, and outcomes to evaluate the effectiveness of the processes. As an added benefit, the system is capable of being programmed to provide real-time quality improvement data for unit-based staff intervention, as well as a dataset available for future research.

The KBNI process is in the early phases of development. The process appears to provide a useful format for formulating and implementing evidence-based recommendations to address all aspects of the nursing process. To date, risk for falls and two other phenomena have been embedded, and evaluation is in progress. The project is challenging because it requires intensive evidence synthesis, new strategies to embed recommendations efficiently and effectively into the workflow, and mechanisms for updating content when new evidence becomes available.

Conclusion

The ACW KBNI provides a useful framework for gathering and synthesizing the best evidence into actionable recommendations for embedding decisionmaking tools to assist nurses. This article describes the process for conducting a comprehensive fall risk assessment and tailoring of prevention interventions to reduce risk for all three fall etiologies. The framework and the

process provide new data fields for documenting the nursing contribution to patient care and supports the retrieval of data to provide answers to quality improvement and research questions.

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References

1. Institute of Medicine. Crossing the quality chasm: A new health system for the 21st century. Washington, DC: National Academies Press; 2001.
2. Joint Commission. 2008 National patient safety goals: Hospital program. Available at: www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/08_hap_npsgs.htm. Accessed February 26, 2008.
3. Hitcho EB, Krauss MJ, Birge S, et al. Characteristics and circumstances of falls in a hospital setting: A prospective analysis. *J Gen Intern Med* 2004; 19: 732-739.
4. Mahoney JE. Immobility and falls. *Clin Geriatr Med* 1998; 14: 699-726.
5. Oliver D, Daly F, Martin FC, et al. Risk factors and risk assessment tools for falls in hospital in-patients: A systematic review. *Age Ageing* 2004; 33: 122-130.
6. Rutledge DN, Donaldson NE, Pravikoff DS. Update 2003: Fall risk assessment and prevention in hospitalized patients. *J Clin Innovat* 2003; 6: 1-55.
7. Lauver DR, Ward SE, Heidrich SM, et al. Patient-centered interventions. *Res Nurs Health* 2002; 25: 246-255.
8. Lang NM, Hook ML, Akre ME, et al. Translating knowledge-based nursing into referential and executable applications in an intelligent clinical information system. In: Weaver C, Delaney C, Webber P, et al, eds. *Nursing and informatics for the 21st century: An international look at the trends, cases, and the future*. Chicago: Healthcare Information and Management Systems Society; 2006. p. 291-303.
9. Agency for Healthcare Research and Quality (AHRQ). Systems to rate the strength of scientific evidence. Available at: www.ahrq.gov/clinic/epcsums/strengthsum.htm. Accessed February 26, 2008.
10. Devine EC. Knowledge-based nursing initiative system for rating the strength of evidence supporting recommendations. In: Devine EC, Kim TY, Johnson B, et al. *ACW Knowledge Based Nursing Initiative evidence table protocol*. Milwaukee, WI: University of Wisconsin-Milwaukee, College of Nursing; 2007: p. 8.
11. Melnyk B, Fineout-Overholt E. *Evidence-based practice in nursing and healthcare: A guide to best practice*. Philadelphia: Lippincott Williams & Wilkins; 2005.

12. Joint Commission. Implementation guide for NQF-endorsed voluntary consensus standards for nursing-sensitive care performance measures: Patient falls (NSC-3) and falls with injury (NSC-4). Available at: www.jointcommission.org/PerformanceMeasurement/MeasureReserveLibrary/nqf_nursing.htm. Accessed February 26, 2008.
13. North American Nursing Diagnosis Association. International. Nursing diagnoses: Definitions and classification. 7th ed. Philadelphia: NANDA-I; 2007-2008.
14. Veterans Health Administration. National Center on Patient Safety toolkit: Falls policy. Available at: www.patientsafety.gov/SafetyTopics/fallstoolkit/notebook/completebooklet.pdf. Accessed February 26, 2008.
15. Agostini J, Baker D, Bogardus SJ. Prevention of falls in hospitalized and institutionalized older people. In: Shojania KG, Duncan BW, McDonald KM, et al, eds. Making health care safer: A critical analysis of patient safety practices. Rockville, MD: Agency for Healthcare Research and Quality; 2001. AHRQ Publication No. 01-E058.
16. Morse JM, Tylko SJ, Dixon HA. Characteristics of the fall-prone patient. *Gerontologist* 1987; 27: 516-522.
17. Morse JM. Preventing patient falls. Thousand Oaks, CA: Sage; 1997.
18. Donaldson N, Brown SD, Aydin CE, et al. Leveraging nurse-related dashboard benchmarks to expedite performance improvement and document excellence. *J Nurs Admin* 2005; 35: 163-172.
19. Myers H, Nikolett S. Fall risk assessment: A prospective investigation of nurses' clinical judgment and risk assessment tools in predicting patient falls. *Int J Nurs Pract* 2003; 9: 158-165.
20. Brown DS, Donaldson N, Aydin CE, et al. Hospital nursing benchmarks: The California Nursing Outcomes Coalition Project. *J Healthc Qual* 2001; 23: 22-27.
21. Schmid NA. 1989 Federal Nursing Service Award Winner. Reducing patient falls: A research-based comprehensive fall prevention program. *Mil Med* 1990; 155: 202-207.
22. Evans D, Hodgkinson B, Lambert L, et al. Falls in acute hospitals. Available at: www.joannabriggs.edu.au/pdf/1_1998_Falls.pdf. Accessed February 26, 2008.
23. Vassallo M, Stockdale R, Sharma JC, et al. A comparative study of the use of four fall risk-assessment tools on acute medical wards. *J Am Geriatr Soc* 2005; 53: 1034-1038.
24. MacAvoy S, Skinner T, Hines M. Fall risk-assessment tool. *Appl Nurs Res* 1996; 9: 213-218.
25. Oliver D, Britton M, Seed P, et al. Development and evaluation of evidence based risk assessment tool (STRATIFY) to predict which elderly inpatients will fall: Case-control and cohort studies. *Br Med J* 1997; 315: 1049-1053.
26. American Geriatrics Society, British Geriatrics Society, & American Academy of Orthopaedic Surgeons panel on falls prevention. Guideline for the prevention of falls in older persons. *J Am Geriatr Soc* 2001; 49: 664-672.
27. Currie LM, Mellino LV, Cimino JJ, et al. Development and representation of a fall-injury risk assessment instrument in a clinical information system. *Medinfo* 2004; 11: 721-725.
28. Evans D, Hodgkinson B, Lambert L, et al. Falls risk factors in the hospital setting: A systematic review. *Int J Nurs Pract* 2001; 7: 38-45.
29. Hendrich A, Nyhuis A, Kippenbrock T, et al. Hospital falls: Development of a predictive model for clinical practice. *Appl Nurs Res* 1995; 8: 129-139.
30. Krauss MJ, Evanoff B, Hitcho E, et al. A case-control study of patient, medication, and care-related risk factors for inpatient falls. *J Gen Intern Med* 2005; 20: 116-122.
31. Myers H. Hospital fall risk assessment tools: A critique of the literature. *Int J Nurs Pract* 2003; 9: 223-235.
32. Rubenstein Z, Josephson KR. The epidemiology of falls and syncope. *Clin Geriatr Med* 2002; 18: 141-158.
33. Heitterachi E, Lord SR, Meyerkort P, et al. Blood pressure changes on upright tilting predict falls in older people. *Age Ageing* 2002; 31: 181-186.
34. Hook M, Winchel S. Fall-related injuries in acute care: Reducing the risk of harm. *Medsurg Nurs* 2006; 15: 370-377, 381.
35. Mina AA, Bair HA, Howells GA, et al. Complications of preinjury warfarin use in the trauma patient. *J Trauma* 2003; 54: 842-847.
36. Peel NM, Kassulke DJ, McClure RJ. Population based study of hospitalised fall-related injuries in older people. *Inj Prevent* 2002; 8: 280-283.
37. Garra G, Nashed AH, Capobianco L. Minor head trauma in anticoagulated patients. *Acad Emerg Med* 1999; 6: 121-124.
38. Ohm C, Mina A., Howells G, et al. Effects of antiplatelet agents on outcomes for elderly patients with traumatic intracranial hemorrhage. *J Trauma* 2005; 58: 518-522.

39. Spektor S, Agus S, Merkin V, et al. Low-dose aspirin prophylaxis and risk of intracranial hemorrhage in patients older than 60 years of age with mild or moderate head injury: A prospective study. *J Neurosurg* 2003; 99: 661-665.
40. Oliver D, Hopper A, Seed P. Do hospital fall prevention programs work? A systematic review. *J Am Geriatr Soc* 2000; 48: 1679-1689.
41. Lyons SS. Evidence-based protocol: Fall prevention in older adults. *J Gerontol Nurs* 2005; 31: 9-14.
42. Shorr RI, Guillen MK, Rosenblatt LC, et al. Restraint use, restraint orders, and the risk of falls in hospitalized patients. *J Am Geriatr Soc* 2002; 50: 526-529.
43. Barnett K. Reducing patient falls project. Available at: www.premierinc.com/safety/topics/falls/downloads/E-14-falls-project-uk.pdf. Accessed February 26, 2008.
44. Bolton LB, Goodenough A. A magnet nursing service approach to nursing's role in quality improvement. *Nurs Adm Q* 2003; 27: 344-354.
45. Gowdy M, Godfrey S. Using tools to assess and prevent inpatient falls. *Jt Comm J Qual Saf* 2003; 29: 363-368.
46. Hougaard J. Developing evidence-based interdisciplinary care standards and implications for improving patient safety. *Int J Med Inform* 2004; 73: 615-624.
47. Kinn S, Hood K. A falls risk-assessment tool in an elderly care environment. *Br J Nurs* 2001; 10: 440, 442, 444-449.
48. McCarter-Bayer A, Bayer F, Hall K. Preventing falls in acute care: An innovative approach. *J Gerontol Nurs* 2005; 31: 25-33.
49. McFarlane-Kolb H. Falls risk assessment, multitargeted interventions and the impact on hospital falls. *Int J Nurs Pract* 2004; 10: 199-206.
50. Poe SS, Cvach MM, Gartrelu DG, et al. An evidence-based approach to fall risk assessment, prevention, and management: Lessons learned. *J Nurs Care Qual* 2005; 20: 107-117.
51. Resnick B. Preventing falls in acute care. In: Mezey M, Fulmer T, Abraham I, et al, editors. *Geriatric nursing protocols for best practice*. 2nd ed. New York: Springer; 2003. p. 141-164.
52. Szumlas S, Groszek J, Kitt S, et al. Take a second glance: A novel approach to inpatient fall prevention. *Jt Comm J Qual Saf* 2004; 30: 295-302.
53. Tideiksaar R. Falls in older persons: Prevention & management. 2nd ed. Baltimore, MD: Health Professions Press; 1998.
54. Meade CM, Bursell AL, Ketelsen L. Effects of nursing rounds: On patients' call light use, satisfaction, and safety. *Am J Nurs* 2006; 106: 58-71.
55. Alcee D. The experience of a community hospital in quantifying and reducing patient falls. *J Nurs Care Qual* 2000; 14: 43-53.
56. Mills PD, Neily J, Luan D, et al. Using aggregate root cause analysis to reduce falls. *Jt Comm J Qual Patient Saf* 2005; 31: 21-31.
57. Meiner SE, Miceli DG. Safety. In: Lueckenotte AG, ed. *Gerontologic nursing*. 2nd ed. St. Louis, MO: Mosby; 2002. p. 232-255.
58. Hauer K, Pfisterer M, Weber C, et al. Cognitive impairment decreases postural control during dual tasks in geriatric patients with a history of severe falls. *J Am Geriatr Soc* 2003; 51: 1638-1644.
59. Brauer SG, Woollacott M, Shumway-Cook A. The interacting effects of cognitive demand and recovery of postural stability in balance-impaired elderly persons. *J Gerontol A Biol Sci Med Sci* 2001; 56: M489-M496.
60. Morioka S, Hiyamizu M, Yagi F. The effects of an attentional demand task on standing posture control. *J Physiol Anthropol Appl Human Sci* 2005; 24: 215-219.
61. Mahoney JE, Palta M, Johnson J, et al. Temporal association between hospitalization and rate of falls after discharge. *Arch Intern Med* 2000; 160: 2788-2795.

Home Health Care Patients and Safety Hazards in the Home: Preliminary Findings

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Abstract

Introduction: Home health care is the fastest growing sector in the health care industry, with an anticipated growth of 66 percent over the next 10 years and with over 7 million patients served each year. With the increasing acuteness of care provided in home health care and the increasing number of frail elderly that make up this patient population, it is important to identify risk factors that affect patient health and safety in this setting. **Methods:** A convenience sample of 1,561 home health aides, attendants, and personal care workers completed a risk assessment survey. Items addressed personal, patient, and home characteristics and health hazards. All activities had prior Institutional Review Board approval. **Preliminary Results:** Ninety-five percent of home health care workers (HHCWs) were female with an average of 8 years experience. The majority of clients were elderly, with a smaller percentage of adult (26 percent) and pediatric (7 percent) cases. HHCWs reported the following exposures at their clients' homes: cockroaches (33 percent), cigarette smoke (30 percent), vermin (23 percent), irritating chemicals (17 percent), and peeling paint (15 percent). The following conditions were also described: clutter (17 percent), temperature extremes (9 percent), unsanitary (12 percent) and unsafe (6 percent) conditions in the home, neighborhood violence/crime (11 percent), and aggressive pets (6 percent). Two percent of respondents reported the presence of guns in the home. Additionally, 12 percent of HHCWs reported signs of abuse of their clients. **Conclusion:** Both HHCWs and home care patients appear to be at potential risk due to a variety of health hazards/exposures in the clients' homes. Given the growing population of both HHCWs and recipients, it is important to document this risk as an important first step in prevention and management.

Introduction

The home care setting is a challenging work environment in terms of patient safety for a number of reasons. First, residential settings may present household-related hazards (e.g., poor indoor air quality, lead paint, toxic substances) that are associated with numerous negative health effects.^{1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12} Second, many of the same well-defined hazards related to health care—such as spread of nosocomial infections, development of resistant organisms, medication errors, and others—are also found in home care settings.^{13, 14, 15} Third, home care may be delivered under conditions that may be uncontrolled. Fourth, health care providers may have limited training or expertise in the area of patient safety and often have little or no direct

supervision.^{16, 17, 18, 19} Finally, risk management is especially problematic in home care because each home is, in essence, a “worksite,” yet all the necessary health care workplace protections for both workers and patients may not be in place or readily available.²⁰

For these reasons, controlling hazards in home care can be difficult. Although we continually add to our knowledge base of patient safety in the acute care setting, our understanding of the health and safety hazards associated with home care is limited and highly reliant on anecdotal and qualitative reports, even though these hazards have important implications for the health and well-being of home care patients. Importantly, an unsafe household can adversely affect not only the patient, but also home health care providers and household caregivers. To address these concerns, risk assessment data are needed to develop evidence-based strategies to reduce risk, including strategies that may require tailoring to this unique health care setting.

As a step in closing the research gap in home care, a large cross-sectional survey of New York City-based home health aides and personal assistants was conducted to assess home health care-associated potential health and safety hazards.

Home Health Care Sector

Home health care is the fastest growing sector in the health care industry, with 66 percent growth projected over the next 10 years.²¹ The sector is large, employing over 1.3 million workers in a variety of occupations, including roughly 1.2 million aides and personal assistants.²¹ Most growth occurred after the enactment of Medicare in 1965, although the agencies were first established in the late nineteenth century. Even more dramatic growth occurred after the 1987 revisions to Medicare, which led to facilitated reimbursement to home care agencies.²² By 2005, over 20 thousand home care agencies were providing care to an estimated 8 million individuals. This likely represents only a fraction of the true number of home care patients, since many receive informal care through non-Medicare-certified agencies or individuals.²²

In general, there are three types of home care agencies: (1) certified home health agencies (CHHAs), (2) long-term home health care programs (LTHHCPs), and (3) licensed home care services agencies (LHCSAs). CHHAs are authorized to serve both Medicare and Medicaid recipients in need of short-term skilled nursing care and to provide nursing, home health aide, personal care, and homemaker and housekeeper services. LTHHCPs, also known as “nursing homes without walls,” provide services that enable individuals eligible for nursing homes to remain at home. They operate under a Federal waiver for home and community-based services and are required to provide all the services provided by a CHHA, as well as case management. Finally, LHCSAs provide at least one of the following services, either directly or through contracts with another program: nursing care, home health aides, personal care, private duty nursing, homemakers, and physical/occupational and speech therapies.

Most formal home care is provided by freestanding proprietary agencies (55 percent), followed by hospital-based agencies (24 percent), with nonprofit public health agencies and nonprofit private agencies providing a smaller portion of home care.²³ Another large and growing type of home care is home hospice care. Since 1983, when Medicare added hospice benefits to the plan, the number of certified hospices grew from 31 to 2,444.^{22, 23} The actual size of the informal, uncertified, and unlicensed home care network is not known, but it is believed to be nearly as large as the formal network.

In addition to over 110,000 registered nurses providing skilled nursing care or supervision in home care, a large workforce, comprising home health aides, home attendants, and personal care workers, provides the bulk of day-to-day care in the home care setting.²⁴ Under medical direction, although without direct supervision, home health aides provide basic medical services that allow patients to convalesce outside of the traditional hospital and hospice setting. They check patients' vital signs, conduct physical therapy, change dressings, and assist with the use of medical equipment. In addition, they may provide other services that neither patients nor their families are able to provide on their own, such as assistance with ambulation, bathing, and grooming the patient. Home health aides may also be asked to perform light housekeeping.²⁴

Personal care workers and home care attendants, commonly referred to as "personal assistants," provide more personal care assistance to patients in the home setting. Their responsibilities primarily focus on activities of daily living (e.g., bathing, grooming, dressing, feeding), housekeeping, and transportation. Such responsibilities usually do not entail providing medical or nursing care, although in practice this is not always the case. Personal care workers and home care attendants may also provide advice about nutrition and hygiene to patients and their families.²⁵

A high school diploma is not generally required for employment as a home health aide or personal assistant. However, home health aides working for agencies that receive funding from the Federal Government must pass a competency test. Additionally, the National Association for Home Care and Hospice offers a national certification for home care aides, which evaluates home health care workers (HHCWs) on 17 unique skills. Training and other certification requirements may vary from State to State for personal assistants and home health care aides.^{24, 25, 26, 27}

It is important to note that HHCWs have an increased incidence of injury compared to other health care and human services workers.^{19, 28} A review by Galinsky, et al., provided exhaustive documentation of overexertion injuries in HHCWs.²⁹ They found that forceful exertions and awkward postures during patient care, especially lifting and shifting patients, were the main risk factors for musculoskeletal disorders in this workgroup. The impact of these types of injuries and the relationship between HHCW health and safety in general, and the safety of patients (e.g., patient falls), have not been assessed. Such an assessment is clearly needed, especially in light of the growing prominence of home care.

With the annual U.S. expenditures for home health care in excess of \$40 billion per year, the scope of home care is broad and, as noted, covers a wide range of services, from assistance with daily living activities to providing the more complex care required by postsurgical or chronically ill patients.³⁰ Even with the increasing acuity of care that is provided in the home setting, the cost per day of home care is significantly lower than that of a nursing home or an inpatient hospital stay (\$109 vs. \$3,838, respectively) and is increasingly more desirable by both patients and their families.²²

Home Care Patients

The patient population served by home health care is large, growing, and increasingly frail and elderly. The increase in home care is being driven by continued efforts at medical cost saving²⁴ that began in the late 1980s when a nationwide campaign to reduce medical costs led to

decreased length of hospital stays and the early discharge of many patients to home care. For example, in 2003, patients were discharged from hospitals after 4.8 days on average; in 1990, the average hospital stay was 6.4 days³¹; in 2000, 48 percent of discharged Medicare patients were discharged to home care.³²

Perhaps the most significant factor affecting home care is the aging post-World War II (“baby-boomers”) cohort. The first wave of the cohort will reach age 65 in 2012, and by 2032, the cohort will have reached age 85,³³ resulting in a dramatic increase in the number of older Americans. For example, in 1960, 16.2 million people in the United States were aged 65 or older; by 2000, that number had increased to 35 million, and by 2030 this number is projected to increase to 72 million.³³

An even greater magnitude of growth is projected for the extremely elderly cohort. In 1960, less than 1 million Americans were 85 years or older; by 2000, this number had increased to 4.2 million, and it is anticipated that by 2030, nearly 10 million Americans will be 85 years or older.³¹ These shifts are due not only to sweeping demographic changes in the population, but also to reductions in U.S. mortality rates. Combined, the result will strain the services provided to the elderly, including home care services. Even though the home care workforce is large, with an estimated 1.3 million workers overall, the projected need is great, with perhaps twice as many home care employees needed by 2030.³⁴ This is especially problematic given that the workforce itself is undergoing similar demographic age shifts and, as is the case with the nursing profession, is steadily experiencing increasing shortages for a variety of reasons.

These demographic changes in the U.S. population can also be seen acutely in the home care patient population. For example, in 2000, almost 70 percent of the Nation’s 8 million patients receiving formal home care were 65 years or older, and 17 percent were 85 years or older. By 2012, this is expected to increase substantially as the baby boomer cohort ages, with perhaps as many as 20 million or more patients needing home care.²²

Other shifts in home care are noted as well. For example, while currently about half of home care patients aged 64 or younger are female, there are nearly twice as many females in the 65 years and older age group.²² Although the vast majority of home care patients receiving formal care are white (90 percent), this is expected to change as a reflection of the increased growth in minority populations.²²

There are also current and projected changes related to the health condition of home care patients. A large proportion of current home care patients have heart disease diagnoses (47 percent), followed by injuries (16 percent), osteoarthritis (14 percent), and respiratory ailments (12 percent),²² and increasingly frail and vulnerable patients continue to enter home care with many highly complex medical problems and multiple diagnoses, thus requiring a greater intensity of care.

All these trends suggest that home care will become even more challenging and that the expectations placed upon the sector, including the caregivers, will most likely become more demanding. By increasing our awareness and understanding of the health hazards inherent in the home care environment, it may be possible to reduce the risk of injury and illness to the home care patient and to improve the quality of work life for the caregiver.

Health and Safety Hazards Associated with Home Health Care

Most of our information regarding home health hazards comes from anecdotal or qualitative reports, and only a few surveys have been conducted. Although there is a wide range of hazards, the hazards generally fall into two major categories: those related to violence or the threat of violence and those related to unsanitary household conditions.

A good overview of the scope of home hazards is provided in a recently published qualitative study by Markkanen, et al.³⁵ Data on occupational hazards were collected from HHCWs participating in focus groups and in-depth interviews. They identified general security/personal safety hazards that could present a threat to patient safety, including unsafe neighborhoods, violent or unstable patients and family members, and potentially dangerous pets. The study participants also raised environmental concerns, including overheated room temperatures, poor indoor air quality, and unsanitary conditions, such as the presence of insects and rodents.

Unsanitary conditions are a special concern, since the spread of infectious disease within the household is well documented, and various procedures in home care could present a risk of infection. Cross-contamination (e.g., transfer of pathogens through direct and indirect contact with raw foods, animals, and contaminated inanimate objects) can place the frail elderly and others at risk. One household area of potential concern in this regard is the bathroom. Gerba, et al., tested the spread and survivability of microbes in household toilets and found that droplets formed during flushing could result in the spread of organisms on various bathroom surfaces and that the droplets remained airborne and viable for extended periods.³⁶ This may become a concern in special cases, such as where the number of enteric pathogenic organisms is high and when hosts are especially vulnerable. Household laundry is also a concern because it has been shown to be a route for the spread of disease. For example, spread of *Staphylococcus aureus* via laundry has been documented.³⁷ A review on domestic hygiene noted that changes in household laundry practices—such as lower temperatures, less use of household bleach, and lower water volume—had an adverse impact on laundry hygiene in general.³⁸ These changes could place home care patients at increased risk of infection.

Studies have also documented the survivability and spread of microbes in the kitchen. Pathogens associated with raw or undercooked food items, such as poultry, have caused disease in household members, including those who are especially vulnerable due to age or immune status.³⁹ For example, cases of salmonellosis related to this type of contamination have been reported.³⁹ Dirty kitchen surfaces, rags, sponges, mops, etc., are potential sources of cross-contamination and can spread disease causing microorganisms in the home care setting.

Mismanagement of medical waste may also be a cause for concern in the home care environment because it can be a source of pathogenic microbes. Although each State regulates the transportation, storage, and disposal of biomedical waste, usually via individual health departments, the home care setting is not easily regulated. Anecdotal reports of improperly disposed sharps (e.g., using empty food containers) are common and can lead to needlestick injuries in caregivers, patients, household members, and sanitation workers. In a recent pilot study of HHCWs, Gershon, et al., found that 13 percent of home health care nurses (N = 72) experienced a needlestick injury in the 12-month period preceding the self-administered survey,

and most of these were disposal-related.⁴⁰ Other authors have documented needlesticks associated with home care, although the studies usually have targeted home health nurses.^{41, 42, 43}

Another area of concern is the reuse of certain single-use disposable items. For example, it has been reported that many diabetes patients repeatedly reuse insulin syringes, without disinfection, until the needle is no longer sharp.⁴⁴ Similarly, in the home care setting, drainage bags may be disinfected and reused, a practice that rarely occurs in the hospital setting.⁴⁵

Urinary drainage systems, normally kept intact for patients with indwelling catheters, may be breeched when the home care patient needs to use a leg bag.⁴⁵ Indwelling devices in general, which are the greatest predictors of nosocomial infection, are increasingly prevalent in home care patients.⁴⁶ Between 1993 and 1995, the Centers for Disease Control and Prevention (CDC) investigated three outbreaks of bloodstream infections in patients receiving home infusion therapy.^{13, 14, 15} Inappropriate disinfection of semi-critical items (e.g., reusable thermometers) is reportedly common.

The issue of home hygiene, including disinfection practices, needs addressing. Unfortunately, we still do not yet have a national surveillance system in place in the United States for health care-associated infections in home care settings, even though this has been suggested.⁴⁶ Specific CDC guidelines for infection control practices for home care have not yet been published, although a number of thorough reviews of home infection control practices and guidance have been provided by national and State organizations.^{44, 45} Although the reviews are somewhat dated, much of the advice remains sound and is currently in practice. The CDC Web site also provides useful references in this regard.⁴⁷

Finally, a topic of special concern in home care, especially urban home care, is the issue of crime and violence. A recent article by Geiger-Brown, et al., includes a thorough review of the risks and risk factors for violence in home care.²⁰ The few studies that have explored this issue have found that verbal abuse was the most commonly reported form of abuse;^{48, 49} in one study, the prevalence was as high as 52 percent.⁴⁹ Other forms of violence or the threat of violence have been reported, with dangerous neighborhoods, family members, and patients most often cited as threatening.^{50, 51} In a small survey by Kendra, et al., administrators and staff were asked to rank factors associated with high-risk assignments with respect to the personal safety of staff members.⁵² Both groups gave similar responses: geographic location, high crime areas, inappropriate patient or caregiver behavior, the threat of infectious diseases, and evening assignments (with only staff reporting this last risk factor).

Methods

Survey Design

In 2006-2007, a health and safety survey was constructed following extensive developmental steps, including in-depth interviews, focus groups, cognitive interviews, and pilot testing. The survey was designed to assess the health hazards associated with the delivery of home health care. Two versions of the survey were prepared, one targeting home health aides, home attendants, and personal care workers, here referred to collectively as “aides”; and the other

targeting home health care registered nurses. This paper focuses on the aides' survey instrument. The 58-item survey included items that addressed the following: demographics of the HHCW, description of the client's residence, level/type of care provided, potential occupational health hazards, potential home health hazards, and use and training on safety devices. The survey was designed to be completed within 30 minutes and was prepared in English at a sixth-grade reading level to facilitate rapid completion. The survey responses were primarily categorical, although some items had 4- to 5-point Likert-type scale response choices, and several items were open-ended. The survey and codebook are available by contacting the corresponding author.

Survey Distribution

Although the survey was anonymous, each participant was asked to sign an informed consent form, and all procedures involving subject participation had the prior approval of the Columbia University Institutional Review Board. A brief one-page document describing the study was provided to potential participants. Because of the well-established difficulty in surveying HHCWs in general, and the additional challenges in recruitment of individuals for whom English may be a second language (as is the case for many home health aides), an in-person recruitment strategy was employed. To facilitate this, a collaborative relationship was formed with an occupational health organization that conducts mandatory health assessments and screenings for home care agencies throughout New York City.

Recruitment of participants took place in the organizations' waiting rooms, conveniently located in offices that were easily accessible to the New York City-based research team. Participants could complete the study survey in private areas located adjacent to the waiting rooms. In some cases, the data collector helped to facilitate the survey administration by reading the questions out loud, although generally, data were collected through self-administration. Data collection days were held until the targeted goal of a convenience sample of 1,500 aides was reached. Participating aides represented numerous agencies. The incentive for participation was a single \$1 scratch-off lottery ticket and enrollment in a lottery drawing for a \$25 gift card prize (chance of winning: 1:100).

Data Analysis

All completed surveys were returned to the study office where they were checked for legibility and completion. Surveys missing substantial amounts of data were not included in the data analysis. All data were double-entered into a database and then reviewed by a data manager to ensure accuracy. Data editing, including recoding and collapsing of variables and the formation of new variables, was followed by basic descriptive analysis of the data, including the calculation of means, medians, percentages, proportions, and standard deviations. All analyses were conducted using SPSS[®] (SPSS, Inc., Chicago IL: SPSS Inc.).

Results

Demographic information is provided in Table 1. The sample of participants was predominantly middle-aged women (mean age, 43.5 years, range 18-82). Most aides (83 percent) reported that

English was spoken at their own home. Participants were more likely to report that they worked as a home health aide rather than as a personal assistant, and nearly 15 percent reported that they performed both jobs.

Most participants had worked in the home care sector for slightly more than 8 years, but some had worked in the field for as many as 35 years. The sample was predominantly unionized (67 percent). The vast majority of the sample (91 percent) commuted to and from work (i.e., home visits) using public transportation, with an average daily travel time of 2.2 hours.

Most aides provided care for a single patient, although some aides had as many as 10 or more patients in a typical week. The majority of the participants' patients lived in apartment buildings (71 percent), with the remainder living in houses (29 percent), assisted living facilities (15 percent), or group homes or shelters (2 percent). Typically, patients were elderly (64 percent), long-term patients (83 percent), although adults (26 percent) in long-term care (77 percent) constituted a sizeable portion of their patient population. Children (7 percent) were also provided care, generally on a long-term basis (66 percent).

As expected, the job duties consisted primarily of assisting with activities of daily living (Table 2), including bathing,

Table 1. Description of the sample, home health care aides, and personal assistants: New York City, 2007 (N = 1,561)

Characteristics	Value [N (%)]
Sex [N (%)] ^a	
Female	1,438 (95.1)
Male	74 (4.9)
Age [mean years (±SD)]	43.5 (±11.8)
Language spoken [N (%)] ^a	
English	1,298 (83.2)
Spanish	341 (21.8)
Russian	39 (2.5)
Chinese	8 (0.5)
Other	174 (11.1)
Job title [N (%)] ^a	
Home health aide	965 (61.8)
Personal care worker/home attendant	672 (43.0)
Both	42 (9.5)
Tenure (years) as a home health aide/attendant [mean (±SD)]	8.3 (±6.7)
Hours worked in home care (per week) [mean (±SD)]	34.1 (±17.9)
Clients seen per week [mean (±SD)]	2.1 (±4.3)
Union affiliation [N (%)] ^a	
Union member	1,016 (67)
Non-union member	501 (33)
Daily commute time (hours) [mean (±SD)]	2.2 (1.8)
Client residence type [N (%)] ^a	
Apartment building	1,107 (70.9)
House	449 (28.8)
Assisted living/senior housing/nursing home	234 (15.0)
Group home/ shelter	33 (2.1)
Other	45 (2.9)
Client residence setting [N (%)] ^a	
Urban	1,177 (91.5)
Suburban	88 (6.8)
Rural	22 (1.7)
Client makeup [N (%)] ^a	
Elderly	1006 (64.4)
Adults	403 (25.8)
Children	111 (7.1)

a Column numbers may not add to 1,561 due to missing values.

toileting, dressing, etc. Although 24 percent of participants reported that they provided wound care, only a small proportion (13 percent) reported using needles. Performing household chores was common: mainly cooking, light housekeeping, and washing laundry. Participants reported activities with the potential for back injuries and muscle strain, such as transferring patients (77 percent), walking and ambulating patients (87 percent), and turning and positioning patients (68 percent).

Infection Control Practices and Safety Equipment and Supplies

Self-reported compliance with infection control measures was generally good. For example, most of the aides (92 percent) reported the use of gloves when the possibility of contact with blood and other bodily fluids was present. Frequent handwashing was very common (97 percent), as was the use of hand gels or foams (83 percent). Many aides (79 percent) used protective aprons as a clothing barrier. Nearly all participants (92 percent) reported quickly cleaning up blood or bodily fluid spills. While most aides (79 percent) avoided eating or drinking in areas where the client received care, a sizeable percentage (21 percent), nevertheless, reported that this sometimes did occur. Poor compliance was noted for handling of contaminated needles, with 66 percent of aides reporting that they usually recapped needles. Sharps containers were used by 80 percent of the sample.

Personal protective gear, gowns, or aprons were reportedly available to just over half (57 percent) of aides. Other protective gear, such as eye goggles and face masks, were only available to 18 percent and 34 percent of aides, respectively. Disposable gloves were the most commonly available item of personal protective gear; 89 percent of aides reported that these were readily available to them.

Table 2. Provision of care, activities performed, reported by home health care aides/personal assistants (N = 1,561)

Activity	Number (%) reporting
Personal care	
Assist client with bathing	153 (13.0)
Assist client with dressing	1,385 (94.2)
Toileting care	1,437 (94.9)
Oral hygiene	1,236 (85.2)
Record vital signs	1,138 (79.2)
Provide urinary catheter/ostomy care	556 (44.8)
Provide wound care	371 (30.6)
Use needles or other sharps	285 (24.2)
Activities	
Cook meals	1,422 (95.1)
Take clients to appointments	1,305 (92.1)
Walk or ambulate clients	1,191 (86.6)
Transfer clients	1,027 (76.8)
Turn and position clients	907 (67.7)
Feed clients	908 (67.6)
Household duties	
Perform light housekeeping	1,461 (97.7)
Change linens	1,433 (96.7)
Wash laundry	1,418 (94.7)
Run errands	1,362 (94.1)

Eight percent of the aides reported that they felt they were at risk of exposure to contagious diseases. However, self-reported hepatitis B virus (HBV) vaccine rates were suboptimal; only 57 percent of participants reported that they had received all three doses, and 10 percent received only one or two doses; 2 percent reported that they had not been vaccinated, because they were HBV antibody-positive. The majority of aides reported tuberculin skin testing (i.e., PPD), with 67 percent reporting annual testing, 19 percent reporting twice-yearly testing, and only 2 percent reporting that they were never tested.

Hazardous Home Conditions

Potential health hazards in the home (Table 3) were frequently reported. Most commonly reported hazards were unsanitary conditions (e.g., insects, rodents) and air pollutants (e.g., animal hair, dust, peeling paint, cigarette smoke, mold). Violence, threats of violence, and abuse were also commonly perceived threats, with threatening neighbors most frequently reported (55 percent), followed by threatening family members (38 percent), threatening patients (31 percent), and aggressive pets (17 percent). Twenty-eight percent of participants reported verbal abuse, and 9 percent of the aides reported racial or ethnic discrimination. Other potential personal safety hazards included evidence of drug use in the home (5 percent) and guns in the home (2 percent).

Table 3. Health and safety hazards in patients' households, as reported by home health care aides/personal assistants (N = 1,561)

Health and safety risk factors	Number (%) reporting
Violence and psychosocial factor	
Verbal abuse	436 (27.9)
Neighborhood violence/crime	168 (10.8)
Racial or ethnic discrimination from the client or client's family	134 (8.6)
Threat of physical harm	128 (8.2)
Drug use in the home	77 (4.9)
Client's neighbors	65 (4.2)
Guns in home	29 (1.9)
Perceived threats ^a	
Threatening neighbors	214 (55.4)
Threatening client's family members	147 (38.1)
Threatening clients	121 (31.3)
Threatening pets	67 (17.4)
Slips/trips/falls hazards	
Messy home/clutter (e.g., loose rugs)	259 (16.6)
Poor lighting in the home setting	78 (5.0)
Environmental hazards	
Animal hair	332 (21.3)
Excessive dust	301 (19.3)
Peeling paint	228 (14.6)
Mold/dampness	156 (10.0)
Air pollution	150 (9.6)
Temperature extremes at client's home	140 (9.0)
Unsafe conditions in the home	92 (5.9)
Loud/irritating noise in the home setting	64 (4.1)
Potential chemical hazards	
Irritating chemicals (e.g., bleach, cleaning agents)	258 (16.5)
Unsanitary conditions	
Cockroaches	512 (32.8)
Mice/rats	360 (23.1)
Unsanitary conditions in the home setting (e.g., dirty toilets)	193 (12.4)

^a Reported by a subset of employees (N = 386), who said they felt threatened.

Signs of patient abuse (e.g., by the patient's family) were noted by 12 percent of the aides. When noted, 77 percent reported this to their supervisor, but 13 percent did not, and the remainder stated that they sometimes reported the abuse.

Practices that could result in harm to both the caregiver and the patient were reported by most of the respondents, for example, turning and positioning, walking and ambulating the client, and transferring and lifting the client. Yet only a small proportion of respondents reported access to safe lifting devices such as Hoyer lifts (20 percent) and/or transfer boards (9 percent). Reports of hazards that could lead to slips, trips, and falls—such as excessive clutter, loose rags, etc.—were not infrequent (17 percent). Poor lighting, which could also result in injuries, was also noted (5 percent).

Other potential health hazards included exposure to irritating chemicals, which were mainly used for cleaning spills. Diluted bleach was most commonly used (51 percent), followed by full strength bleach (9 percent) and bleach mixed with other chemicals (8 percent).

Health and Safety Training

Almost all aides (90 percent) reported training in workplace health and safety. This included training on safe lifting (83 percent); the proper use of Hoyer lifts (73 percent); electrical safety (58 percent); fire safety and evacuation (81 percent); personal safety (74 percent); respiratory protection (52 percent); slip, trip, and fall prevention (73 percent); and standard precautions and infection control (78 percent). However, in the past 12 months, 6 percent said they did not receive any safety training, and 53 percent reported receiving only one to two sessions of safety-related training, including infection control. Roughly one-third (36 percent) of the aides reported receiving three or more safety-related training sessions in the previous 12 months.

Discussion

These results document a high prevalence of a number of health and safety hazards associated with home care. They generally support earlier, primarily qualitative findings on home health hazards and establish that home care patients and HHCWs may be at risk of exposure to a range of unsafe conditions. While this large data set was limited to just one geographic area, it is representative of the New York City home care aides population and is most likely representative of any large urban area in the United States.

Several aspects of these findings deserve special mention. First, the infection control practices, although generally acceptable, were suboptimal in certain areas. The lack of availability of even the most basic personal protective equipment, such as gloves (11 percent) and aprons (43 percent), is worrisome. In some cases, sharps handling and disposal practices were not in compliance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard.⁵³ While aides are not supposed to handle needles, anecdotal reports from focus groups that were held in the development phase of this study suggest that this is very common when clients have been prescribed injectable insulin. These needles are often left for disposal by the aide. If sharps containers are not provided, aides recap before discarding them in the regular trash or, in some cases, into household containers. Given the fact that more than 50 percent of the aides received safety-related training only once or twice a year or less, additional

training, specifically on infection control, appears warranted. Agencies should not only ensure that aides have all the necessary equipment and supplies, but also that they are trained in their proper use. This is especially true for safe transfer equipment, such as Hoyer lifts, which can be difficult to use. However, very few aides actually had these available to them.

Unsanitary conditions were quite common. During questionnaire development, the study team conducted field observations and, almost uniformly, observed clutter, unhygienic practices, poor lighting, overheating, and loose rugs. The quantitative data presented here confirm these observations. These conditions may result from the inability of patients—many of whom are infirm and elderly and often live alone with few resources—to maintain a safe and orderly household. In some cases, the personal care attendant does perform household chores and thus has more control over the situation. However, in cases where other household members perform these chores, additional training or support may be required. Policies and procedures for addressing this issue should be the subject of further inquiry and interventional studies. This is important, not only in terms of the risk that unsanitary conditions present for the transmission of infectious disease, but also because some of these hazards increase the risk of injury (e.g., falls), and some conditions (e.g., excessive clutter) are fire safety hazards.

Hepatitis B vaccination rates were generally lower than recently published rates for other health care work groups. A large sample of nonhospital-based registered nurses had an 84 percent rate of complete series.⁵⁴ Slightly more than 50 percent of the aides in our sample reported receiving all three doses. Under the Bloodborne Pathogens Standard, home health aides would be classified as having potential risk of exposure to blood and potentially infectious materials. Therefore, the hepatitis B vaccine and annual bloodborne pathogen training must be offered to them at no cost.⁵³ However, some aides are not employed by a single agency full time and, thus, might not be eligible for this coverage. Given the close personal contact with patients and body fluids, such low rates of HBV vaccine coverage are a concern. Since infected aides might also present a risk of HBV transmission to their patients, universal vaccination should be encouraged and supported.

The perception of risk of personal injury was high. Threatening neighbors, clients, and family members; dangerous neighborhoods; and the presence of illicit drugs and guns in the home increased this perception. As noted in earlier studies, verbal abuse was common. A large proportion of our HHCW sample (68 percent) reported that they can refuse a case, and 65 percent said that they had done so in the past. These results are somewhat lower than those reported by Kendra, et al., in a small sample of home care staff, where 85 percent of staff reported that they could refuse a high safety risk assignment.⁵² However, their sample of 62 staff members might have included full-time registered nurses who may have been more willing to decline than a part-time aide. It was telling that, while all administrators in the Kendra, et al., study said that no negative ramifications would result from refusal, only 37 percent of staff agreed, with the remainder leaving this question blank. The potential adverse impact on patients who were refused was acknowledged by both administrators and staff in that study. In our sample, in cases where aides refused to provide care, it is unknown how this affected their employment or the provision or quality of the care their patients received.

Agencies and staff have implemented several strategies to improve the safety of home health care staff. These include extensive preplanning, personal escorts, frequent communication,

providing cell phones, additional training, and encouraging staff to carry chemical spray and weapons. Other strategies that have been considered include alternative care sites, early morning visits, and reliance on local police for protection.⁵² The implementation rate or efficacy of these strategies is not known.

This study had several strengths and limitations. As noted, the sample was confined to one geographic area, although aides were employed by many different agencies, and the sample demographics were representative of New York City aides as a whole. Because the survey was available only in English, there may have been response bias. However, in instances where it was requested, the questions were read out loud, which may have mitigated this bias to some extent. Also, in order to be employed in New York State, aides were required to have at least a basic understanding of the English language.

Another potential concern is that aides may have given socially desirable responses to some of the sensitive questions (e.g., those on patient abuse). However, the surveys were anonymous, and there was no evidence that certain questions were left largely unanswered.

In summary, this study presented evidence from a large sample of home health aides indicating a high prevalence for certain home care-associated health hazards, many of which might be amenable to intervention. Much more research is needed in this understudied health care sector. Additional risk assessment studies, especially targeting home care patients, and intervention-type studies are especially warranted.

Conclusion

The underlying question of these home care-associated hazards is the extent to which they adversely impact patient quality of care. When staff are concerned about personal risk and are at risk of exposure to numerous and varied health hazards, quality of care may be compromised. Unaddressed household health hazards also present a direct risk to the health and safety of the patient and other household members.

The financial constraints currently imposed on agencies are significant and may only increase with time. Agencies need to be reimbursed adequately so that aides can be hired as full-time employees with eligibility for benefits, including health care benefits. Training time, both for trainers and trainees, must also be reimbursed so that training does not impose a financial hardship. Adequate funding is also needed for appropriate safety equipment and supplies. The impetus for improvements for reimbursement is made clear in a timely article on the pathways to improvement in the health of the U.S. population.⁵⁵ The authors suggest that the United States should focus its attention on the most vulnerable segment of the population—in most cases the very population served by home care agencies. In order to improve the health and well being of home care populations, these larger issues will require policy changes at the highest levels.

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References

1. Brunekreef B, Dockery DW, Speizer FE, et al. Home dampness and respiratory morbidity in children. *Am Rev Respir Dis* 1989; 140: 1363-1367.
2. Dales RE, Burnett R, Zwanenburg H. Adverse health effects among adults exposed to home dampness and molds. *Am Rev Respir Dis* 1991; 143: 505-509.
3. Dales RE, Zwanenburg H, Burnett R, et al. Respiratory health effects of home dampness and molds among Canadian children. *Am J Epidemiol* 1991; 134: 196-203.
4. The healthy homes initiative: A preliminary plan. Washington, DC: Department of Housing and Urban Development, Office of Lead Hazard Control; 1999. Available at: www.hud.gov/offices/lead/library/hhi/HHIFull.pdf. Accessed April 18, 2008.
5. Dowd MD. Childhood injury prevention at home and play. *Curr Opin Pediatr* 1999; 11: 578-582.
6. Jacob B, Ritz B, Gehring U, et al. Indoor exposure to molds and allergic sensitization. *Environ Health Perspect* 2002; 110: 647-653.
7. Leaderer BP, Belanger K, Triche E, et al. Dust mite, cockroach, cat, and dog allergen concentrations in homes of asthmatic children in the northeastern United States: Impact of socioeconomic factors and population density. *Environ Health Perspect* 2002; 110: 419-425.
8. Litonjua AA, Carey VJ, Burge HA, et al. Exposure to cockroach allergen in the home is associated with incident doctor-diagnosed asthma and recurrent wheezing. *J Allergy Clin Immunol* 2001; 107: 41-47.
9. Matte TD, Jacobs DE. Housing and health: Current issues and implications for research and programs. *J Urban Health* 2000; 77: 7-25.
10. Phipatanakul W, Eggleston PA, Wright EC, et al. Mouse allergen. II. The relationship of mouse allergen exposure to mouse sensitization and asthma morbidity in inner-city children with asthma. *J Allergy Clin Immunol* 2000; 106: 1075-1080.
11. Saegart S, Klitzman S, Freudenberg N, et al. Healthy housing: A structured review of published evaluations of U.S. interventions to improve health by modifying housing in the United States 1990-2001. *Am J Public Health* 2003; 98: 1471-1477.
12. Klitzman S, Caravanas J, Deitcher D, et al. Prevalence and predictors of residential health hazards: A Pilot Study. *J Occup Environ Hyg* 2005; 2: 293-301.
13. Danzig LE, Short LJ, Collins K, et al. Bloodstream infections associated with a needleless intravenous infusion system in patients receiving home infusion therapy. *JAMA* 1995; 273: 1862-1864.
14. Do AN, Ray B, Banerjee S, et al. Bloodstream infection associated with needleless device use and the importance of infection-control practices in the home health care setting. *J Infect Dis* 1999; 179: 442-448.
15. Kellerman S, Shay DK, Howard J, et al. Bloodstream infections in home infusion patients: The influence of race and needless intravascular access devices. *J Pediatr* 1996; 129: 711-717.
16. Cohen MA, Tumlinson A. Understanding the state variation in Medicare home health care: The impact of Medicaid program characteristics, state policy, and provider attributes. *Med Care* 1997; 35: 618-633.
17. Hayashi R, Gibson JW, Weatherly RA. Working conditions in home care: A survey of Washington state's home care workers. *Home Health Care Serv Q* 1994; 14: 37-48.
18. Meyer JD, Muntaner C. Injuries in home health care workers: An analysis of occupational morbidity from a State compensation database. *Am J Ind M* 1999; 35: 295-301.

19. Myers A, Jensen RC, Nestor D, et al. Low back injuries among home health aides compared with hospital nursing aides. *Home Health Care Serv Q* 1993; 14: 149-155.
20. Geiger-Brown J, Muntaner C, McPhaul K, et al. Abuse and violence during home care work as a predictor of worker depression. *Home Health Care Serv Q* 2007; 26: 59-77.
21. Bureau of Labor Statistics, U.S. Department of Labor. Career guide to industries, 2006-2007 edition. Available at: <http://www.bls.gov/oco/cg/cgs035.htm>. Accessed April 12, 2008.
22. National Association for Home Care & Hospice. Basic statistics about home care. 2008. Available at: www.homecareaware.org. Accessed July 10, 2008.
23. Home Care Association of New York State. Home care aware. Available at: <http://www.homecareaware.org>. Accessed April 12, 2008.
24. Bureau of Labor Statistics, U.S. Department of Labor. Nursing, psychiatric, and home health aides. Available at: www.bls.gov/oco/ocos165.htm. Accessed April 12, 2008.
25. Bureau of Labor Statistics, U.S. Department of Labor. Personal and home care aides. Available at: <http://www.bls.gov/oco/ocos173.htm>. Accessed April 12, 2008.
26. Office of Administrative Law Judges, U.S. Department of Labor. Dictionary of occupational titles. Available at: <http://www.oalj.dol.gov/libdot.htm>. Accessed April 12, 2008.
27. National Association for Home Care & Hospice. Educational opportunities. Available at: www.nahc.org/education/home.htm. Accessed April 18, 2008.
28. Ono Y, Lagerstrom M, Hagberg M, et al. Reports of work related musculoskeletal injury among home care service workers compared to nursery school workers and the general population of employed women in Sweden. *Occup Environ Med* 1995; 52: 686-693.
29. Galinsky T, Waters T, Malit B. Overexertion injuries in home health care workers and the need for ergonomics. *Home Health Care Serv Q* 2001; 20: 57-73.
30. Centers for Medicare & Medicaid Services. Office of the Actuary. Available at: www.cms.hhs.gov/ReportsTrustFunds/. Accessed June 9, 2008.
31. DeFrances CJ, Hall MJ, Podgornik MN. National hospital discharge survey; 2003. Available at: www.cdc.gov/nchs/data/ad/ad359.pdf. Accessed April 12, 2008.
32. Medicare home health community beneficiaries 2001. Washington, DC: Department of Health and Human Services, Office of the Inspector General; 2001. Report No. OEI-02-01-00070. Available at: www.oig.hhs.gov/oei/reports/oei-02-01-00070.pdf. Accessed April 18, 2008.
33. Federal interagency forum on aging-related statistics. Older Americans update 2006: Key indicators of well-being . Washington, DC: U.S. Government Printing Office; 2006. Available at: digitalcommons.ilr.cornell.edu/key_workplace/283/. Accessed April 18, 2008.
34. Markkanen P, Quinn M, Galligan C, et al. There's no place like home: A qualitative study of the working conditions of home health care providers. *J Occup Environ Med* 2007; 49: 327-337.
35. Markkanen P, Quinn M, Galligan C, et al. There's no place like home: A qualitative study of the working conditions of home health care providers. *J Occup Environ Med* 2007; 49(3): 327-337.
36. Gerba CP, Wallis C, Melnick JL. Microbiological hazards of household toilets: Droplet production and the fate of residual organisms. *Appl Microbiol* 1975; 30: 229-237.
37. Kundsinn RB. Staphylococcal disease in the home. *Clin Med* 1966; 3: 27-29.
38. Terpstra PMJ. Domestic and institutional hygiene in relation to sustainability: Historical, social and environmental implications. *Int Biodeterior Biodegradation* 1998; 41: 169-175.
39. Mead PS, Slutsker L, Dietz V, et al. Food related illness and death in the United States. *Emerg Infect Dis* 1999; 5: 607-625.
40. Gershon R, Pogorzelska M, Qureshi K, et al. Home health care registered nurses and the risk of percutaneous injuries: A pilot study. *Am J Infect Control* 2008; 36: 165-172.
41. Backinger CL, Koustenis GH. Analysis of needlestick injuries to health care workers providing home care. *Am J Infect Control* 1994; 22: 300-306.
42. Beltrami EM, McArthur MA, McGerr A, et al. The nature and frequency of blood contacts among home healthcare workers. *Infect Control Hosp Epidemiol* 2000; 21: 765-770.
43. Perry J, Parker G, Jagger J. Percutaneous injuries in home healthcare settings. *Home Healthc Nurse* 2001; 19: 342-344.
44. Simmons B, Trusler M, Roccaforte J, et al. Infection control for home health. *Infect Control Hosp Epidemiol* 1990; 11: 362-370.
45. Rhinehart E. Infection control in home care. *Emerg Infect Dis* 2001; 7: 208-211.

46. Manangan LP, Pearson ML, Tokars JJ, et al. Feasibility of national surveillance of health care associated infections in home care settings. *Emerg Infect Dis* 2002; 8: 233-236.
47. Guidelines for infection control in home care settings. Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention. Available at: www.cdc.gov/ncidod/dhqp/gl_home_care.html. Accessed April 15, 2008.
48. Barling J, Rogers AG, Kelloway EK. Behind closed doors: In-home workers' experience of sexual harassment and workplace violence. *J Occup Health Psychol* 2001; 6: 255-269.
49. Sylvester BJ, Reisener L. Scared to go to work: A home care performance improvement initiative. *J Nurs Care Qual* 2002; 17: 71-82.
50. Fazzone PA, Barloon LF, McConnell SJ, et al. Personal safety, violence, and home health. *Public Health Nurs* 2000; 17: 43-52.
51. Loveless LE. Workplace violence: A report to the nation. Iowa City: University of Iowa, Iowa Injury Prevention Research Center; 2001.
52. Kendra MA, Weiker A, Simon S, et al. Safety concerns affecting delivery of home health care. *Public Health Nurs* 1996; 13: 83-89.
53. Occupational exposure to bloodborne pathogens – OSHA. Final rule. *Fed Register* 1991; 56: 64175-64182.
54. Gershon RM, Qureshi KA, Pogorzelska M, et al. Non-hospital based registered nurses and the risk of bloodborne pathogen exposure. *Ind Health* 2007; 45: 1-10.
55. Schroeder SA. We can do better - improving the health of the American people. *N Engl J Med* 2007; 357: 1221-1228.

Cause Analysis

The New York Model: Root Cause Analysis Driving Patient Safety Initiative to Ensure Correct Surgical and Invasive Procedures

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Abstract

Available data have not yet demonstrated a reduction in the incidence of wrong-patient, wrong-site procedures. In an effort to reduce these occurrences, a panel of experts was convened to update New York State's 2001 Pre-Operative Protocol. The panel analyzed 254 root cause analyses submitted to the New York Patient Occurrence Reporting and Tracking System (NYPORTS) and reviewed the Joint Commission's Universal Protocol and the current literature. Emerging themes related to wrong procedure events included communications, team dynamics, patient identification, orientation/training, use of available information, site marking, "time out," and time pressures. The scope and specificity of the New York State Surgical and Invasive Procedure Protocol (NYSSIPP) are expected to reduce the incidence of procedural maloccurrences. NYPORTS provides useful information about systems errors and effectiveness of prevention strategies. This paper provides a model for other agencies interested in establishing protocols to reduce these preventable events.

Introduction

Wrong-patient, wrong-side, or wrong-site surgical and invasive procedures, while unusual,¹ are the most obvious examples of systems failures in health care. Despite more than a decade of attention to these occurrences, the development of protocols by professional organizations,^{2, 3, 4, 5, 6} State agencies,⁷ the Veterans Health Administration,⁸ and the Joint Commission,^{9, 10} and the tasking of hospitals to implement systems under the Joint Commission's "Universal Protocol,"¹¹ events continue to be reported in undiminished numbers¹² in the operating room and in other clinical areas where invasive procedures take place. Whether improved reporting has contributed to this trend is not clear. Although a minority of these events result in significant harm to patients,¹ major injuries and death have been reported. In addition, they waste time, effort, and resources and bring discredit to health care providers.

The Institute of Medicine (IOM) report, *To Err is Human*,¹³ recommended mandating and standardizing clinical error reporting systems in order to provide a body of information that can

be used for process improvement. Many States have mandatory error-reporting requirements, and the Federal voluntary reporting program¹⁴ that is an outgrowth of IOM's recommendation is under development. In New York State, a mandatory reporting requirement was implemented in 1985 pursuant to State legislation designed to reduce medical malpractice. The reporting system has gone through several design changes to reach its present form as the New York Patient Occurrence and Tracking System (NYPORTS). Hospitals and diagnostic and treatment centers must report certain defined types of events, using standardized case definitions, via a Web-based system. Serious events warranting a root cause analysis (RCA) must be reported within 24 hours and the analysis completed within 30 days. Reports have been used to provide "best practice" examples to providers and to implement quality improvement projects.¹⁵

In January 2006, after a serious wrong-side surgery event at a New York hospital in 2005 and a review of recent NYPORTS adverse events, the New York State Department of Health convened the Procedural and Surgical Site Verification Panel with the goal of strengthening the State's 2001 guidelines. The 21-member panel comprised experts in their fields including: orthopedic surgery, neurosurgery, ophthalmologic surgery, ob/gyn surgery, general surgery, anesthesia, and radiology, as well as operating room (OR) registered nurses, certified registered nurse anesthetists, OR clinical nurse specialists, nurses, hospital association representatives, and attorneys. The Department of Health provided staff support to the committee.

The Panel analyzed wrong-site, wrong-side, and wrong-invasive-procedure cases meeting NYPORTS definitions from 2003 to 2005 to provide detailed information on actual events, causes, and corrective actions taken by hospitals to reduce future errors. They used a consensus process to develop the New York State Surgical and Invasive Procedure Protocol (NYSSIPP),¹⁶ which sets a standard of care for New York hospitals and diagnostic and treatment centers. This protocol was released in September 2006 and is currently the standard of care for invasive procedures in New York State.

This paper describes the findings of the case analysis and how the details of the protocol were chosen in response to those findings.

Methods

Hospitals in New York State are required to report wrong-side, wrong-patient, and wrong-procedure surgery and other invasive procedures to NYPORTS. Required information includes date, location, type of surgery/procedure, and other demographic data about the patient; a narrative description of the event; and an in-depth RCA with a report of corrective actions, including systems improvements and a literature search. These events fall into one of two NYPORTS codes (Table 1).

Between 2003 and 2005, 347 events were reported. All of the Code 911 cases and 2 years of Code 912 cases were analyzed by at least one nurse and one physician to ascertain causative factors and collect corrective actions. The distribution of causative factors was compared to data from the Joint Commission's Sentinel Event reporting process.

Table 1. NYPORTS codes related to wrong-side, wrong-patient, and wrong-procedure surgery and other invasive procedures

	NYPORTS Code 911	NYPORTS Code 912
	Wrong-patient, wrong-site surgical procedure	Incorrect procedure or treatment – invasive
Definition	- Any procedure performed in the operating room or ambulatory surgery suite. - Only include procedures that have proceeded to surgical incision.	- Invasive procedures are defined as those involving puncture or incision of the skin, or insertion of an instrument or foreign material into the body. - Includes procedures performed in settings other than the OR.
Exclusions	Occurrence with the administration of anesthesia only (Code as 912).	Venipuncture for phlebotomy, diagnostic tests without contrast material.

An expert panel was formed to consider the information and propose modifications to the Department of Health’s existing guideline for site marking, consistent with the Joint Commission’s Universal Protocol. The Committee met in person twice and communicated through weekly telephone conferences for several months to develop a protocol that would address the information provided by the case review. The Panel came to a consensus and created the New York State Surgical and Invasive Procedure Protocol,¹⁶ which was published in September 2006. Hospitals and diagnostic and treatment centers across New York State were required to implement the protocol by March 2007.

Results

In 2003, 2004, and 2005, 347 wrong-side, wrong-site, or wrong-procedure events were reported to the New York State Department of Health NYPORTS database. Each of these cases required that an RCA be performed and that corrective actions be implemented and monitored.

Of the Code 911 cases, 23 (44 percent) were wrong site, 27 (52 percent) were wrong side, and 2 (4 percent) were wrong patient. The most common wrong-site procedures were fingers (seven events) and spinal levels (seven events). The most common wrong-side cases were herniorrhaphies (three cases). The two wrong-patient cases were: (1) a lens intended for patient A was implanted into patient B after the sequence of patients

Table 2. Cases reported

	2003	2004	2005
Code 911	9	21	22
Code 912	93 ^a	104	98

a 2003 Code 912 cases were not analyzed

was changed from the original operative schedule, and (2) a resident placed a triple-lumen catheter into the wrong patient.

Of the Code 912 cases analyzed, 68 (34 percent) were wrong-procedure cases, 51 (25 percent) were wrong side, 33 (16 percent) were wrong patient, 29 (14 percent) were wrong equipment, and 21 (11 percent) were wrong site. These errors occurred in a wide variety of locations (Table 3).

Table 3. Settings of Code 912 cases

Setting	N	%
OR	75	37
Radiology	52	26
Bedside	20	10
Interventional radiology	15	7
Endoscopy suite	6	3.5
Dental clinic	6	3.5
Dialysis	5	2.5
Emergency room	5	2.5
Delivery room	3	1
Other (clinic, NICU, ICU, PACU)	15	7
Total	202	100

NICU = neonatal intensive care unit; ICU = intensive care unit; PACU = post-anesthesia care unit

Among cases reported from the OR, a number were due to inadequate or inaccurate historical information, such as a planned appendectomy in a patient whose appendix had already been removed and a planned inferior vena cava filter (IVC) insertion in a patient who already had a functional IVC filter. One patient had a partial mastectomy based on another patient's pathology report because of specimen mislabeling. Some intraoperative errors were reported under this code (e.g., wrong segment of colon connected to a colostomy).

Of the Code 912 cases, 19 were reported because of wrong-side administration of local or regional anesthetic, including blocks of the wrong shoulder (five), eye (five) and knee (femoral block, four). Wrong-equipment cases were primarily intraocular lenses (70 percent) or knee components (20 percent). Of the latter, two of the four cases occurred when the vendor representative handed the wrong component to the surgeon.

Code 912 cases frequently involved radiology. Almost half of the cases involved the incorrect procedure, sometimes varying widely from what had been ordered (e.g., MRI of head instead of an esophagram). However, the majority were due to different modalities in the same area (e.g., CT scans with or without contrast or different isotopes than what had been ordered). There were

15 cases in interventional radiology, six of which were wrong side, and three that were wrong site. Three patients had the wrong type of catheter inserted.

Of the 20 Code 912 errors in bedside procedures, eight were chest-tube cases (two wrong patient, six wrong side). In all cases, the pre-procedural verification had not been performed; in each case, other contributing root causes were identified. Of the remaining bedside cases, three involved infusion of the wrong medication into various body cavities.

The expert committee assembled to review the data derived from the RCAs, identified commonalities in the causes of the adverse events, and grouped them into categories (see list below). Some of the categories overlapped within cases. We noted that most Code 911 and Code 912 events had at least three root causes (suggesting a specific and direct causal relationship), as well as multiple contributing factors (e.g., “environmental conditions” increasing the chance of the adverse event). Complex cases had as many as 10 root causes. Findings in the New York State data were similar to those reported nationally to the Joint Commission.¹⁰

Common root causes of NYPORTS Code 911 and Code 912 cases, listed in no specific order, included:

- Communication failures.
- Inadequately designed procedures/systems.
- Noncompliance with existing procedures.
- Team issues: informal norms, hierarchy problems.
- Inadequate orientation and training.
- Inaccurate/incomplete scheduling information.
- Consent – availability, legibility, accuracy, and consistency with other documents.
- Incomplete history and physical.
- Inadequate patient identification and assessment.
- Inadequate pre-operative/pre-procedural verification process.
- Inconsistent, absence of, or unclear site marking.
- Room set-up, positioning, prepping, and draping variation.
- Lack of, or inadequate “time-out.”
- Failure to have complete information available (x-ray, lab, or pathology reports).
- Failure to correlate available information.
- Production/time pressures, including case urgency.
- Lack of compliance monitoring of existing systems.

The committee also reviewed the corrective actions undertaken by each facility in response to their RCA. These fell into two general areas: (1) facilitating accurate communication, and (2) redesigning processes along the continuum of the procedural event. Many facilities lacked effective policies regarding patient identification and site marking, and policy violations were frequent. Corrective actions frequently involved strengthening the policy or policing it more

effectively, but the committee evaluated a significant number of detailed suggestions as it sought to create a protocol that encompassed as many “best practices” as it could. During its deliberations, the committee evaluated the relative safety merits of specific requirements against the likelihood that more rules would be perceived as onerous and disruptive by a busy staff.

In August 2006, the committee came to consensus on the New York State Procedural and Surgical Site Verification Protocol. After review by the Department of Health and approval by the Commissioner of Health, the protocol was distributed to hospitals and diagnostic and treatment centers during the fall of 2006. A series of educational forums were held across New York State to present and promote adoption of the protocol.

Effective March 1, 2007, the protocol became the official standard for all sites in New York State where surgery and invasive procedures were performed. Over 750 participants from hospitals and diagnostic and treatment centers attended, including nurses, physicians from multiple specialties, (e.g., internists, radiologists, surgeons), quality and risk-management professionals, and hospital association and personnel administrators. Presentations included a detailed description of a recent wrong-sided surgical sentinel event that occurred at a community hospital in New York State; background information on medical errors; in-depth analyses of the occurrences reported; root causes, contributing factors, corrective actions/risk reduction strategies; and the process the committee followed in developing the protocol and NYSSIPP itself. Time was allotted for questions from the audience related to the protocol at each forum.

Discussion

According to the National Quality Forum (NQF), “never events” are “errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility.”^{17,18} The NQF identified 27 such events (increased to 28 when the report was revised in 2006). Surgery on the wrong side of the body, wrong site, or wrong patient led the list.

These events occur for a variety of reasons, such as poorly designed systems, inadequate training, communication errors, and failure to follow policy and procedures. In addition, there are human factors that can disrupt even well-designed systems, including the traditional operating room hierarchy. In its ground-breaking report *To Err is Human*,¹³ the Institute of Medicine recommended mandatory State-level reporting of significant health care errors.

The goal of reporting is to create a body of data that can be used to identify the causes of errors and direct corrective actions at the systems level. Such a reporting program has been in place in New York State for many years. In 1998, the system was revised to its current form, the New York Patient Occurrence and Tracking System.¹⁹ This system uses rigorously defined data definitions and a Web-based electronic reporting tool to capture a variety of patient occurrences in hospitals and diagnostic and treatment centers, including many on the NQF’s list.

Wrong-side, wrong-site, wrong-patient events continue to be reported to State agencies and the Joint Commission in undiminished numbers. One study estimated that 1,200 to 2,700 events occur annually in the United States.²⁰ Based on a review of 20 years' experience at Harvard in over 2 million surgical cases, the incidence of such errors was estimated to be 1 in 112,000. In 3 years, 337 cases were reported in New York State. Of these, two-thirds occurred in settings other than the operating room. Increasingly complex and invasive procedures now occur routinely in other settings, particularly imaging areas. Such units might not have the experience that operating room personnel have with systematic patient and site identification and an orderly flow of information. Bedside procedures, such as thoracentesis, might be performed by house staff or consultants who might not have primary source information, such as x-ray images, readily available.

The expert committee that analyzed the NYPORTS data created a protocol that addressed the complete scope of the invasive procedure process, from initial scheduling through actual procedure. Although built on, and consistent with, the Joint Commission's Universal Protocol, it has a greater level of detail in order to make it clear to users what the members of the Panel viewed as "best practice" (Table 4). The Panel concluded that the Universal Protocol would have had a greater impact in preventing the wrong-sided/wrong-sited events we reviewed if there had been increased process standardization (i.e., include scheduling, consent, and imaging components in the protocol) and greater adherence to the protocol (e.g., total participation by all members of the team in the "time out"; monitoring for compliance with the protocol).

Can protocols substantially reduce (or eliminate) error? In one study,¹ the authors felt that the Universal Protocol would have been ineffective in preventing the error in five cases of the 13 charts available for review. Of those five cases, one was caused by failure to properly identify the patient when printing MRI images. This is covered by the National Patient Safety Goals and need not be included in an invasive procedure protocol. Another case, involving a change in the surgical plan, could have been avoided by restarting the verification process. Two cases involved failure to properly describe lesions; the NYSSIPP protocol dictates that such confusion should stop the procedure until a definitive identification can be made. A case of a wrong-rib resection was a true operative mistake, although clinical guidelines—such as using fluoroscopy during such procedures—might reduce the likelihood of this error.

Any system can be undermined by failures of common safety behaviors. Good systems for reducing procedural maloccurrences need to extend as far as they can into error-prone elements at the margins of the procedure. This is why the NYSSIPP protocol addresses surgical scheduling and consent and has such detailed specificity on radiologic image availability, orientation, and confirmation. Ultimately, the success of any protocol depends on the culture of safety that surrounds it.

Table 4. Differences between NYSSIPP and the Universal Protocol

Section of NYSSIPP	NYSSIPP comparisons to Universal Protocol (UP)
Scheduling	• Not included in UP. • Detail required in scheduling (implant, equipment, no abbreviations). • Information received must be verified.
Consent documentation	• Increased detail required (layman's terms; spell out side/sites; no changes permitted after signatures obtained).
Pre-operative verification process	• Multiple specific steps with increased detail in NYSSIPP. • Must take place before entering OR (exception detailed).
Pre-operative checklist	• A pre-operative or pre-procedural verification checklist is required.
Marking & verifying the operative site	• Images required to be present in OR, viewed by 2 individuals, and orientation of images confirmed. • Second time out for spine surgery including second image. • Alternative to patient marking in specific exceptions – special purpose wristband.
Time out	• <i>All</i> work should cease during the “time out.” • <i>All</i> members of the team (surgical, anesthesia, nursing) must focus on the “time out.”
Required policy and procedure	• The institutional policy and procedure must specify the actions to be taken when a discrepancy occurs at any step in the process. • Responsibilities must be more specifically defined.
Compliance monitoring	• Compliance monitoring of NYSSIPP is an integral part of a facility's performance improvement/quality assurance activities. • The role of monitoring and leadership in setting expectations is key.

NYSSIPP = New York State Surgical and Invasive Procedure Protocol; UP = Universal Protocol; OR = operating room

Conclusions

Analysis of cases reported to a centralized database under a mandated statewide reporting system formed the basis for extending The Joint Commission's Universal Protocol to reduce the incidence of wrong-patient, wrong-side, or wrong-site surgical and invasive procedures. We found that the elements necessary for success included in-depth analysis of NYPORTS events, a literature search, formation of an expert panel, consensus-driven protocol development, and educational forums several months before the implementation date. This protocol has become the standard of institutional performance in New York State.

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References

1. Kwaan MR, Studdert DM, Zinner MJ, et al. Incidence, patterns and prevention of wrong-site surgery, Arch Surg 2006; 141: 353-358.
2. Statement on ensuring correct patient, correct site and correct procedure surgery. Chicago, IL: American College of Surgeons; 2002 Available at www.facs.org/fellows_info/statements/st-41.html. Accessed March 27, 2008.
3. Eliminating wrong site surgery, Patient Safety Bulletin #1; A joint statement of the American Academy of Ophthalmology, the American Society of Ophthalmic Registered Nurses, and the American Association of Eye and Ear Hospitals; 2001. Available at www.aao.org/education/statements/safety/site.cfm. Accessed March 27, 2008.
4. Sign, mark & x-ray (SMaX): Prevent wrong-site surgery. Burr Ridge, IL: North American Spine Society; 2001. Available at: www.spine.org/Pages/PracticePolicy/ClinicalCare/SMaX/Default.aspx. Accessed March 27, 2008.
5. Association of PeriOperative Registered Nurses (AORN) Statement on correct site surgery. Denver, CO: Association of PeriOperative Registered Nurses; 2005. Available at: www.aorn.org/PracticeResources/AORNPositionStatements/PositionCorrectSiteSurgery/. Accessed March 27, 2008.
6. Advisory statement on wrong site surgery. Rosemont, IL: American Academy of Orthopaedic Surgeons; 2003. Available at: www.aaos.org/about/papers/advistmt/1015.asp. Accessed March 27, 2008.
7. New York State surgical and invasive procedure protocol for hospitals, diagnostic and treatment centers, ambulatory surgery centers, and individual practitioners; 2006. Available at: www.health.state.ny.us/professionals/protocols_and_guidelines/surgical_and_invasive_procedure/docs/protocol.pdf. Accessed March 27, 2008.
8. Ensuring correct surgery and invasive procedures. VHA Directive 2004-028. Washington, DC: Veterans Health Administration; 2004. Available at: www.va.gov/NCPS/SafetyTopics/CorrectSurg/CorrectSurgDir.DOC. Accessed March 27, 2008.
9. Sentinel Event Alert, Issue 6. Lessons learned: Wrong site surgery; Oakbrook Terrace, IL: The Joint Commission; 1998 Aug 28. Available at: www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_6.htm. Accessed March 27, 2008.
10. Sentinel Event Alert, Issue 24. A follow-up review of wrong site surgery; Oakbrook Terrace, IL: The Joint Commission; 2001 Dec 5. Available at: www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_24.htm. Accessed March 27, 2008.
11. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery™. Oakbrook Terrace, IL: The Joint Commission; 2003. Available at: www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf. Accessed March 27, 2008.

12. Sentinel event trends: Wrong-site surgeries reported by year. Reported on Joint Commission teleconference on Wrong Site Surgery, June 21, 2007. Available at: www.jointcommission.org/NR/rdonlyres/6F94288C-EC8E-4B95-91F6-0A1C96C09708/0/se_trends_wss_reported.gif. Accessed March 27, 2008.
13. Kohn, LT, Corrigan, JM, Donaldson, MD, eds. To err is human: Building a safer health system. Washington, DC: National Academies Press; 1999.
14. The Patient Safety and Quality Improvement Act of 2005. Overview, June 2006. Rockville, MD: Agency for Healthcare Research and Quality. Available at: www.ahrq.gov/qual/psoact.htm. Accessed March 27, 2008.
15. Novello AC. New York State patient occurrence and tracking system report, 2002-2004. Available at www.health.state.ny.us/nysdoh/hospital/nyports/annual_report/2002-2004/docs/2002-2004_nyports_annual_report.pdf. Accessed March 27, 2008.
16. Novello AC. New York State surgical and invasive procedure protocol; 2006. Available at: www.health.state.ny.us/professionals/protocols_and_guidelines/surgical_and_invasive_procedure/docs/protocol.pdf. Accessed March 27, 2008.
17. National Quality Forum. Serious reportable events in healthcare: A consensus report. Washington, DC: National Quality Forum; 2002.
18. Kizer KW, Stegun MB. Serious reportable events in healthcare. Advances in patient safety: From research to implementation. Vol. 4, Programs, tools, and products. AHRQ Pub. 05-0021-4. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol4/Kizer2.pdf. Accessed March 27, 2008.
19. Flink, E, Chevalier, EC, Ruperto, A, et al., Lessons learned from the evolution of mandatory adverse event reporting systems. Advances in patient safety: From research to implementation. Vol. 3, Implementation issues. AHRQ Pub. 05-0021-3. 2005. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol3/Flink.pdf. Accessed March 27, 2008.
20. Seiden, SC, Barach, P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: Are they preventable? Arch Surg 2006; 141: 931-939

Department of Veterans Affairs Emergency Airway Management Initiative

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Abstract

Over the last 2 years, the U.S. Department of Veterans Affairs (VA) undertook a radical transformation of out-of-operating-room emergency airway management. As a result of root cause analyses on issues encountered in airway management responses, the VA gathered baseline data on who was providing airway management, use of devices to ensure correct placement of the endotracheal tubes, and difficulties encountered in intubations. The results mirrored rates of complications recorded in the literature (i.e., difficulties in over 10 percent of cases and esophageal intubations in 6 percent). During off-tours, anesthesia service was not available in many places. As a result, residents and others were sometimes performing airway management without significant experience or expertise. Furthermore, in one-third of the cases, no confirmatory adjunctive devices were being used to ensure the correct placement of endotracheal tubes. This paper describes the national efforts that resulted in mandated competencies and a demonstrated knowledge base beyond Advanced Cardiac Life Support for those performing emergency airway management, the required use of confirmatory adjunctive devices, and a national effort to support and nurture these changes.

Introduction

Over 11,000 times a year within the U.S. Department of Veterans Affairs (VA), an emergency airway management event occurs outside of the operating room. Prior to the efforts described here, well-trained, competent individuals handled the majority of these emergencies. They had the requisite skills in airway management and the appropriate tools available. However, the VA's National Center for Patient Safety identified some cases in which clinicians attempted to perform airway management without sufficient proficiency, expertise, support, or use of adjunctive devices that allowed confirmation of the placement of the endotracheal tube. This manuscript describes how the VA assessed the problem and the steps taken to remedy it.

Root cause analyses submitted by facilities in the years prior to this project provided examples of some system vulnerabilities that needed to be addressed. In some facilities, assessment of exhaled carbon dioxide was not used to verify tracheal placement of an endotracheal (ET) tube because such devices were not readily available outside of the operating room (OR). This resulted in an undetected esophageal intubation. In another example, a resident was uncertain of the ET tube's location and inserted an additional tube because there was no way to verify if either tube was in the trachea, thereby resulting in a delay in establishing the patient's airway. In another case, surgical and medical residents both believed they were in charge of a patient and

the leader of the code team; this resulted in a delay in establishing the patient's airway. Due to the unavailability of a Certified Registered Nurse Anesthetist (CRNA), a resident was called to reintubate a patient and was unable to establish an airway. The patient's condition deteriorated until the CRNA arrived and successfully intubated the patient.^a

This paper describes the rationale for the VA Airway Management Initiative, the specifics of the VA national policy, how it was implemented, support from national societies' position papers, and issues encountered with implementation.

Methods

The VA confirmed the need for this effort by reviewing the available literature and by capturing internal baseline data on complications associated with intubations, including who was performing emergency airway management. Reported rates of complications and esophageal intubations approximated rates found in other studies and reinforced the need for systemic fixes to address these issues.

We sent surveys to all VA inpatient facilities to gather data on how emergency airway management was being conducted (i.e., who covered for such incidents), the hours during which coverage was available, and whether adjunctive devices were used to confirm successful tracheal intubation.

We also conducted a review of the VA's own tort claims settlement, which provided additional support for this initiative, helping to make the business case for such an activity. There were 65 settlements in the VA tort claims database over 12 years (1988 – 2000) for improper intubations or inductions, totaling \$5,129,852. This equated to an average settlement of \$78,921. These claims included some cases that occurred within the operating room. Our database was unable to differentiate those that occurred due only to emergency airway management.^b

Although patient safety was the paramount consideration in planning for emergency airway management, the Veterans Health Administration (VHA) also had to consider the scope of practice, along with legal and licensing issues. This led us to also perform a literature and regulatory review regarding emergency airway management. After reviewing survey data, tort claim data, and the medical literature and regulatory documents, we instituted the management plan described below.

Results

Survey of Facilities

To gather national rates of difficult and unanticipated esophageal intubations in the VA, the National Center for Patient Safety (NCPS) developed a survey in conjunction with VHA's

^a Internal review of root cause analysis cases related to intubation.

^b Internal communication with William Weeks, MD, MBA, and Tina Foster, MD, MHSA, VHA Patient Safety Field Office, White River Junction, VT, 2001.

Director of Anesthesia. The survey was sent by e-mail to patient safety managers at all 163 VA hospitals in September 2002. A total of 135 surveys were returned to NCPS, representing an 83 percent response rate. Only three of the returned surveys lacked complete information; nine of the facilities that responded did not perform non-OR emergency intubations. In total, the survey respondents estimated that there were 11,007 non-OR emergency intubations per year in VA hospitals. Given that we had some nonrespondents, this represents a low estimate.

Respondents estimated that 12.3 percent (N = 1,354) of non-OR emergency intubations in VA hospitals were unusually difficult to accomplish. Furthermore, 6.5 percent (N = 715) of the total intubations resulted in at least one episode of inadvertent esophageal intubation. This equates to nearly four cases per day that are difficult to accomplish and two per day that result in inadvertent esophageal intubation. Again, these are consistent with other studies and literature on this subject.¹

At most VA medical centers (VAMCs), multiple disciplines provide coverage for emergency airway management. However, the proportion shifts dramatically from regular tour to off-tour hours. During regular tour hours, an anesthesia provider is available in 86 percent of the facilities. During off-tours, only 45 percent of facilities have anesthesia providers available. Because the survey did not ask who performed the intubations, we do not have good data on what proportion of the intubations are actually performed by each type of provider.

Based on survey results, in 2002, over half of VA facilities used colorimetric analyzers (CO₂ analyzers) to confirm tracheal placement, in addition to clinical assessment of breath sounds. Less than 1 percent used only syringes or only self-inflating bulbs; 30 percent of all reported cases involved no adjunctive devices, which equates to nine cases per day, or 3,370 per year, in which no adjunctive devices were used within the VA to confirm tube placement.

The regulatory and legal literature provide relatively little guidance as to who can manage an airway, and there really are few legal precedents. A search of a database^c of appellate decisions bearing on this question found no directly relevant cases. However, it is clear that nonphysician personnel undertaking what traditionally has been a physician provided service are held to the same standards of task performance as physicians who would usually perform the same task.^d Thus, it was incumbent upon the VHA to ensure that whoever performed emergency airway management be trained at a level consistent with the skill level that is expected for a physician.

Many articles document the success of nonphysician providers in airway management once training is provided; their success rate is generally much higher than it is for physicians not specifically trained in airway management. Paramedic success rates in field intubations generally hover in the 90 to 98 percent range under conditions that often are quite trying.²

One respiratory care department published their experience as back-up providers of endotracheal intubation following failed attempts by nonanesthesiologist physicians.³ Their success rate was 90 percent, remarkable in light of the fact that these were patients for whom a physician had

^c Westlaw®, West Publishing Co, Eagan, MN.

^d Belmon vs. St. Frances Cabrini Hospital, 427 So 2d 541 (1983).

already failed. Noteworthy is the fact that the providers in this study all performed 12 or more successful OR intubations yearly and had ongoing training requirements.

Discussion

After reviewing the results of our multipronged investigation (root cause analyses, tort claims, and literature review), the VA elected to embark on a national plan to ensure the quality of around-the-clock airway management.

The Department of Veterans Affairs addressed these issues by rolling out a national initiative requiring demonstrated competency for those performing emergency airway management on live patients and the use of adjunctive devices to confirm placement of the endotracheal tube. Specifically, the new VA national policy:

- Stipulates that those performing intubations must have privileges or scope of practice to perform intubations.
- Establishes the criteria for privileging clinicians.
- Ensures that there is a training program for those seeking to be privileged in intubations at each VA facility.
- Directs that an adjunctive device be used to confirm tube placement. On the use of adjunctive devices, the VA national policy supports the recommendations of the American Heart Association (AHA) guidelines, which state that “a CO₂ colorimetric device is appropriate when there is a perfusing rhythm; otherwise, use a syringe or bulb designed to confirm endotracheal tube placement.”⁴

One of the major challenges was to change the mindset that only physicians can effectively perform airway management, and that physicians should be the first choice for airway management and intubation, irrespective of their experience or proficiency. Encouragement has been given to evaluate the available staff during off-tours and consider respiratory therapists, advanced practice nurses, and others to be trained to perform emergency airway management.

We felt that we needed, at a minimum, to meet the community “standard of care.” In a legal case, the standard of care is not a written code but is defined on an ad hoc basis by a judge or jury.⁵ From the perspective of the VHA group considering this issue, we felt we needed to provide the same standard as comparable facilities in the community. Thus, a nursing home facility without acute care issues might meet that standard by having personnel trained in supporting the airway until paramedics arrive, whereas an acute care hospital needs to have immediate access to an individual trained in tracheal intubation.

Personnel

The most important consideration as we established this program was to ensure that patients receive the best care appropriate to their situation. The literature review suggested that automatically having physicians responsible for airway management did not necessarily result in the best possible care. We felt there were three key issues to consider in terms of who should be trained:

1. Availability of personnel in the hospital 24 hours a day, 7 days a week.
2. Educational background.
3. Skills.

Anesthesia personnel (anesthesiologists or certified registered nurse anesthetists) are in-hospital around the clock in fewer than 30 percent of VHA hospitals. Although no data were available regarding other physicians traditionally trained in intubation (such as emergency room physicians, intensivists, and some surgical specialties), we felt that 24-hour coverage by such specially trained clinicians was not common.

All VHA hospitals have personnel trained in Advance Cardiac Life Support (ACLS). However, as pointed out in the ACLS Provider Manual,⁶ the goal of that course is to ensure that “all members of a resuscitation team...understand the concept of tracheal intubation and the steps involved in successful intubation...and be able to recognize when intubation is being done incorrectly.” There is no expectation that the course provides sufficient training to assure competency, and in fact, the manual recommends that it be done only by those who perform intubation frequently or take renewal courses frequently.

In some hospitals, emergency airway management had been provided by residents, often in specialties where intubation training is not routine, such as internal medicine or surgery. This was identified in our review of adverse events as a factor in some cases of failed management.

Given that emergency airway management and endotracheal intubation are within the scope of practice for respiratory therapists, they have tended to be the alternate provider of choice in many VHA hospitals. However, other hospitals have sought different solutions. In one hospital, two internal medicine chief residents live on the hospital grounds for a year and provide coverage after initial training in the OR.

Another solution described by one VHA facility is a two-tiered system, whereby respiratory therapists are the initial responders for patients in cardiac arrest. However, for patients requiring tracheal intubation but able to wait up to 30 minutes, they call in an anesthesiologist.¹

Adjunctive Devices

Even in the best of hands, emergency airway management can be difficult. At Hartford Hospital, 10 percent of 2,833 out-of-operating room intubations required three or more attempts with an initial esophageal intubation rate of 9.7 percent.¹ If not recognized, esophageal intubation guarantees the patient will not survive. In the review of adverse outcomes in the VHA, several cases had presumed successful intubations only to have esophageal intubation ultimately demonstrated.

During intubation, seeing the endotracheal tube pass through the cords is a useful indication of likely success. However, a review of closed malpractice claims performed by the American Society of Anesthesiologists Closed Claims Project documented numerous cases in which trained anesthesiologists felt the tube had gone through the cords when in fact it had not.⁷

Following intubation, observation of the patient provides an initial indication of tracheal intubation—mist in the tube and a rise and fall of the chest being key indicators. Again, these signs are fallible. Hence, after reviewing the literature, we wrote our Airway Management Directive to require adjunctive evidence of successful intubation.

In the operating room, the presence of end-tidal CO₂ provides a sensitive and specific indicator of successful tracheal intubation. Although generally reliable for out-of-OR use, during cardiac arrest, these indicators may fail. The lack of perfusion means that carbon dioxide may not be reaching the lungs and, thus, end-tidal CO₂ indicators may falsely suggest an unsuccessful intubation. In such situations, an “esophageal detector device” (EDD) may be useful. These devices generally include a bulb syringe that is deflated and then connected to the endotracheal tube. If the tube is in the esophagus, the EDD should not reinflate as rapidly as it would when in the trachea, as a significant volume of air is not normally present in the esophagus. However, a false result can occur if air has been insufflated into the trachea during bag-and-mask ventilation. Conversely, a false result may occur if the tube is in the trachea, but secretions are plugging the trachea or there is little air in the respiratory system due to obesity or obstructive airway disease.

Adjunctive devices greatly increase the likelihood of ensuring proper location of an endotracheal tube—especially when combined with observation of tube placement and chest motion—and should increase patient safety. Such adjunctive devices are also supported by numerous medical societies and organizations that have, after very careful deliberation, endorsed the use of adjunctive devices. Endorsing organizations include the AHA,⁴ the American College of Emergency Physicians,⁸ the American Society of Anesthesiologists,⁹ and the National Association of EMS Physicians.¹⁰

Gaining Buy-in and Seeking Feedback

The process of implementing the VA emergency airway management policy was designed to allow for input and the development of support from different stakeholders throughout the VA. To this end, representatives from the field were included from the earliest stages. They were involved in developing the specific language for the national policy, testing the policy within their local facilities, and acting as ombudsmen with their respective peer groups. Chiefs of staff, patient safety officers, respiratory therapists, anesthesiologists, and field advisory committees for anesthesia, medicine, surgery, and critical care were all involved in the review and critique of the final guidance.

Specifics of the VA Policy

The VA national policy addresses emergent and urgent airway management that occurs outside the operating room, such as during a code, where respiratory distress is active or anticipated. We stipulated that this might involve bag-and-mask ventilation, oral or nasopharyngeal airway, tracheal intubation, or surgical airway.

Some of the specific language of the VA policy is as follows:

Purpose: This Veterans Health Administration (VHA) Directive addresses the appropriate competencies of those who perform urgent and emergent airway management outside of VHA facility operating rooms, and the confirmation of successful endotracheal tube placement through the use of devices, such as carbon dioxide (CO₂) monitors or esophageal detection devices, in conjunction with auscultation.

[There is] ... a requirement for using a device or devices to confirm tube placement in concert with auscultation. Auscultation alone is not sufficient evidence of correct tube placement. Devices that can confirm the tube placement (e.g., portable capnography, esophageal bulbs, syringes, or colorimetric devices) must be used in conjunction with auscultation of breath sounds in all cases of airway management. Use of devices to confirm endotracheal tube placement does not supersede or preclude other aspects of appropriate care, such as the use of x-ray imaging to verify the position of the endotracheal tube and to ensure that both lungs, rather than just the right lung, are ventilated.

End-tidal carbon dioxide (ETCO₂) detectors may provide a false indication of esophageal intubation in cardiac arrest patients because of poor systemic perfusion that delivers little CO₂ to the lungs for exchange or in cases of florid pulmonary edema. EDDs, on the other hand, may provide a false reading of esophageal intubation in obese patients or those with copious pulmonary secretions.

Local policy needs to allow for the appropriate use of both devices in a complementary fashion, depending upon the clinical situation, along with auscultation. For example, the American Heart Association's 2004 *Handbook of Emergency Cardiovascular Care*¹¹ recommends the use of a syringe or bulb as an initial check in cases of cardiac arrest, and the use of a colorimetric device if there is a perfusing rhythm.¹²

The policy requires a demonstrated competency in airway management, subject matter expertise, and a demonstrated proficiency in procedural skills. ACLS certification is not adequate in and of itself. Specific requirements include: (1) knowledge of the major anatomic structures of the airway; (2) ability to formulate and verbalize an appropriate alternative plan, if initial attempts at intubation are unsuccessful; and (3) knowledge of the indications and contraindications for pharmaceutical agents, especially muscle relaxants, for use in airway management.

Proficiency in procedural skills is defined as:

- Successful (i.e., without complications) endotracheal intubations with an actual patient, not a mannequin.
- Successful (i.e., without complications) cases of ventilating an unconscious patient using a bag and mask and either an oral or nasopharyngeal airway.
- Use of alternative methods of intubation that are in practice at each hospital with an actual patient, not a mannequin (e.g., use of the Laryngeal Mask Airway (LMA®), Combitube®, or other means).¹²

Residents and Trainees and Extraordinary Circumstances

To address intubations by residents and trainees gaining these competencies, we included the following specific language:

“Resident staff or other clinical trainees are to be considered in compliance with this policy if they perform endotracheal intubation and airway management under the supervision of a licensed independent practitioner who is appropriately privileged for airway management or an Advance Practice Nurse or Certified Registered Nurse Anesthetist (CRNA) who has a scope of practice that includes airway management.”¹²

Of paramount concern is that the patient in an emergency receives the appropriate care. It is the expectation that there should be very few circumstances in which no individual with the requisite skills for airway management is available at a VA facility, as stipulated in the national guidance. However, to deal with this potentiality, the following language was included:

“In extraordinary circumstances, where an individual is not available with the demonstrated competency in airway management per the requirements of this directive, clinicians may exercise their judgment in the appropriate response with the overarching goal being the care and safety of the patient. If this situation should occur, facilities will conduct an analysis as to why this vulnerability existed and initiate appropriate systems fixes to minimize a repeat occurrence.”¹²

Implementation

Educational materials from existing programs were made available for others to use so that they would not need to develop them *de novo*. Sample policies, educational materials, links to online videos on intubations, FAQs, and information on contact people at other facilities were all provided and made available. (Note: For those interested, the corresponding author can be contacted to provide electronic copies of these materials.)

These materials, vetted with field experts, included pre- and post-tests and steps for preparation and success in intubation, and drew upon an existing body of knowledge.^{6, 13, 14, 15, 16, 17} To assist facilities, the following is an example of a competency checklist and assessment tool that can be used during an observed intubation:¹⁸

- Assessed airway for signs of possible difficult intubation.
- Laryngoscope and suction checked.
- Mask ventilation established.
- Scope placed in left hand.
- Right hand used to open mouth.
- Blade placed to displace the tongue to the left.
- Blade pulled rather than levered on the teeth.
- Tube placed with tip coming in from the right side (and hand not in line of sight).
- Number of attempts needed for successful intubation.

The VHA faced a number of challenges in implementing this policy, including entrenched medical culture, training availability, and costs. However, the change in policy had the backing of national clinical VHA leadership in surgery, anesthesiology, and critical care, as well as senior administrative leadership, facilitating our ability to face those challenges.

Airway management and tracheal intubation are dramatic and frequently life-preserving or life-saving measures. Consequently, physicians have a natural desire to be able to provide that care. However, as the literature demonstrates, physicians without specific training in airway management tend to have a relatively low success rate. The concept that intubation is now a skill that requires privileges was a real culture change, even though many other skills need to be specifically mentioned in privilege.

Another cultural issue raised by facilities was, “How will our residents get experience with airway management, if they are not permitted to do it?” The culture change for resident education was that the skill needed to be learned just as any other skill is learned, with education and mentoring. Residents whose programs do not routinely include such training can be encouraged to seek out training in the operating room or, possibly, to participate in a mentored situation during out-of-OR intubations.

For some institutions and individuals, identifying a nonphysician as the responsible individual created cultural issues. Here is an example of how this might be an issue: Hospital policy identifies trained respiratory therapists as being responsible for intubation. An attending physician for the patient is present at a cardiac arrest and wishes to do the intubation but is not privileged and not trained, so the therapist needs to proceed. This is a real change from traditional medicine.

For many institutions, training availability is an issue. Our office created a Web site with text, graphic, and video training. Whereas use of mannequins for initial training was encouraged, the task force agreed that actual patient experience under observation—not just for tracheal intubation, but also for bag-and-mask ventilation—was mandatory. The latter skill is highly dependent on patient anatomy and is not well learned from a mannequin.

A recent study suggested that mannequin simulations may be as good as human subject training for paramedics.¹⁹ However, that study required 10 hours of mannequin training, at which point the success rate was still only 88 percent. It was our feeling that demonstrating skills in human subjects is critical, not only for high success rates for intubation, but also for developing and being able to appropriately implement an alternative plan for failed intubations.

Many VHA facilities are relatively small, and the opportunities for training are limited. Furthermore, new developments in anesthesia, such as laryngeal masks, mean fewer and fewer patients are being intubated. This has been an ongoing challenge for small facilities, which is why they have been encouraged to partner with larger facilities or nearby community hospitals.

For some nonacute care facilities (eg, long-term care facilities) that rarely have resuscitation situations, the concept that intubation should not be attempted was a culture shift. Intubation by

untrained individuals sometimes results in esophageal intubation. In communities with trained paramedics, such facilities were encouraged to seek a waiver permitting trained paramedics to be the responders, with initial airway support provided while awaiting the paramedics' arrival.

When instituting the new Directive, we were concerned that cost might be an issue. Potential solutions generally involved some cost. A solution that would have been the most costly was to add in-house anesthesia staff or emergency medicine physicians with airway training. We are not aware of any facilities that did this. Other less obvious costs included overtime for respiratory therapists to attend training sessions in operating rooms plus travel costs for some personnel to go to other facilities for training. Surprisingly, we received almost no negative feedback concerning costs, presumably because of the near-universal recognition of the need for trained individuals.

Conclusions

The U.S. Department of Veterans Affairs identified a significant issue through their patient safety program: in some circumstances, clinicians (oftentimes residents) were being placed in a position of performing airway management, despite their lack of competency and proficiency and without the availability and use of adjunctive devices to confirm tube placement. By proceeding deliberately in the development of a national policy and initiative, the VA successfully transitioned to a current position of mandated use of confirmatory adjunctive devices that are inexpensive but have high sensitivity and specificity. Furthermore, by drawing upon the existing professional communities for feedback and support, the VA eased this transition.

Support materials were developed, vetted, and shared across the system to further help in this endeavor. Next steps will involve gathering information from facilities regarding confirmatory adjunctive devices being used, types of professionals now providing airway management, and other requisite needs to assist in continuing improvement.

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References

1. Mort TC. Emergency tracheal intubation: Complications associated with repeated laryngoscopic attempts. *Anesth Analg* 2004; 99: 607-613.
2. Pepe PE, Copass MK, Joyce TH. Prehospital endotracheal intubation: Rationale for training emergency medical personnel. *Ann Emerg Med* 1985; 14: 1085-1092.

3. Zyla EL, Carson J. Respiratory care practitioners as secondary providers of endotracheal intubation: One hospital's experience. *Respir Care* 1994; 39: 30-33.
4. American Heart Association. Placement: Secondary confirmation. In: Handbook of emergency cardiovascular care. Dallas, TX: American Heart Association; 2004. p. 78.
5. Ginsburg WH. When does a guideline become a standard? The new American Society of Anesthesiologists guidelines give us a clue. *Ann Emerg Med* 1993; 22: 1891-1896.
6. American Heart Association. Adjuncts for airway control, ventilation and oxygenation. ACLS provider manual. Dallas, TX: American Heart Association; 1997. p. 1-17.
7. Cheney FW, Posner KL, Caplan RA. Adverse respiratory events infrequently leading to malpractice suits. A closed claims analysis. *Anesthesiology* 1991; 75: 932-939.
8. American College of Emergency Physicians. Verification of Endotracheal Tube Placement. Available at: www.acep.org/practres.aspx?id=29846. Accessed February 23, 2008.
9. American Society of Anesthesiologists. Practice guidelines for management of the difficult airway. *Anesthesiology* 2003; 98: 1269-1277.
10. O'Connor RE, Swor RA. Verification of endotracheal tube placement following intubation. National Association of EMS Physicians Standards and Clinical Practice Committee. *Prehosp Emerg Care* 1999; 3: 248-50.
11. Handbook of emergency cardiovascular care. Dallas, TX: American Heart Association; 2004.
12. Department of Veterans Affairs, Veterans Health Administration. VHA directive 2005-031: Out of operating room airway management. Available at: www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1292. Accessed February 23, 2008.
13. Stehling LC. Management of the airway. In Barash PG, ed. *Clinical anesthesia*. Philadelphia: JB Lippincott; 1989: p. 543-560.
14. ASA task force report. Practice guidelines for management of the difficult airway. *Anesthesiology* 2003; 98: 1269-1277.
15. American Heart Association. Adjuncts for airway control, ventilation and oxygenation. ACLS provider manual. Dallas, TX: American Heart Association; 1997. p. 1-17.
16. Konrad C, Schüpfer G, Wietlisbach M, et al. Learning manual skills in anesthesiology: Is there a recommended number of cases for anesthetic procedures? *Anesth Analg* 1998; 86: 635-639.
17. Kopacz D, Neal J, Pollock J. Residency training in regional anesthetic techniques: Is experience with more than 40 attempts necessary? *Reg Anesth* 1997; 22: 205-211.
18. Bishop MJ, Michalowski P, Hussey JD, et al. Recertification of respiratory therapists' intubation skills one year after initial training: An analysis of skill retention and retraining. *Respir Care* 2001; 46: 234-237.
19. Hall RE, Plant JR, Bands CJ, et al. Human patient simulation is effective for teaching paramedic students endotracheal intubation. *Acad Emerg Med* 2005; 12: 850-855.

Using Root Cause Analysis to Reduce Falls in Rural Health Care Facilities

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Abstract

Prevention of patient falls is a significant patient safety concern in both acute and long-term health care settings. West Virginia's quality improvement organization, the West Virginia Medical Institute, worked collaboratively with the State's Patient Safety Improvement Corps, a national training program cosponsored by the Agency for Healthcare Research and Quality (AHRQ) and the Department of Veterans Affairs, on an AHRQ Information Technology Implementation Grant to assist health care institutions in reducing their rate of patient falls. We have done this by training 300 health care workers in root cause analysis (RCA) and by encouraging health care facilities to implement their own falls prevention programs, in which RCA is an essential tool to discover the cause of the initial fall and find ways to prevent recurrences.

Introduction

Fall prevention is important in both acute care and long-term care settings. Falls account for at least 40 percent of all accidents in hospitals and are the leading cause of injury and death among older adults.¹ Factors such as increased age, visual impairment, a history of falls, medications, incontinence, dizziness, delirium, and certain diagnoses are all potential risks for falls in this population.² Rural America is characterized as older, sicker, and poorer than its urban counterpart, suggesting that the risk for falls would be potentially greater here.³ In 1994, the total annual cost for fall injuries for adults age 65 or older was \$27.3 billion, and by 2020, it is estimated that the cost will reach \$43.8 billion.⁴

Previous studies have shown that fall-related injuries can be reduced by interventions that improve patient safety practices,⁵ and that such interventions are also important to hospital administrators and staff. In a study of patient safety priorities among rural hospital administrators and patient safety staff, falls were listed second, after adverse drug events, as a top priority.⁶

One method of reducing falls is to determine the underlying causes of falls through a process known as root cause analysis (RCA).⁷ RCA provides a structured and process-focused framework for approaching errors, and it lends organization to efforts to learn from previous mistakes.⁸

The Patient Safety Improvement Corps (PSIC) is a national training program, jointly sponsored by the Agency for Healthcare Research and Quality (AHRQ) and the United States Department

of Veterans Affairs (VA), to train health care staff in safety techniques. The primary goal of the PSIC is to improve patient safety by providing the knowledge and skills necessary to conduct effective investigations of reports of medical errors using RCA.

As part of the West Virginia Medical Institute's (WVMI) participation in an AHRQ grant ("Partnering to Improve Patient Safety in Rural West Virginia," UC1 HS01 4920-02), we formed a PSIC team and launched a collaborative project to reduce falls, using the RCA methods taught in the PSIC program. Members of the team included representatives from the West Virginia Office of Health Facility Licensure and Certification (OFLAC), two West Virginia rural hospitals, and WVMI, the Federally designated quality improvement organization (QIO) for West Virginia, Pennsylvania, and Delaware. The goals of our West Virginia PSIC team were to:

- Reduce the rate of falls in the inpatient setting by identifying and implementing a post-fall assessment tool. This tool was used to determine contributing factors that were either intrinsic to the patient (e.g., orthostatic hypotension, vision impairment, dementia) or extrinsic but in the patient's immediate environment (e.g., physical changes, lack of adaptive devices, noise level).
- Learn how to use the VA's RCA tool as a resource from which to draw interventions to prevent falls
- Initiate Statewide education of health care providers on the application of the RCA.

Background (Pilot Study)

Using the PSIC's RCA process, we first conducted a pilot project in two facilities: a small, rural acute care hospital and a rural critical access acute care hospital with a long-term care facility. The pilot ran from February 1, 2005 through September 30, 2005. Facilities in the pilot study were able to report their falls data by using an online incident reporting tool provided by Quantros, Inc. (Quantros, Inc. Occurrence reporting and management system; Milpitas, CA) through the AHRQ grant. The tool allowed them to gather specific data on the fall, including date of fall; cause of fall; restraint use; whether a fall assessment was completed; whether a fall protocol was in place at the time of the fall; and the main cause of the fall (Figure 1).

The hospitals' interdisciplinary team (IDT) conducted an RCA on each fall. Members of the IDT included representatives from all disciplines that were involved in the patient's care (e.g., nurses, physicians, therapists, and housekeeping). RCAs were used to identify causes specific to each fall and to help pinpoint areas for interventions to prevent future falls. Each of the facilities effected a change in the RCA process that they felt would increase their chances of successfully preventing a repeat fall. For example, one facility included families and patients in the RCA as part of the IDT; the other facility chose to perform the RCA during the shift in which the fall occurred.

Although the number of total fall events in the pilot study was small, the results were encouraging. The rural acute care hospital experienced an 84 percent decrease in initial falls (from 19 to three) and a 100 percent decrease in repeat falls (from 10 to zero). The critical access

Did hospital staff attempt to minimize the impact of the fall by ASSISTING the patient's descent to the floor? *		☒ Yes ☐ No ☐ Not Documented
Was the Fall/Accident ATTENDED by hospital staff? *		☐ Yes ☐ No ☐ Not Documented
Identify the MOST SIGNIFICANT injury as a result of the Fall/Accident: *		Please Select...
Specify Other Injury:		
Risk Related Details		
Was the patient assessed for being at risk? *		☐ Yes ☐ No
Was the patient determined to be at RISK of falling according to the most recent risk assessment? *		☒ Yes ☐ No
Was a Prevention/Precautionary PROTOCOL implemented prior to the Fall/Accident? *		☐ Yes ☒ No
Attending/Consulting MD Orders prior to the Fall/Accident: *		Please Select...
Restraints Related Information		
Did the patient have restraint orders prior to fall? *		☐ Yes ☐ No ☐ Not Documented
Were restraints in use at the time of Fall/Accident?: *		☐ Yes ☐ No
What type of restraint was in use?: *		Please Select...
Fall/Accident Cause Related Information		
Activity Engaged in by the patient Prior to Fall/Accident: *		Please Select...
Other Patient Activity:		
Fall/Accident Factors & Relationship Details		
Identify Environment of Care factors that could have contributed to the Fall/Accident: *		Please Select...
Specify Other Environmental Factor:		
What was the main patient factor associated with the Fall/Accident? *		Please Select...
Other Patient Factor:		
Medications administered prior to Fall/Accident		
Are there any Medications the patient is on that could have contributed to the Fall/Accident? *		☐ Yes ☐ No ☐ Unknown
Were any of the following types of medications administered to the patient?		
Analgesics/Narcotics:	☐	Cardiac:
Diuretics:	☐	Bowel Prep:
Sedatives:	☐	Other Medication:
Specify Other Medication Group:		
Were any of the medications indicated above administered within 12 hours of the Fall/Accident?		☒ Yes ☐ No ☐ Unknown

Figure 1. Fall-reporting section of the Quantros online incident reporting tool.

acute care hospital, with the long-term care facility, saw a 60 percent decrease in initial falls (from five to two) and a 100 percent decrease in repeat falls (from one to zero).

Through the use of RCAs, the staffs at these two facilities discovered that their own individual programs for identifying patients at high risk for falls and for implementing safety strategies for preventing initial falls were not working well. This finding led to further changes in falls implementation programs. Specifically, staff were not routinely completing falls risk assessments at admission, nor were they completing the post-fall assessment tools. In response to this finding, one risk manager added an annual training on falls prevention for all staff, rather than just for new staff.

Based on the positive results from this pilot study, we moved forward with plans to implement a statewide program for any West Virginia health care facility or home health care agency that wished to participate. Training sessions were held throughout the State for staff from interested facilities to learn how to perform RCAs and to learn from others their “best practices” for reducing falls. In addition, monthly conference calls were held with participating health care facilities to discuss best practices and issues relating to staff involvement in learning to perform RCAs.

Methods

In October and November 2006, WVMI hosted two separate learning sessions for over 300 health care workers in West Virginia. The learning sessions were led by speakers from the State PSIC, including the project manager for the AHRQ Health Information Technology (HIT) Implementation Grant, who was also a member of the PSIC.

The learning sessions taught the RCA process, emphasizing that the RCA approach could be used in any health care setting. The training focused on processes that avoided individual blame and spotlighted the cause of the fall. The VA RCA Tool Kit was used as the basic outline for the learning sessions.⁷

Health care providers participating in the training sessions were encouraged to join the State’s Falls Prevention Collaborative project. Participation in the Collaborative involved a commitment to conduct RCAs of falls occurring at their facilities, develop and implement intervention(s) to prevent repeat falls, and collect and report data on falls for the 6 months prior to and the 6 months after the intervention. Those that chose to join were asked to send WVMI retrospective baseline data on all falls occurring in their facilities between April 1, 2006 and September 30, 2006 (the 6 months preceding the statewide group learning session). In some facilities, hospital leaders provided additional training on RCAs for their staffs during October and November 2006.

When a patient experienced a fall, the facilities collected data using either the Web-based incident-reporting tool (Figure 1) (for facilities participating in the AHRQ grant), or they provided the same information using a paper fall-assessment tool (Table 1).

After a fall was reported, the IDT leader interviewed the patient, the staff, and any member of the patient’s family who might have witnessed the event. The IDT then conducted an RCA to

determine the intrinsic and extrinsic factors related to the fall and identified and implemented patient-specific interventions based on the results of the investigation.

We asked each participating facility to collect falls data prospectively for the period between December 1, 2006 and May 31, 2007 and send them to us. We used a single quality measure to monitor results of this project: fall rate, expressed as falls per 1,000 patient days.

Throughout the collaborative project we conducted monthly conference calls to discuss “best practices” and “lessons learned” with the health care facilities. Guest speakers from participating health care facilities talked about the project and discussed problems or concerns they had encountered while performing RCAs and how they overcame these problems. One long-term care facility stated that it conducted “mini-RCAs,” an abbreviated version of the formal RCA process, since there was not enough time for employees to do a full RCA on each fall.

Some of the “lessons learned” aided in the RCA discovery process. One hospital’s IDT discovered that patients or family members could sometimes be the best source of information regarding how and why a patient fell. Facilities employed a number of interventions based on what they learned through their RCA process, including having patients put on their call light when they went to the bathroom, using informative signs in the patient room, and training staff in proper lifting techniques and how to transfer patients.

Results

Thirteen facilities (11 hospitals and 2 long-term care facilities) participated in this project. The long-term care facilities were excluded from the final data analysis because they recorded “near miss” falls differently from the hospitals, specifically as actual falls, potentially skewing the results. Of the 11 facilities whose data were included in the results, eight were rural facilities participating in the AHRQ HIT grant, including six critical access hospitals (CAHs).

For data of this type, it is often difficult to establish meaningful denominators. In analyzing the falls data, we decided to use patient days as the denominator (since it is relatively consistent across facilities), and number of falls as the numerator. Rates are expressed as falls per 1,000 patient days.

The total falls per 1,000 patient days across all facilities decreased 45 percent, from 133.9 at baseline to 73.05 at remeasurement. The mean falls per facility per 1,000 patient days decreased from 12.17 at baseline to 6.64 at remeasurement. The median falls per facility per 1,000 patient days decreased from 4.94 to 3.02 between baseline and remeasurement (Figure 2).

Variation decreased significantly as well: the range from the 10th to 90th percentile decreased from 2.24 to 21.2 at baseline to 2.11 to 7.40 at remeasurement (Table 2). Nine of the 11 facilities experienced a decline in falls per 1,000 patient days from baseline to remeasurement (Figure 3). Falls data for each of the participating facilities are detailed in Table 2.

Table 1. West Virginia Falls Project Assessment Tool

Patient data (de-identify when sending to WVMI)	Date of fall (12/1/06 to 5/31/07)	Cause of fall (climbing, reaching, transferring, walking, unknown, other; please specify)	Restraints?		Fall assessment done?		Was patient determined to be at risk for a fall?		Was fall protocol in place?		What was the main factor associated with the fall?
			Yes ^a	No	Yes	No	Yes	No	Yes	No	(see list) ^b

a If Yes, please specify restraint type: e.g., 2-point, 4-point, handmits, vest, wrist, other.

b Examples of factors associated with falls: **Extrinsic** includes bed/side rails; call light not used; crowded room; foot wear; flooring; tub/shower; wet floors; noise level; poor lighting; other (please specify); and unknown. **Intrinsic** includes: bowel/bladder problems; changes in clinical condition; confused/disoriented; dizziness; hypotension; intentional act; loss of balance; seizure; medications; electrolyte imbalance; weakness/fainting; other (please specify); and unknown.

of discharges _____

of inpatient days _____

Table 2. Changes in falls per 1000 patient-days during 6-month periods before and after statewide RCA learning sessions

Facility	<u>Before RCA learning sessions</u> April 1, 2006 to September 30, 2006			<u>After RCA learning sessions</u> December 1, 2006 to May 31, 2007			Absolute change in falls per 1000 patient days
	Inpatient days	Number of falls	Falls per 1,000 patient days	Inpatient days	Number of falls	Falls per 1,000 patient days	
Hospital A	283	6	21	344	1	3	-18
Hospital B	1,417	7	5	1,523	5	3	-2
Hospital C	4,918	9	2	5,180	9	2	0
Hospital D	745	49	66	889	32	36	-30
Hospital E	7,146	16	2	7,619	23	3	1
Hospital F	3,552	19	5	4,443	27	6	1
Hospital G	3,690	11	3	3,718	10	3	0
Hospital H	1,826	30	16	3,917	29	7	-9
Hospital I	6,956	26	4	6,649	14	2	-2
Hospital J	11,699	65	6	10,880	57	5	0
Hospital K	14,768	57	4	15,043	39	3	-1
Total	57,000	295	134	60,205	246	73	-61
Mean	5,182	27	12	5,473	22	7	-6
Median	3,690	19	5	4,443	23	3	-1
10 th %-ile			2			2	
90 th %-ile			21			7	

Discussion

While this project resulted in a decrease in the number of falls overall, the participating facilities experienced barriers and challenges to performing an RCA after each fall. One barrier for some facilities was simply maintaining a sufficient number of trained staff to complete the RCAs in a timely manner; this problem was exacerbated by high staff turnover.

Staff training and motivation to follow through continue to be a challenge that facilities must overcome if RCAs are to become standard practice in the falls protocol.

Nonetheless, we have noted an overall increased interest and involvement in performing RCAs related to falls in West Virginia health care facilities as a result of this statewide falls prevention training effort. Anecdotally, the IDTs in several facilities have informed us that they have found it beneficial to meet more frequently than originally scheduled, including meeting as soon as possible after a fall occurs. They also have found that patients and their family members, as well as staff, have contributed useful information toward finding the cause of initial falls that can be used to prevent subsequent falls. For example, in one facility when the IDT asked a patient's family member the cause of a fall, the family member informed them that "He [the patient] likes his sweater close to him, and he fell trying to reach for it."

An important outcome of the staff involvement in collaborative efforts with other facilities is their heightened awareness of the need for early identification of potential causal factors of inpatient falls and the role this plays in an overall improvement in patient safety.

However, periodic re-education of the staff is vital to make sure all components of the falls prevention program are in

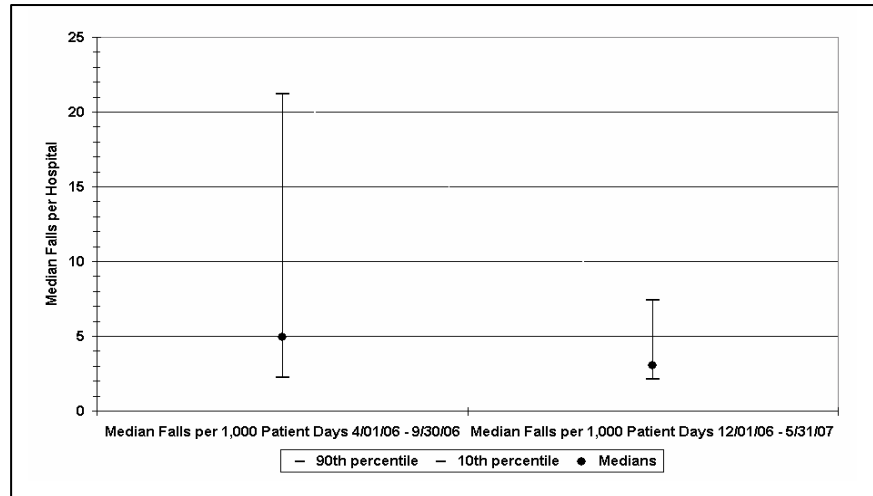


Figure 2. Median falls per hospital per 1,000 patient days from baseline to remeasurement: 10th and 90th percentiles.

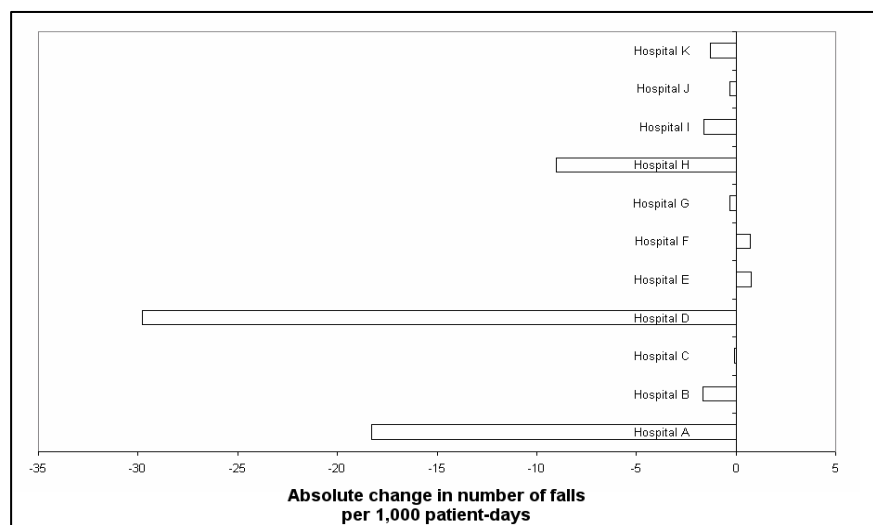


Figure 3. Absolute change in number of falls per 1,000 patient days from baseline to remeasurement for each participating hospital.

place—a lesson learned in the pilot phase of this study. These components include the completion of the initial fall risk assessments and implementation of fall prevention measures. This is particularly true for small rural providers that are likely to see fewer events by virtue of their low census.

Conclusions

RCA can be an effective tool for reducing the rate of falls in acute care facilities, even for the smallest of rural health care providers, and it can be easily taught in group settings. Statewide learning sessions are an efficient method of conducting such instruction. Group learning sessions also provide an opportunity for similar facilities to discuss best practices and lessons learned, in addition to any problems or concerns encountered during the RCA process.

By leveraging the training received from the AHRQ PSIC and the funding and analytic expertise from the AHRQ HIT Implementation grant, West Virginia was able to realize a statewide collaborative falls prevention effort that trained over 300 health care providers in performing RCAs. Furthermore, the overall project promoted a statewide learning community through collaborative efforts, such as the generation of peer group patient safety benchmarks.

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References

1. Papaioannou A, Parkinson RC, Ferko N, et al. Prediction of falls using a risk assessment tool in the acute care setting. *BMC Med* 2004; 2: 1.
2. Szumlas S, Groszek J, Kitt S, et al. Take a second glance: A novel approach to inpatient fall prevention. *Jt Comm J Qual Saf* 2004; 30: 295-301.
3. Eberhardt MS, Ingram DD, Makuc DM, et al. Urban and rural health chartbook. Health, United States, 2001. Hyattsville, MD: National Center for Health Statistics; 2001.
4. Englander F, Hodson TJ, Terregrossa RA. Economic dimensions of slip and fall injuries. *J For Sci* 1996; 41: 733-746.
5. Ray WA, Taylor JA, Brown AK, et al. Prevention of fall-related injuries in long term care: A randomized controlled trial of staff education. *Arch Intern Med* 2005; 165: 2293-2298.
6. Casey MM, Wakefield M, Coburn AF, et al. Prioritizing patient safety interventions in small and rural hospitals. *Jt Comm J Qual Patient Saf* 2006; 32: 693-702.
7. Root cause analysis tools. Ann Arbor, MI: Department of Veterans Affairs, National Center for Patient Safety; 2007. Available at: www.va.gov/ncps/CogAids/RCA/index.html. Accessed March 9, 2008.
8. Wald H, Kaveh S. Root cause analysis. In: Making health care safer: A critical analysis of patient safety practices. Evidence Report/Technology Assessment No. 43 (Prepared by University of California at San Francisco-Stanford University Evidence-based Practice Center under Contract No. 290-97-0013). AHRQ Pub. 01-E058. Rockville, MD: Agency for Healthcare Research and Quality; 2001. Available at: www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat1.section.59569. Accessed March 9, 2008.

Common Cause Analysis: Focus on Institutional Change

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Abstract

The Children's Hospital of Philadelphia has created a mechanism for sharing root cause analysis (RCA) findings with senior leaders through annual common cause analysis (CCA). As each RCA is completed, reports are shared with senior leaders and discussed each month at the Patient Safety Advisory Committee meeting. We have found it helpful to summarize these findings each year by organizing the action items into themes. This practice was initiated 2 years ago, and as a result, several high-scoring items have been included on the organizational operating plan for the upcoming fiscal year. Given that endorsement by senior leadership is key to initiating change, these data have proven beneficial to gain this endorsement.

In a year, an average of 25 events, including serious events and near misses, are evaluated. Of those 25 events, about 16 undergo a formal RCA, yielding approximately 10 action items each. These are sorted according to various headings, such as by department and by National Center for Patient Safety Triage Card™ categories (human factors communication, training, fatigue and scheduling, barriers, rules/policies/procedures, and environment). Once themes are identified, action items are listed under the appropriate theme. Themes are then prioritized by scoring for severity, occurrence, and detectability. Findings presented to senior leaders and other appropriate groups provide objective data for departments. Staff members who conduct RCAs are included in discussions to provide details of the findings and recommendations. They are also included whenever possible in efforts to make changes. This process closes the loop for those conducting the RCA. Once items are added to the organizational operating plan, multiple issues can be addressed through one effort, raising the level of commitment to address the items.

Introduction

Root cause analysis (RCA) is a widely recognized tool utilized by high-risk industries to identify underlying causes upon retrospective analyses of events. RCA has been systematically introduced into health care as a part of the patient safety movement. Typically, RCA in health care is performed in response to a single patient safety event or a cluster of similar events with the goal of identifying causal factors. These factors necessitate a detailed plan for improvement in response to the event. Organizations in which numerous RCAs are conducted can easily become overwhelmed with the list of improvement actions. In addition, this process may not reveal deeper themes and more common causes of patient safety events. Necessary improvement actions may be broader in scope than a particular case may reveal. In some cases, the findings from a single case may cause an organization to take action, only to learn that the action was only a partial solution, or worse yet, the action produced unintended negative consequences.

At The Children’s Hospital of Philadelphia, a less well-known approach—common cause analysis (CCA)—is utilized. CCA helps us analyze data from RCAs, which in turn allows us to recognize trends and establish themes in patient safety. CCA ultimately allows us to gain support for leveraging change by prioritizing and incorporating the identified themes into an annual organization-wide operating plan.

Conducted annually, CCA consists of a review of all RCA findings from the previous year. The process includes:

- Assessing all identified action plans based on identified vulnerabilities.
- Determining the extent to which action plans were completed.
- Sorting and analysis of data to identify common themes.
- Assigning risk priority numbers (RPNs) to themes, in a manner similar to the risk prioritization used in failure modes and effects analysis (FMEA).
- Discussing and reviewing CCA findings with key stakeholders and ultimately senior administrative and medical leadership.
- Using the themes, once they are validated, to shape institutional priorities.

Senior leaders at our institution convene annually to create an organizational operating plan, which defines priorities and goals for the coming year. The plan is organized according to a “five-pillar model”:

1. Quality and patient safety.
2. Service.
3. People.
4. Growth.
5. Finance.

Each pillar identifies the highest priority projects for the coming year and defines key measures that are carefully tracked and reported regularly across the institution.¹

For the past 2 years, vulnerabilities identified through the CCA process have been incorporated into the development of the annual organizational “Quality and Patient Safety” pillar. This course of action assures that appropriate resources and attention are devoted to the most important patient safety vulnerabilities. The outcome of this process also inspires an increased level of commitment and investment for staff members who participate in RCA teams, as their efforts are validated by institutional response to RCA findings. In this way, staff members and physicians are able to appreciate the importance that the organization places on patient safety.

Background

In recent years, improving patient safety has been identified as one of the key challenges in health care. Professional and consumer literature constantly draws attention to human error and the frailties of our health care system. One of the critical transforming concepts of safety science

is that a “system,” not an individual acting alone, predominates in establishing safety. The patient safety movement seeks to build a culture in which systems mitigate human error and prevent harm to patients.²

The basic premise of the systems approach is that humans are fallible, and errors are to be expected, even in the best people and organizations. When an error results in harm to a patient, it should be regarded as a consequence rather than cause, having its origins in upstream systemic factors.³ In other words, systems should be designed to mitigate human error. The system becomes the focus in creating an environment that is safe for patients and employees.

Reason’s “Swiss Cheese Model” (Figure 1) is often used to depict the way systems place barriers designed to prevent harm and create safe processes.⁴ Yet, every barrier has weaknesses. “Active failures” are unsafe acts committed by people who are in direct contact with the patient or system. They include slips, lapses, mistakes, etc. “Latent conditions” are the inevitable systems failures, that relate to design—such as alarms that are not trustworthy, understaffing, or poor product design.

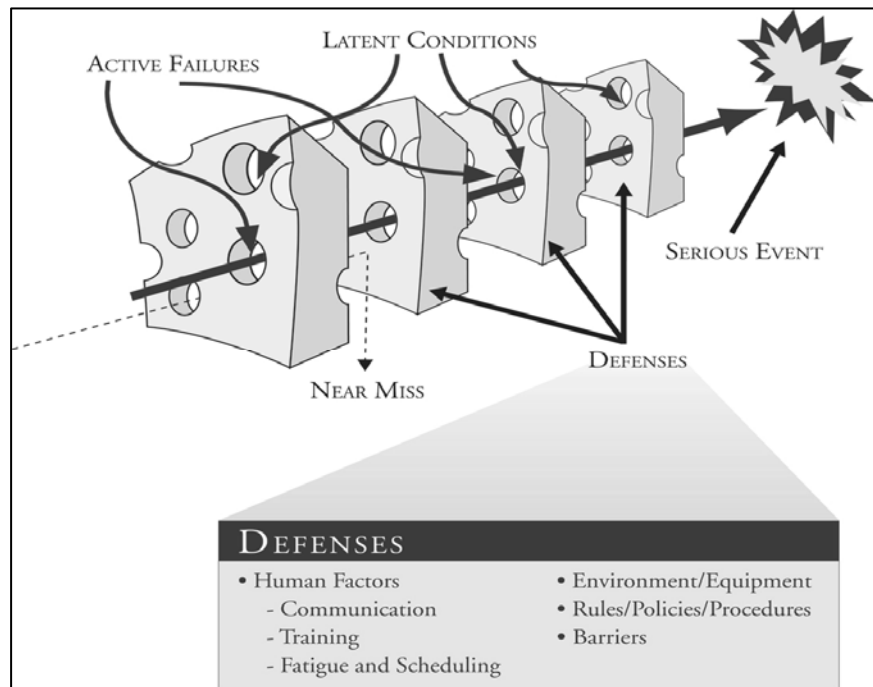


Figure 1. The “Swiss Cheese Model” depicting the way systems place barriers designed to prevent harm and create safe processes.

Source: Adapted from Reason 2002 and US Department of Veterans’ Affairs NCPS Triggering and Triage Cards™

Individually, one active failure or latent condition may not threaten patients, but they can align to allow a human error to result in a harmful serious event. Left unchanged, a system can only be expected to continue to achieve the same results. To achieve a different level of performance, it is essential to change the system in ways that improve its ability to intercept errors.⁵

The medical model has traditionally been one of looking at human error and assigning blame to the error. However, failure to recognize and address the system context in which clinicians provide patient care will doom subsequent clinicians to initiate the same chain of events, resulting in an injury to future patients. Identifying system deficiencies and vulnerabilities requires specifically designed analytic tools. RCA is one such tool.

When confronted with many system vulnerabilities, institutional leaders often need further guidance in prioritizing the approach to address these vulnerabilities. In this report, we describe our experience using CCA to learn about the deeper causes of patient safety events that have been identified using RCA, and about the associated methodology that help prioritize opportunities for improving patient safety at an organizational level. CCA is used in industry as a method of identifying the common causes of errors. However, it has not been widely used in health care.⁶ Like many safety techniques that are developed, practiced, and accepted in high reliability industries, such as aviation and nuclear energy, CCA also offers value when applied to health care.

To understand how we have adapted CCA, it is important to first review our RCA methodology. Although RCA—or an intense analysis of patient safety events—has been mandated for sentinel events by the Joint Commission since 1997, institutions vary widely in their approaches to this requirement.⁷ In the Commonwealth of Pennsylvania, additional requirements have been in place as a part of the Medical Care Availability and Reduction of Error Act (MCARE), or Act 13 of 2002.⁸ The RCA program is designed to meet the requirements of our regulatory organizations and more importantly, to assure that the organization’s standards and commitment to patients are upheld.

At The Children’s Hospital of Philadelphia, the RCA method was developed with a goal of reducing variation in the process, to achieve reliable results and to optimize the investment of time by front-line clinicians. A dedicated team of Clinical Process Managers facilitates all of the RCAs in conjunction with a team leader and team members, who are selected for each case from relevant front-line staff.

To have a reality-based discussion about an event, representatives from front-line staff are critical members of each team. These individuals work daily within the system and provide authoritative information regarding its failure points as well as potential solutions. Immediately following the identification of a near miss or serious event resulting in patient harm, an RCA team is chartered through the Patient Safety Officer. The assigned Clinical Process Manager then recruits a physician or nurse team leader with expertise relevant to the event. Next, five to six additional front-line staff and physician members are chosen to make the team representative of the major roles involved in the event. Individuals actually involved in the event are interviewed to assure that the team is working with accurate information, but they are not included in the RCA team.

Following a substantial amount of pre-work and investigation by the Clinical Process Manager, the team plans three to four 2-hour team meetings. In addition to analyzing the event in question, these meetings serve to teach participating clinicians to view the event from a systems perspective. They learn the language of systems thinking and maintain a focus on systems and processes while avoiding blame and hindsight bias.^{3, 9, 10, 11, 12, 13, 14} Participants advance their knowledge of patient safety, and most importantly, they identify vulnerabilities and formulate action plans through consensus on the suggested improvements.

This RCA methodology was adopted from that used by the U.S. Department of Veterans Affairs National Center for Patient Safety (NCPS). It starts with a process flow developed for the event. The team carefully reviews each step leading up to the event. Three questions are asked:

1. What happened?
2. What usually happens?
3. What should happen?

The goal is to have a thorough review through repeated questioning. At each juncture, we ask “Why?” five times, to be sure every relevant aspect is revealed.¹⁴ For this to occur and to assure that real root causes are identified, it is imperative to provide an environment that supports open, honest discussion.

RCA teams use the NCPS Triage Cards™, a cognitive aid that guides participants in evaluating an event.^{15, 16} The standard, objective questions on these cards help keep the RCA process thorough and credible and provide a mechanism for determining the real source(s) of the vulnerability. The questions posed in NCPS Triage Cards™ are divided into categories that reflect potential contributing factors (Table 1):

- **Human factors: communication**—assesses issues related to communication, flow of information, and availability of information. This is the category with the highest frequency of identified vulnerabilities, both nationally and at our institution.^{17, 18}
- **Human factors: training**—assesses issues related to routine job training, special training, and continuing education.
- **Human factors: fatigue/scheduling**—examines the influence of stress and fatigue, which may result from change, scheduling, staffing issues, sleep deprivation, or environmental distractions, such as noise.
- **Environment/equipment**—evaluates factors related to use and location of equipment, fire protection and disaster drills, codes, specifications, and regulations.
- **Rules/policies/procedures**—assesses the existence and accessibility of directives used to inform and implant a consistent approach to various care processes, including technical information for assessing risk, a mechanism for feedback on key processes, and relevant committees or other leaders who inform the development of these rules.
- **Barriers**—assesses the effectiveness of the barriers or processes put into place to protect patients from harm and the interaction or relationship to rules/policies/procedures.

Once vulnerabilities are identified in all of the relevant categories, the team is charged with identifying potential improvements. Assigning of this work may begin during the RCA process, but improvement actions are often initiated even before completion of the RCA.

Once an analysis of the event is completed, the team prepares a final report, which includes the identified vulnerabilities by category and priority, as well as recommended improvement actions. The report is made available first to the team, to those involved in the event, to relevant leaders at all levels of the organization, to the committees responsible for patient safety, and to senior leaders. The report is then presented to the Patient Safety Advisory Committee, which comprises

unit level medical directors, nursing leadership, pharmacy, information systems, risk management, and other administrative leaders.

At the committee meetings, a triage process identifies the most important actions and potential process owners, with a focus on action items that are appropriately handled locally or are within the scope of existing committees. For example, if it is determined that the hospital formulary does not clearly specify dosing information related to a certain medication, the Therapeutic Standards Committee would be the body with the authority to make these changes. Pharmacy, as an agent of the Therapeutic Standards Committee, would lead this work to edit the formulary in consultation with physician experts.

Table 1. Department of Veterans Affairs National Center for Patient Safety triage categories

Triage Category	Questions
Human factors: communication	• Were issues related to patient assessment a factor in this situation? • Was a lack of information or misinterpretation a factor in this event? • Was communication a factor in this event?
Human factors: fatigue and scheduling	• Were personnel issues a factor in this event?
Human factors: training	• Were issues related to staff training or staff competency a factor in this event? • Was equipment involved in any way?
Environment and equipment	• Was equipment involved in any way?
Rules, policies, and procedures	• Were appropriate rules/policies/procedures – or the lack thereof – a factor in this event?
Barriers	• Was the failure of a barrier designed to protect the patient, staff, equipment, or environment a factor in this event?

Source: NCPS Triage Cards for Root Cause Analysis. VA National Center for Patient Safety; www.va.gov/ncps/CogAids/triage/index.html.

All vulnerabilities and suggested improvement actions are documented in an RCA database, which is also used to track completion of improvement actions. Not only does this RCA database assist in tracking progress, it is also integral to the conduct of the annual CCA.

Because no single person or department completely owns the responsibility for actions, this improvement process can be complex. For example, if an RCA were conducted and a vulnerability identified with a piece of equipment with an inherent patient safety risk, the departments involved might include nursing—possibly the primary group to use this equipment, the supply chain, which has the link to the manufacturer, and the physicians or others who write orders related to the piece of equipment.

If safety concerns with a given piece of equipment are identified, sorting this topic by NCPS categories might reveal “Environment & Equipment” issues. The need for a “Rule/Policy/Procedure” may be a factor if it is determined that safety information was not available to the end user. Finally, if the equipment was used incorrectly, “Human Factors Training” may be a concern. Assigning departments and NCPS categories to vulnerabilities can be challenging, but more detail in this part of the process provides direction for later improvements.

An average of 25 to 30 serious events and high-risk near miss situations are identified each year, and RCA is conducted for about half of these. The other half are discussed and reviewed in other forums, including multidisciplinary morbidity and mortality conferences, where systems vulnerabilities may also be identified. Over a 2-year period from June 2005 through June 2007, 35 RCAs yielded 375 vulnerabilities. Some were addressed immediately: changes in order sets, reference information, training, etc. However, many identified vulnerabilities were more complex and required significant resources and goals in order to be addressed fully.

Methods

Each RCA identifies on average about 10 improvement actions, and the RCA database contains the action plans related to all the identified vulnerabilities. The overwhelming number of vulnerabilities and action plans rapidly saturated the organization’s ability to make all recommended changes, and it became evident that a systematic method was needed to organize data in a way that would help prioritize improvement efforts. Evaluation of trends and patterns across the organization became the impetus for the development of a CCA.

The Department of Veteran’s Affairs NCPS has been analyzing aggregate RCA findings to improve patient safety by focusing on one topic at a time, including patient falls, medication errors, or missing patients.¹⁹ Our methodology does not categorize the RCA findings by incident type, but the aggregate findings obtained through our CCA process provide a powerful tool to focus and prioritize findings and themes for senior leaders.

The first step of the CCA involved sorting data within each of the NCPS categories. Each year, action items in the RCA database that were less than 100 percent complete were sorted so that we could identify themes. Degree of completion was defined using the following possible scores:

- 0 percent: no action taken.
- 25 percent: process owner assigned and first meeting has taken place.
- 50 percent: recommendations for change identified by team.
- 75 percent: implementation of some changes, or pilot study.
- 100 percent: improvement action completed.

Of the 375 vulnerabilities identified between June 2005 and June 2007, 165 (44 percent) met the criteria to be included in the CCA. First, they were sorted according to primary department. This entailed isolating department(s) with authority to make change(s) and identifying relevant department(s). Items were then sorted according to NCPS categories.

After items were sorted into departmental and NCPS categories, trends emerged and themes were identified encompassing multiple items. Once themes were identified, the process of scoring began. To score themes objectively, a criticality index was employed, and Risk Priority Numbers (RPN) were assigned.²⁰ The mechanism for assigning an RPN was the same as that used in “Failure Modes and Effects Analysis (FMEA).” Each theme was scored in three categories – severity, occurrence, and detectability. Each of these three factors was assigned a score using a scale of 1 to 10. The scores were then multiplied for a total RPN that ranged from 1 to 1000. Institutional experience with FMEA suggested a standard for an RPN cutoff point of 250; themes scoring higher than that threshold were considered priority action items that merited a plan of action.

- **Severity (S)** involves evaluating the potential outcome for the patient. For example, if there were no effect at all, the score would be $S = 1$; if there were a moderate effect or temporary harm, the score might be $S = 5$; a catastrophic event or multiple deaths would rate an S score of 10.
- **Occurrence (O)** evaluates the risk of the event occurring again. The likelihood that an event might almost never occur or occur $<1/1,000$ times would rate a score of $O = 1$; if the possibility that something might happen again were slight, e.g., 2 to $3/1,000$, the O score might be 5; if the risk of recurrence were almost certain, e.g., $>300/1000$, the score would be $O = 10$.
- **Detectability (D)** refers to the clinician’s ability to recognize when an error has occurred and to respond before an adverse outcome affects the patient. For example, an event that was obvious and immediately self-revealing would receive a score of $D = 1$; if we had to wait for an early warning/symptom of the problem to show up in a test or alarm, then the D score might be 5; if it were impossible to detect the problem in time to react or if it went completely unnoticed, the score would be $D = 10$. Error detectability can also relate to a process. For example, a medication error at the point of ordering might be detected at one of many steps, whereas an error at the point of administration would be less apparent; hence, the latter would receive a higher detectability score.

To assess inter-rater reliability, each RCA Clinical Process Manager independently scored each theme for severity, occurrence, and detectability. Clinical Process Managers then engaged in a discussion to assure that individual scores truly reflected severity, occurrence, and detectability. The results of this discussion led to a consensus and confirmed the RPN.

Once these steps were completed, the annual CCA report was developed to include themes with an RPN of over 250. Common causes or themes were ranked in descending order by RPN, and the report was finalized. Before making the report public, findings were tested with relevant leaders for face validity.

While significant emphasis was placed on developing and recognizing themes or common causes, ultimately some proportion of action items and vulnerabilities could not be reasonably incorporated into any of the top five or six themes. These remained in our RCA database for continued tracking.

In our experience, a subset of action items were thoroughly assessed and found to be “not feasible.” An example of a patient safety vulnerability for which the recommended action item was “not feasible” might have related to the transfer of patients on night shift. For a variety of reasons, transferring a patient from one unit to another during off-hours poses great challenges. Since circumstances can arise that require patient transfer at night, it would not be feasible at this time to create a rule or standard that no patients be transferred on night shift. Instead, we focused on understanding and communicating the vulnerability, reducing the frequency, making the night shift transfer process safe, and creating systems and safeguards around this known vulnerability.

Items determined to be “not feasible” remained listed in the RCA database and thus provided evidence to support relevant efforts to mitigate their impact, even if they could not be completely addressed. Some “not feasible” items related to technology limitations. Since there is always the potential to incorporate solutions as technologies evolve, they remain in the database and are re-evaluated regularly.

Case Example

The following is a step-by-step example of how the RCA and CCA processes combined to improve care. The scenario described, although altered somewhat from our actual data, provides a realistic representation of our process.

Below is a sampling of action items representative of those taken from one RCA, which contributed to a theme in our CCA. The action items are representative of a serious event that involved a patient found with the cardiorespiratory monitor alarms disabled and additional cases where monitors linked to a nurse call system failed.

Sample RCA suggested improvement actions:

1. Institute a policy and provide education stating that the nurse caring for the patient is the only person who may disable the cardiorespiratory monitor alarms, with the stipulation that the nurse needs to be physically present at the patient’s bedside to take this action.
2. Reduce variation in practice and guide clinicians by creating a cardiorespiratory order set in the electronic Computer Physician Order Entry system.
3. Add priority capabilities to the central alarm system on the unit where the event occurred.
4. Reduce variation in the types of monitors used in medical-surgical units. Replace all monitors throughout the network with a standard monitor.
5. Develop the practice and an associated policy for the “Code Blue” function to be integrated with the nurse-call system.
6. Write SOPs (Standard Operating Practices) and incorporate these into the standards of care and patient care policies for the nurse-call system.

The first step, as described above, was to look at the departments involved or impacted. In this case, biomedical engineering played a significant role. Front-end users needed to develop policies and consider education and standards of care, so other departments cited included nursing, respiratory therapy, physical therapy, occupational therapy, speech, child life, and

physicians. Existing organizational groups—such as Clinical Decision Support, the Medical Devices Committee and others—provided a mechanism for expediting the work.

After sorting by department, items were sorted by NCPS category. In this case, “Environment and Equipment” and “Rules, Policies and Procedures” both represented categories of vulnerabilities. “Human Factors Communication” and “Human Factors Training” also contained vulnerabilities. Sorting for trends among affected departments and NCPS categories allowed us to identify a theme. Themes each involved multiple departments and matching NCPS categories. For example, other themes might relate more specifically to the department of surgery, to issues of procedures and communication in the operating room, or a theme related to those issues might emerge.

In evaluating these findings, the following statement captured the essence of these items as they related to the internally published “Common Cause” or theme that was a part of the annual CCA: “Evaluate and implement a safe and effective nurse-call system. Include, but do not limit to an evaluation of staffing requirements, downtime procedures, and standard operating practices for all users.” The RPN for this item was 576 (S = 8, O = 9, D = 8).

For reporting purposes, all action items and vulnerabilities are bulleted under the theme, along with identifiers relating them to specific RCAs, and tracked in the RCA database. In general, the CCA results in five or six main themes each year. In a review of the process, these themes account for the majority of identified vulnerabilities and improvement actions from RCA. Themes are presented in rank order; organizational prioritization includes such considerations as resource availability and other pillar plan priorities.

In the case described above, capital budget was planned to purchase new monitors, so the recommendation of the RCA team—to have the same cardiorespiratory monitors throughout the organization—was quickly implemented. The critical nature of the RPN score provided the impetus for the creation of a team to address all components affecting the monitor: order set, creation of policy, standards around which members of the health care team can safely disable alarms, etc. The degree of urgency directly correlated with the severity of this situation, and work was accomplished in a timely manner.

Nurse-call issues were also assigned to special teams to address the specific issues identified and to evaluate the patient-to-nurse communication system and make improvements. These numerous actions taken by CCA-driven teams have resolved 20 individual items. More importantly, though, they have addressed the deeper underlying theme with respect to the vulnerabilities of patients on cardiorespiratory monitors.

Although improvement work was initiated at the completion of the RCA on the monitoring case, it was not until related findings were collected from several RCAs using the CCA approach that the organization understood the depth and breadth of the vulnerabilities. This new understanding related to the cardiorespiratory monitoring systems and the associated nurse-call system as the two are utilized as integrated technology with monitor alarm notifications sent via the nurse-call system. It was at this point that the item was incorporated into the organization’s annual operating plan. As a result, the work accelerated to the level needed in order to make the

significant changes in practice, changes in equipment, and continued improvement of all associated systems across the institution. Changes of this breadth and scope often require significant allocation of resources, personnel, and time. They would not be expedited without a credible prioritization process, such as we provided by CCA.

The initial improvement team included biomedical engineering, physician and nursing leaders and front-line staff, respiratory therapy, occupational therapy, physical therapy, speech, child life, a nursing educator, and a team facilitator from the Center for Quality and Patient Safety. The team worked to test and implement standards of care and hard-coded the expected practices in policies. A broad education program was initiated, and a system for measuring performance was put into place. Periodically, the team was asked to report to the Patient Safety Committee to assure that the work was progressing and to identify major barriers that might require leadership intervention. At the same time, additional teams were set up to evaluate the nurse-call system and the integration with the cardiorespiratory monitoring system. Staffing patterns changed, and responsibilities for alarm response were better defined. Education and training of clinical support staff assured that they understood their role in cardiorespiratory monitoring.

Discussion

CCA has been an extremely effective method for distilling individual patient safety findings to prioritized themes that have a powerful impact when presented to operational and physician leaders, as well as the hospital's board of trustees. The findings from this process are a guiding foundation in the development of the organization's Operating Plan for Quality and Patient Safety in each of the past 2 years.²¹ The five or six annual themes with an RPN score >250 become a prioritized quality and patient safety goal. Executive sponsorship is defined, operational leadership is assigned, and an improvement team is chartered to test, implement and spread the changes needed to bring about improvement. Measures are tracked monthly, and regular progress reports are provided in a number of forums. When the identified area for improvement is limited to a single clinical department, as opposed to being organization-wide, the goal is incorporated into the department's operating plan, and improvement continues on a smaller scale.

To make this process effective, Clinical Process Managers from the RCA team provide department leaders with detailed summaries of their findings and review cases that were influential in the items encompassed in the theme. Although an established process for sharing findings with leaders assures that they see each RCA report, a synopsis of findings that applies to their area is powerful. A meeting that includes leaders from the appropriate area provides an opportunity for questions to be asked and for clarification of each item. These sessions often lead to brainstorming about how to improve patient safety systems. Whenever possible, RCA Clinical Process Managers, who facilitated the related work, are included in the actual planning in order to provide insight, or in some cases, to facilitate or support working groups. This process helps convey nuances that a high level report cannot, and it allows information to be shared with the front-line staff who participated in teams.

To be recognized as effective, a patient safety program must identify the critical priorities and make improvements to address those priorities. The CCA report is a vital tool in prompting

action, since it inspires a greater degree of confidence that the identified problems represent the most important vulnerabilities that need to be addressed. Competing priorities at the level of patient care units create difficulty in determining how to incorporate new work that results from RCA. CCA findings can help department leaders align their efforts with organizational priorities. Overall, this process provides greater confidence that we are working on the most critical issues and, hopefully, improving patient care and making it safer.

Next Steps

For the CCA described here, RCA findings were the primary source of data (Figure 2). Although we carefully worked to contemplate broad, system ramifications and also looked at their severity and potential impact on patient safety, we realized that many additional sources of information could be systematically incorporated into this process.

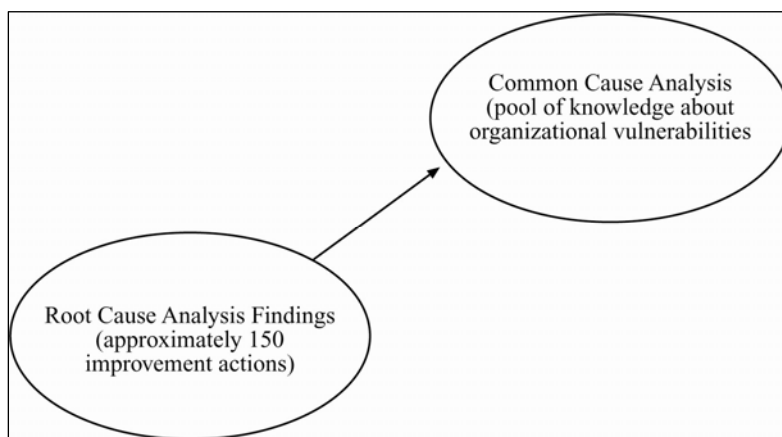


Figure 2. Common cause analysis: Years 1 and 2.

Input from RCAs is ultimately limited to the relatively few cases that warrant this type of analysis. In the future, an increased breadth of information will be utilized for conducting CCA (Figure 3). Although we have an incident reporting database, a new electronic safety reporting system currently being implemented will expand the quality of patient safety event data. This system ultimately will provide information from families and patients, as well as from employees. It will be a rich source of data for aiding in identifying institutional vulnerabilities, with much more robust data mining capabilities. Aggregate data from FMEAs, infection control findings, and a newly developed process within our institution called Mini-RCA (in which we train unit-based staff in the method so that it can be applied to more near miss events) will also enrich the analysis process in the future. Although patient safety considerations generated by various accrediting bodies (e.g., the Joint Commission, regulatory bodies such as the Centers for Medicare &

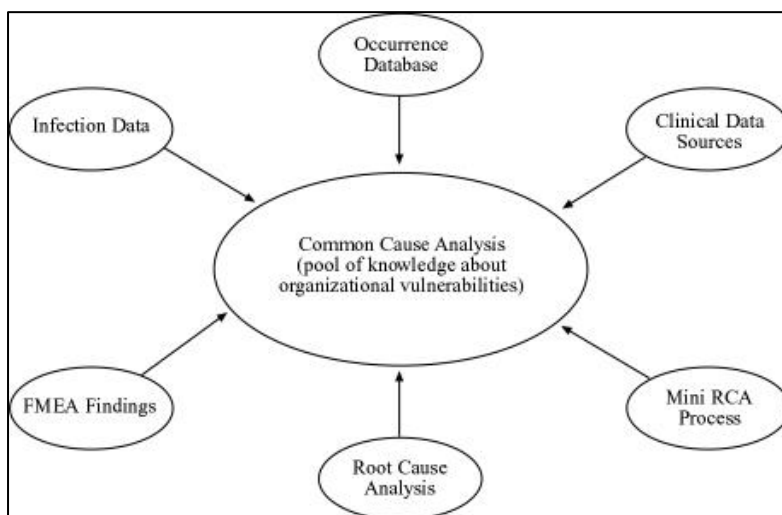


Figure 3. Common cause analysis: What's next?

Medicaid Services, national patient safety advocacy groups, and others) will continue to influence patient safety priorities, our clinicians will always give higher priority to data from internal experience, as developed through CCA.

There are many driving forces in patient safety, but one of the benefits of an institutional CCA is the unique and specific findings it generates, which relate to actual events and near miss scenarios. Patient safety work becomes much more compelling when it relates to one's own experiences. The significance placed on patient safety improvement work in our institution affirms that it is the top priority, and it inspires clinicians to participate in RCAs, report their experience, and mobilize their energy to contribute to improvement initiatives.

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References

1. Studer Group LLC. Hardwiring excellence. Gulf Breeze: Fire Starter; 2003.
2. Morath JM, Turnbull JE. To do no harm. San Francisco: Jossey Bass; 2005.
3. Reason J. Combating omission errors through task analysis and good reminders. *Qual Saf Health Care* 2002; 11: 40-44.
4. Reason J. Human error: Models and management. *Br Med J* 2000; 320: 768-70.
5. Berwick DM. Improvement, trust, and the health care workforce. *Qual Saf Health Care* 2003; 12: 448-452.
6. Heising CD, Rasmussen NC, Mak CH. Common cause analysis: A review and extension of existing methods. Massachusetts Institute of Technology, Cambridge (USA) Energy Lab. 1982 Oct. No. PB-166520; MIT-EL-82-038.
7. Sentinel event policy and procedures. Oakbrook Terrace, IL: Joint Commission; 2005. Available at: www.jointcommission.org/NR/rdonlyres/F84F9DC6-A5DA-490F-A91F-A9FCE26347C4/0/SE_chapter_july07.pdf. Accessed January 20, 2008.
8. Medical care availability and reduction of error (MCARE) Act; March 20, 2002. Available at: www.psa.state.pa.us/psa/lib/psa/act_13/act_13.pdf. Accessed January 10, 2008.
9. Leape LL. Error in medicine. *JAMA* 1994; 272: 1851-1857.
10. Nolan TW. System changes to improve patient safety. *Br Med J* 2000; 320: 771-773.
11. Shappell SA. The human factors analysis and classification system – HFACS. U.S. Department of Transportation, Federal Aviation Administration. 2000 Feb. DOT/FAA/AM-00/7.
12. Kaye R, Crowley J. Medical device use-safety: Incorporating human factors engineering into risk management. U.S. Department of Health and Human Services, Food and Drug Administration. 2000 July; 1497.
13. Gosbee J, Anderson T. Human factors engineering design demonstrations can enlighten your RCA team. *Qual Saf Health Care* 2003; 12: 119-121.

14. Scarrow PK, Routon C, White SV. Michael Cohen on medication error reporting and patient safety. *J Health Care Qual* 2005; 27: 29-36.
15. Bagian JP, Gosbee J, Lee CZ et al. The Veterans Affairs root cause analysis system in action. *Jt Comm J Qual Patient Saf* 2002;28: 531-545.
16. NCPS triage cards for root cause analysis. VA National Center for Patient Safety; 2007. Available at: www.va.gov/ncps/CogAids/triage/index.html. Accessed January 10, 2008.
17. Bagian JP, Lee C, Gosbee J, et al. Developing and deploying a patient safety program in a large health care delivery system: You can't fix what you don't know about. *Jt Comm J Qual Patient Saf* 2001; 27: 522-532.
18. Root cause analysis statistics. Oakbrook Terrace, IL: Joint Commission. Available at: www.jointcommission.org/NR/rdonlyres/FA465646-5F5F-4543-AC8F-E8AF6571E372/0/root_cause_se.jpg. Accessed January 10, 2008.
19. Dayton E, Henrikson K. Communication failure: Basic components, contributing factors, and the call for structure. *Jt Comm J Qual Patient Saf* 2007; 33: 34-47.
20. Neily J, Ogrinc G, Mills P, et al. Using aggregate root cause analysis to improve patient safety. *Jt Comm J Qual Patient Saf* 2003; 29: 434-439.
21. Partnership for patient care. Failure mode and effect analysis: A practical guide; Plymouth Meeting, PA: Emergency Care Research Institute; 2006. Available at: www.ecri.org. Accessed January 11, 2008.

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Peer Reviewers—Volume 1

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