Advances in Patient Safety: New Directions and Alternative Approaches

Volume 4. Technology and Medication Safety

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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
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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.

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Editors

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Prologue

Technology and Medication Safety

Mary L. Grady, BS

This volume comprises papers devoted to the development and use of technology—principally health information technology (health IT)—and strategies to enhance medication safety, both of which are critical to improving the delivery of safe, effective health care.

We are already using health IT in a number of ways: to help prevent medical errors, including adverse drug events; reduce costs through streamlining processes and providing more targeted, efficient care; help patients manage their chronic illnesses; enhance the delivery of targeted, patient-centered care; measure provider and facility performance; and facilitate rapid access and dissemination of accurate medical information in the event of a public health emergency.

Health IT can provide access to real-time information to support clinical decisionmaking, promote evidence-based care, organize and streamline the referral process, facilitate the order entry process, and consolidate patient information into one easily accessible, accurate, and up to date source. The use and usefulness of health IT are evolving, and we certainly will see many new applications of health IT in the coming months and years. New forms of information packaging and presentation will be critical in helping health IT grow and develop as health care itself changes over time.

Many examples of health IT in action are included here. Topics range from the use of hand-held assistive technology to the implementation of decision support systems and the application of health IT in the operating room. Other authors focus on the challenges that must be faced and overcome if we are to make the most of health IT and its seemingly limitless potential to improve the care provided by the Nation's health care system, including: costs (particularly start-up costs, which can be substantial), provider resistance, concerns about privacy and the security of health data, and the unintended consequences that can sometimes occur.

These barriers can, however, be overcome. For example, one paper examines the impact of implementing an electronic health record (EHR) system on work processes and patient care in a busy labor and delivery unit. Other authors describe the positive effects of computerized provider order entry (CPOE) on turnaround times for laboratory, radiology, and pharmacy orders. Concerns about confidentiality and system reliability are addressed by several groups of authors.

Several papers focus on anticipating and overcoming the unintended consequences that sometimes result from the implementation of health IT. For example, one paper discusses the development and implementation of a homegrown CPOE system that was designed to minimize unintended consequences and maximize the potential of e-prescribing

technology to improve patient safety. System reliability and safety are the focus of an article that introduces the concept of "safeware"—a comprehensive approach to hazard analysis and the design, operation, and maintenance of the hardware and software systems involved in health IT.

The second half of this volume is devoted to medication safety. Medication prescribing is the most frequently used therapeutic intervention, and the majority of office visits result in a prescription. Indeed, pharmaceuticals are an essential tool available to clinicians to treat acute illnesses and manage chronic conditions. Yet the use of medications—including prescription and generic drugs, as well as herbal supplements—is not without risk. Underuse, overuse, adverse events, and medical errors associated with medications can cause serious harm to patients and increase health care costs.

Medication errors are a frequent cause of adverse drug events, and they can occur at any point in the process—i.e., during ordering, transcription, or administration. Many approaches have been proposed and tried over the years to improve medication management and minimize adverse drug events, ranging from increased involvement of pharmacists, to e-prescribing technologies, to computer-based medication monitoring.

Authors in this section approach the problem of medication safety from several different angles. They describe systems to detect potential errors, prevent the dispensing of inappropriate medications, monitor respiration and dispense patient-controlled analgesia (PCA), and monitor the medication use of Medicare beneficiaries at high risk of adverse drug events. One group of authors examined the feasibility of detecting medication errors through self-observation of office transactions along with chart review in a primary care practice that did not use electronic ordering. Another paper reports on a multicenter trial to evaluate a medication therapy management program that included pharmacist visits for seniors at high risk for drug-related problems.

Still other papers focus on the benefits and drawbacks of automated medication dispensing machines in hospitals; the use of "smart" PCA pumps with continuous respiratory monitoring in postoperative patients; the feasibility and usefulness of a community-wide electronic shared medication list that is portable and accessible to patients, caregivers, and health care practices; the development, use, and outcomes of a medication safety program that attempts to imbed research in practice; the utility of home visits to learn more about medication errors in children; the need for and role of pharmacists in emergency medicine; and the risks associated with using prescription drugs with herbal and dietary supplements.

In summary, the papers in this volume present a wide array of approaches that use health IT and other mechanisms to improve the delivery of safe and appropriate care, improve medication safety, and make the most efficient and effective use of America's scare and ever more costly health care resources. The authors represented here are working on finding tools and solutions that will move us forward and help us achieve a safer, more efficient health care system that is second to none.

Health Information Technology

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

Robert L. Wears, MD, MS; Nancy G. Leveson, PhD

Abstract

Information technology (IT) is highly promoted as a mechanism for advancing safety in health care. Ironically, little attention has been paid to the issues of safety in health care IT. Computer scientists have extensively studied the problem of assured performance in safety-critical computing systems. They have developed a conceptual approach and set of techniques for use in settings where incorrect or aberrant operation (or results from correct operation that are aberrant in context) might endanger users, the public, or the environment. However, these methods are not commonly used in health care IT, which generally has been developed without specific consideration of the special factors and unique requirements for safe operations. This article provides a brief introduction for health care professionals and informaticians to what has been called “safeware,” a comprehensive approach to hazard analysis, design, operation, and maintenance of both hardware and software systems. This approach considers the entire joint sociotechnical system (including its operators) over its entire lifecycle, from conception through operation and on to decommissioning. Adoption of safeware methods should enhance the trustworthiness of future health IT.

Introduction

Twenty-five years ago, Lissane Bainbridge coined the phrase “ironies of automation” to refer to the observation that introducing automation into a complex sociotechnical system to improve safety and performance often simultaneously introduced new problems into the system that degraded safety and performance.[1, 2] Despite this experience, the belief that advanced information technology (IT) is a critical mechanism by which to improve the safety of health care is strongly held by academics, public officials, and vendor, business, and civic groups.[3, 4, 5, 6, 7, 8, 9] The anticipated benefits of health care IT are presented in these discussions as a sort of manifest destiny—difficult, to be sure, but ultimately inevitable. While there have been many discussions about the challenges,[10] costs,[11] priorities,[10] and other planning issues[12] in implementing IT, there has been virtually no discussion about how to make health IT itself safe for patients, practitioners, and health care organizations. The irony of seeking safety through systems that may not be safe to begin with seems to have been lost in the enthusiasm for remaking health care via IT.

Past experience with IT has not shown it to be an unequivocal success.[13, 14] Hardware failures have propagated in unexpected ways to remote, ostensibly unrelated components on a common network[15, 16]; system upgrades have lead to missing[17] or false laboratory information[18]; programming mistakes have similarly led to incorrect guidance in decision support[19]; and

computerized provider order entry, the ”Holy Grail” of safety efforts, has led to new forms of failure.[20, 21, 22, 23] These problems have led to a small but slowly growing realization that the hazards of implementing IT in a field as complex as health care have only just begun to surface. However, even this awareness has been limited, as the focus has been almost entirely on problems related to the human-computer interface[20, 22] and unintended consequences due to changes in work practices.[21] The problem that the technology itself might be inherently unsafe—that it might lead to adverse outcomes due to internal faults, interactions with users or external devices, or even when the system is operating as intended by the programmers and in the absence of human factors or work practices problems—has barely been recognized in these discussions.

Technology-related safety problems have been well recognized in the computing world, however, and a substantial body of work has developed since the 1980s concerning IT safety in safety-critical systems.[24, 25, 26, 27, 28, 29] In a wide variety of domains (e.g., military, aerospace, nuclear power, rail transport), a systematic approach to identifying, reducing, or mitigating computer-related risks is now considered standard, and the burden of proof for demonstrating that a system (or modification to a system) is safe is placed on the vendor, developer, or implementer, rather than being placed on the customer to demonstrate that it is not safe.[30]

It seems ironic that the movement to promote safety through IT seems uninformed by the field of safety-critical computing. As an example, an informal search of the *Science Citations Index* for references to three well-known texts related to computing safety[25, 27, 28] revealed no citations in medical informatics or clinically relevant journals (of 211 total). While this is by no means a definitive mapping of the relationship between the two fields, it seems reasonable to conclude that there is little evidence for their interaction. Although questions have occasionally been raised about the safety of clinical IT, they have been couched primarily in the form of concerns about whether and for what types of systems regulation should be required.[31, 32]

This lack of awareness of the field of safety-critical computing stems, in part, from the origins of health informatics, which arose at a time in which a major question was whether it was possible that IT could contribute usefully to health care. This gap has been exacerbated by a gradual change in IT usage in health care, as systems that were originally developed either as business-related, transaction-oriented systems or as research-related ”proofs of concept” have slowly and subtly become transformed into safety-critical, process-control systems.

The development, operation, and maintenance of such systems differ in important ways from common IT practices. Thus, health care faces the hazard of having safety-critical processes dependent on IT systems that are not designed, operated, and maintained using safety-critical methods. Finally, and more subtly, the changes in human and system behavior caused by the introduction of IT into health care and the unsafe conditions that may result as a consequence are difficult to envision and so often go unaddressed.

The purpose of this article is to bridge the gap between two scientific communities that could mutually inform each other’s work in a synergistic way, by:

- Introducing the field of safety-critical computing to researchers, developers, and practitioners in health care who are interested in using health IT to advance safety and quality but may have been unaware of its existence.
- Outlining some basic principles and practices of safety-critical computing.
- Guiding readers who wish to become more knowledgeable about safety-critical computing to additional resources for more detailed study and application of these methods.

Case Study

To illustrate the types of safety problems that might be intrinsic to IT (compared to arising from human-computer interface or work practice issues), we briefly review a case study (described in greater detail by Cook and O'Connor[33]).

On a Friday night shift in a large, tertiary care hospital, a nurse reported to the pharmacy that the medications just delivered to the floor in the unit dose cart for a particular patient had never been ordered for that patient. While they did match the recently printed Medication Administration Record (MAR), comparison to the previous day's MAR showed substantial changes, and there was no record in the chart of any relevant orders. The pharmacy's computer records for the patient in question matched the recent MAR, but before the discrepancy could be understood, more discrepancies from other nursing units, in all areas of the hospital, began to be reported; all concerned drugs that matched the current MAR in the computer but were wrong for the patient.

As the magnitude of the problem mounted, the pharmacy technician called a senior pharmacist who realized that a serious, hospitalwide crisis was upon them. The computer system was somehow producing an inaccurate fill list, such that neither the MAR nor the unit dose carts already on the wards could be trusted. Early Saturday morning, a plan was devised to send all the unit dose carts back to the pharmacy and to manually recreate the deliveries needed from the previous day's printed MARs and the handwritten orders in the charts. These manual procedures enabled the hospital to continue functioning through the next 24 hours, albeit at great effort, until the system could be repaired and then "brought up to date" so that its internal representation of the "patient-medication state" of the hospital matched the external world. As far as is known, no patient suffered serious harm from this event.

The ultimate explanation for the event involved multiple factors. The pharmacy software was from a major vendor but had been customized with a special dose-checking routine in the aftermath of a severe accident. It had not been upgraded regularly due to the need to rewrite and retest these special procedures after each upgrade. Extensive backup procedures were in place and operational. On the day of the event, the software had detected a database fault, which the hospital's IT department and the vendor attempted to fix. The fix did not work satisfactorily, so part of the database was reloaded from the most recent backup tape; after this, the system appeared to function correctly.

Due to a complex technical problem in the database management software unrelated to the previous fault, the reload was incomplete in ways that were not apparent to the operators, leaving the MAR database internally corrupted. Fundamentally, the system had performed as designed,

but the design had not anticipated the set of circumstances that led to internal database corruption and did not have the capability to detect or respond to such damage.

Ironically, one critical factor in the successful recovery was that the entire system was not automated. Correction and recovery would have been much more difficult if not only the MAR system, but also the order entry and the dispensing functions, had been integrated into the same flawed system.

This case illustrates a number of important safeware principles: (1) normal operations are no assurance of correct operation; (2) testing has limited value in establishing system safety; and (3) system maintenance can be a major hazard in complex systems.

Safeware Principles: A Brief Outline of the Safeware Approach

Safety in software-intensive systems has been a concern in other industries for decades, and much has been learned about how to introduce IT into a safety-critical system. In this section, we outline some basic principles and the approach widely used in software system safety. Only a brief introduction is possible here; for more information see Leveson.[25]

Guiding Principles

- The first basic principle is that safety is a system problem, not a software or IT problem. Computer behavior that may be perfectly safe in one system context may be unsafe in a different environment. Computers are not an inherently dangerous technology, in the sense that, say, petrochemical refining is inherently dangerous. Computers do not present hazards directly but rather only become unsafe when used in an environment in which mishaps and unacceptable losses can occur. Therefore, building and ensuring safety starts at the system level, not the component or software level.
- A second principle is that safety and reliability are not only different properties, they are sometimes conflicting. Reliable software (i.e., software whose performance is invariant) is not necessarily safe, and safe software does not have to be reliable. In some instances, increasing reliability can actually decrease safety (e.g., the computer continues to do something even though that behavior is unsafe in the current environment, and vice versa, the safest behavior under certain conditions may be to stop operating and switch to some fail-safe mode). In addition, “failing” (i.e., discontinuing operation) is not the most important safety issue with software. Most accidents are caused not by the computer stopping, but by it operating but doing something unsafe. It is relatively easy to protect the system against total failure, but it is much more difficult to protect it against unsafe software operation.

The field of system safety (and software system safety) has its roots in the intercontinental ballistic missile (ICBM) systems of the 1950s, when very complex, largely autonomous, software-intensive systems were built, in which accidents would have catastrophic consequences that could not be blamed simply on human operators. System safety is a subdiscipline of system engineering and encompasses many of the same principles:

- Safety must be built into a system from the beginning; it cannot be added to a completed design or tested into a system.
- Accident and loss prevention require a top-down approach that deals with systems as a whole and not just components of the system.
- Accidents are not caused by component failures alone. In fact, in software-intensive systems, accidents are much more likely to result from dysfunctional and unsafe interactions among normally operating (not failed) components.
- Accidents can be prevented using hazard analysis and design for safety to eliminate or control hazards.
- In software-intensive, complex systems, qualitative rather than quantitative approaches need to be emphasized as quantitative procedures must necessarily omit important but unmeasurable factors and therefore may be misleading.

System safety starts from hazards and emphasizes hazard analysis and control as a continuous, iterative process applied throughout system development and use. Once hazards have been identified, they are handled by either elimination from the system design if possible, or if not, by preventing or minimizing their occurrence, controlling them if they occur, and minimizing damage (in that order).

As an example, consider a computer-controlled analgesia or insulin pump (both of which, historically, have been involved in serious patient injury and death). The most critical hazard is administration of unsafe levels of the medication. Eliminating the hazard might be possible by substituting a less dangerous drug. If that's not possible, then steps must be taken to prevent an overdose, to detect and counteract it if it occurs, and to initiate emergency treatment to minimize damage from an overdose.

To provide this protection, a formal system safety process can be used. Surprisingly, the use of such a process is not expensive, and it may be much less costly than applying expensive and ineffective testing and assurance programs. The rest of this section briefly describes the system safety and software system safety process.

Safety Over the System Life Cycle

The guiding principle for this approach is that safety must be designed into the system and software from the beginning. Attempting to add it to a completed design is not only extremely expensive, but it also is not very effective. Obviously, this is a significant issue for clinical systems that have been created by layering them over pre-existing business or research systems in which safety was not an important concern. To be most effective, system safety needs to be considered during program/project planning, concept development, system design, system implementation, configuration control, and operations. The tasks associated with these life cycle stages are technically complex and cannot be described briefly; readers should consult more detailed works or seek expert assistance in these areas. The following provides a guide to these activities:

During program/project planning. Develop safety policies and procedures and specify a system safety plan. This plan includes how software safety will be handled. Construct a system safety management structure—including well-defined authority, responsibility, and accountability for safety—and define appropriate communication channels for safety-related information. Ideally, keep the safety management system and team separate from the development system and team. This structure must include responsibility, accountability, authority, and communication channels for the IT developers as well as the system developers. Finally, create a safety information system, including a hazard tracking system.

During concept development. Identify and prioritize hazards (typically using severity). As architectural designs are considered and selected, elimination and control of hazards will be a major decision factor. Once the architecture is defined, specify safety-related system requirements and constraints for the development and operation of the system.

During system design. Hazard analysis is applied to the design alternatives to:

- Determine if and how the system can get into the hazardous states.
- Eliminate the hazards from the system design, if possible.
- Control the hazards in system design if they cannot be eliminated.
- Identify and resolve conflicts among design goals using safety as one of the decision criteria.

After the system safety analysis and design are complete. Trace unresolved hazards to the system components, including hardware, software, and humans. Generate safety requirements and constraints for each of the components from the system safety requirements and constraints.

During system (and component) implementation. Design safety into the components (using the safety requirements and constraints provided as a guide) and then verify the safety of the constructed system. It is important to note that testing for safety, particularly for software systems, is not practical. Only a very small part of the entire software state can be tested. Accidents usually occur when factors have been forgotten or not accounted for in the software or system design, and those same factors will almost surely be omitted in testing as well.

There are some aspects of safety that should be tested (e.g., special processes or procedures for handling specific hazards), but little confidence can be placed on the results. One cannot test safety into a system. Designing safety into software may involve such software engineering practices as defensive programming, assertions and run-time checks, separation of critical functions, elimination of unnecessary functions, exception handling, and others.

At implementation. Use the documentation developed as a by product of safety management during development to produce a formal "safety case" argument for the safety of the system. Such formal analyses of system safety are now required for safety-critical systems in industry in the United States and European Union[34] and should be continuously maintained and updated as experience is gained in operations (including near misses and accidents), thus becoming a continuing argument for system safety.[35]

During operations and maintenance. Evaluate all proposed changes for safety using the same hazard analyses and assumptions (that should have been recorded) used during development. However, changes are not always planned, so periodic audits and performance monitoring are required to verify that the assumptions underlying the safety analysis used in the development process still hold.

Finally, incident and accident analysis is clearly necessary, which implies that there is a way to detect and communicate when safety-related incidents occur. Feedback must be established to ensure that human behavior is not changing over time in a way that could violate the system safety assumptions used during development and to check for other types of changes that could lead to mishaps.

Further Considerations

Sometimes an assumption is made that if software has been executing safely in one environment, it will be safe in another environment. This assumption is false. In fact, most software-related accidents have involved reused software. Safety is a system property, it is not a component property; software that executes perfectly safely in one environment can be hazardous in another.

Not only must the environment be analyzed for safety during initial development (as discussed above in terms of identifying and controlling hazards), but also the potentially hazardous behavior of any reused software must be carefully analyzed and evaluated and controlled. In many cases, it will be cheaper and safer simply to reimplement the software for the new system.

Commercial off-the-shelf (COTS) software presents a particular dilemma. Some companies producing medical software and IT often assume that they can simply provide a version that everyone can use. This is not realistic. IT must be tailored for the larger system in which it will operate (which always has unique features), and the safety of the system (in the proposed environment) has to be carefully analyzed. In addition to their own vulnerabilities, COTS systems bring unknown vulnerabilities into the operating system employed (typically in many different versions) and the hardware platform (similarly, in many different versions).

A Guide to Further Learning

Safety in computer systems is a large and active field. In this section, we suggest several sources that should be useful for those interested in safer IT or a more detailed exposition of safeware principles.

- *Computer-Related Risks*[27] is a classic text on accidents and near misses related to faults in IT systems. *The Risks Digest*[36] can be viewed as an online continuation of this work. It is moderated, regularly updated, searchable, and well regarded in the computer science world.
- *Safeware: System Safety and Computers*[25] has become the classic text on IT safety and gives a detailed exposition of principles, specific applications, and analyses of a set of well-known IT accidents.
- *Safety-Critical Computer Systems*[28] is a similar text, not quite as comprehensive and with a bit more focus on embedded systems.

- *Trust in Technology: A Socio-Technical Perspective*[29] provides an overview of the nature of safe, trusted IT and how it might (or might not) be implemented and operated.

Conclusion

The traditional approach to producing software is to determine the requirements, implement them, and then try to assure that there are no errors in either. The problems with this approach from a safety standpoint are that correct implementation of the requirements does not guarantee safety, and it is impossible to ensure that software is "perfect." In fact, perfect (error-free) software does not exist. The alternative proposed in this article is to begin by envisioning the states the system should never get into and then work backward to design, implement, maintain, and operate the system such that either those states cannot be reached, or if they are reached, they are detected and handled safely before losses occur.

One serious problem related to the safety of health IT is the as yet unanswered question of who is responsible to see that systems are designed, implemented, operated, and maintained with safety as a central feature. Currently, a good deal of health IT is not subject to regulatory oversight; purchasers have little leverage in negotiations with vendors on safety issues; and both purchasers and vendors may have limited understanding of the hazards of such systems and effective means of managing them. This is an important social (ethical) regulatory issue that will need to be addressed constructively in order to ensure that these principles are actually applied in health IT. Health care would do well to follow the lead of other hazardous industries and develop ways to ensure that the burden of proof for demonstrating that a system is safe is placed on the vendor, developer, or implementer, rather than being placed on the customer to demonstrate that it is not safe.[30]

Key Messages

The key messages of this article are:

- Safety is a system problem, not just an IT problem.
- While IT has the potential to greatly improve quality and safety in medicine, that result is not guaranteed; the way in which IT is designed, implemented, maintained, and operated will determine what kind of result ensues.
- To ensure that safety is improved and not inadvertently compromised requires a systems approach and analysis of the overall sociotechnical system in which the IT will be embedded.
- Much has been learned about how to design, implement, maintain, and operate safety-critical IT in other settings; that knowledge could usefully inform attempts to introduce IT into health care to advance safety goals.

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Improving Perioperative Patient Safety Through the Use of Information Technology

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Abstract

The perioperative care process is a unique and challenging environment. Perioperative clinicians are increasingly focused on how to improve patient safety. Proven software design approaches and standards are available. If they are focused on the challenges in the perioperative environment, they can be an important catalyst to transform surgical care. Opportunities abound for informatics-based improvements in perioperative care. Additional perioperative work groups and industry partnerships need to be created. Health care standards should be reviewed to ensure full support of perioperative requirements. The complexities of the perioperative environment make technology implementation challenging, and the unique issues in this environment must be addressed when technology is deployed. There is a growing focus on the importance of technology use within health care. Too often the vision and priorities of national health care technology modernization efforts have not focused on the unique requirements of perioperative care.

Perioperative Care: A Unique Environment

The perioperative arena is a unique environment that includes many challenging variables: complex clinical care performed by teams; high cost, sophisticated technologies that often do not interoperate; and a large array of supplies, instruments, and implants that are difficult to manage. These variables create an environment of massive complexity and, unfortunately, are a source of a significant percentage of patient safety-related adverse events.[1] The types of errors that can occur during the surgical process—patient misidentification, surgical site misidentification, and medication errors and omissions—are all more likely to occur, given the combination of high complexity and poor use of technology.

The information technology (IT) sophistication offered to the perioperative environment does not match the requirements of clinicians, administrators, and even clerical staff. Surgical information systems have not kept pace with the demands of the perioperative process and still generally only provide basic functionality in the areas of patient/case scheduling, case planning and management, staffing, OR suite management, nursing perioperative documentation, and charge collection for hospital billing.

Little attention has been given to physician (surgeon or anesthesiologist) clinical documentation, professional fee charging, surgical suite medication administration and documentation, or to integrating the information and technologies available throughout the perioperative environment.

It is not a surprise then that IT adoption has been low, with only approximately 6 percent of hospitals nationwide utilizing a comprehensive perioperative information management system.[2]

Compared to the environment of a primary care or specialty medical practice, patients in the operating room (OR) environment are subject to infrequent but high-intensity visits. During the perioperative process of care, clinicians from several different disciplines care for patients in a simultaneous, real-time fashion. A single patient might be treated by five or more nurses, two or more physicians, associated pharmacists, radiology technicians, and blood bank staff. Many other types of support personnel also directly affect a surgical case and, therefore, the safety outcomes. These include patient transporters, sterile supply staff, janitors, schedulers, and others. With the exception of the attending surgeon, all other clinical and support perioperative staff do not typically meet their patients until the time of surgery and have, at best, very limited postoperative followup.

Other than a quick determination of the facts pertaining to a particular procedure, perioperative clinicians and staff have little opportunity to become familiar with surgical patients. This lack of familiarity with and knowledge about patients could predispose perioperative team members to such errors as patient misidentification, miscommunication of the planned procedure, and omission of allergies or antibiotics. These deficiencies are magnified at times of patient transfer or handoff from one care team to another, which occurs at multiple points: from surgical clinics to the preoperative preparation areas, to the OR, to the post-anesthesia care unit, to the intensive care or other inpatient care unit, and ultimately to followup care in the surgical clinical or primary care office.

Many items and issues need to be planned and coordinated for a surgical case to be successful. Multiple clinicians and care teams must partner and not only share patient information, but they also must integrate their work into a larger care process for the surgical patient. Many types of equipment, instruments, medications, blood products, and supplies must be planned and prepared to be at the same time and place, and typically, a different department or group manages each item (e.g., central supply, sterile instrument processing, patient transport, pharmacies, blood banks, surgical pathology, and other departments). The OR staff must also integrate their work with many other departments, such as recovery units, surgical clinics, radiology, laboratory, emergency department, critical care units, and others.

Similar to the “five rights” defined for medication management (right drug, right dose, right route, right time, right patient), in perioperative care, an amazing number of tasks, data, and technologies must come together correctly for patient safety and good clinical outcomes. Not only must the five “rights” of medication administration be done correctly—since highly sophisticated medications are administrated during and after surgical cases—but 15 additional items also must be precisely managed (Table 1). These many items are the basis for the complexity of a surgical case, and a failure or delay in any of them typically is the trigger for an error that can cause harm to the patient.

Beyond these many issues, the inherent nature of surgical cases creates an often unpredictable environment. Surgeries can take more or less time than planned, and emergent surgeries could present during the course of a shift. This reality makes it very hard to plan and schedule cases

and can quickly destroy a surgical schedule. For example, if a case early in the day runs late, it will delay the other cases scheduled for that surgical suite for the rest of the day.

The dynamic nature of cases and the entire perioperative support process add their own elements of complexity to perioperative management and place extra demands on any software used to support surgical care.

Finally, the need to maintain a sterile environment has forced surgical departments to be physically secured and closed off from the rest of the hospital or clinic. This isolation makes patient handoffs and data sharing even more difficult.

Table 1. People, equipment, and technologies that must be "right" for perioperative case safety and optimization

1. Patient
2. Time
3. Nurses
4. Surgeons
5. Anesthesiologists
6. Surgical support staff
7. Instrument case carts
8. Surgical equipment
9. Supplies
10. Medication
11. Medication dosing
12. Medication route
13. Surgical pathology
14. Medical gases
15. OR suite
16. OR suite cleaning
17. OR suite configuration and preparation
18. Patient data from electronic medical record
19. Clinical images
20. Surgical schedule

Perioperative Technology

The perioperative clinical process has been supported by a narrowly defined niche design approach to software. Software is required that offers a new vision and more holistic design, provides integrated function and supports the inherent complexity of the perioperative environment, has a sophisticated deployment, and supports and integrates all relevant technologies. Such an undertaking would require an unprecedented depth of partnership for all parties involved in creating and supporting technology in this area.

The technology requirements for the perioperative environment must be supported from a holistic viewpoint. Each technology element must integrate with the larger set of technologies used in the OR and throughout the perioperative process, including all aspects of information technology and clinical equipment. To enable data sharing, all perioperative data and knowledge bases must share common metadata. They also must support all clinical and administrative data for perioperative care, from the initial identification of a surgical case, through surgery, recovery, and ongoing outcome analysis. Clinical vocabularies and other data descriptors must support the needs of all perioperative issues. Databases supporting this process must be modernized to include all types of data, images, text, knowledge, and equipment usage involved in the surgical case.

Workflow for clinicians must be made faster and easier, not slower and more complicated. Data should be entered once with real-time decision support and shared ubiquitously as needed. This must be enabled by high levels of surgical equipment and software application interoperability throughout the perioperative process. Data interoperability would dramatically reduce data redundancy and errors. All data generated by clinical equipment should flow into clinical databases without manual re-entry, thus increasing clinical acceptance and accuracy of data by reducing user workload and transcription errors.

An example of how perioperative requirements have not been fully addressed is the national focus on the much heralded software created to support computerized physician order entry (CPOE), which makes possible direct, online order entry of medications by physicians. CPOE software is highly focused on the inpatient care unit environment. As soon as a physician creates a clinical order, that order is sent directly to the pharmacy for pharmacist review; the drug order is filled; and then a nurse administers the drug, guided by online medication administration software. However, this CPOE paradigm does not come close to matching the needs of an anesthesiologist in an OR suite who typically performs all three functions: ordering, filling, and administration. Furthermore, typical CPOE software does not support the planning of and preparation for an OR case in terms of medication inventories, after-case documentation, and inventory replenishment.

Optimal software design must be able to support clinical tasks and simplify, rather than complicate, the process of clinical documentation. Technology must be used to promote and improve workflow and workplace ergonomics. It should not make tasks more difficult for surgical teams and clinicians, as is the case when technologies do not fit into an optimized care process design.

Need for a High Level of Technical Interoperability

Over time, two distinct types of health care technology have emerged in the perioperative environment, each having its own areas of specialization in technology applications. Health care information technology (HIT) refers to broadly functional software applications. By contrast, clinical information technology (CIT) describes clinical equipment, clinical imaging, and some types of instruments. These two types of technologies usually are created and supported by different vendors, typically using different standards, and are often focused on different outcomes. In many hospitals, it is common to find HIT and CIT utilizing different networks, or at least subnets, that are secured from each other. Technologies within the HIT or CIT categories often do not interoperate, or share relevant data; it is even more rare for technologies to interoperate between these two categories. See the Appendix for a glossary of abbreviations and key terms relevant to HIT.

Examples of HIT include software applications that support admitting, scheduling, clinical documentation, pharmacy, laboratory, and other departments. HIT is typically deployed to meet the needs of a broad process or a function. Interoperability has improved between software modules of this type. Data interface standards, such as Health Level 7 (HL7) are used to share patient level data. The growth of vendor-created integrated software suites has also improved the interoperability of data between specific software modules.

CIT includes picture archive and communications systems (PACS) and various clinical imaging technologies, robotic surgical systems, perfusion pumps, mechanical ventilators, infusion pumps, anesthesia delivery systems, automated medication cabinets, and others. Any and all of these technology resources might be critical in the performance of a single surgical procedure. CIT is focused on specific clinical tasks and can be highly sophisticated. These technologies are often regulated by the Food and Drug Administration (FDA) and, therefore, can be difficult and time-consuming to change quickly or interoperate with other technologies. Standards include the

Digital Imaging and Communications in Medicine (DICOM) to exchange clinical images, and the ANSI/ IEEE 1073 standard—the Medical Information Bus (MIB) that defines how to connect critical care bedside medical devices and HIT software applications. Future products need to break through this legacy of technologies and software that were designed as if they were the only element of technology used during a case. They need to create new levels of partnership to ensure that technology used in the perioperative environment fully interoperates with all other relevant technologies.

Perioperative Informatics

The unique requirements of surgical specialties and the perioperative care process have been dramatically undersupported in informatics research and field work. A critical foundation for improving the way technology and information support perioperative clinicians would be an improvement in perioperative focus in informatics, to help create the required focus and knowledge set needed to support perioperative care.[3] Opportunities abound for informatics-based improvements in perioperative care. Additional perioperative work groups and industry partnerships need to be created. Various health care standards should be reviewed to ensure full support of perioperative requirements. Table 2 summarizes some of the proposed perioperative informatics focus areas and opportunities.

The reality of surgical case prioritization and timing must be supported by a real-time, current-state schedule that changes dynamically and automatically as work load varies. Old time versions of schedules (paper or grease boards) should be replaced by electronic schedule display boards that can be viewed by all people in various roles. Examples of how surgery schedule access must be supported include:

- Large screen “tracker boards” in key locations.
- Secure Web pages.
- Handheld PDAs.
- Wireless voice over IP network (VoIP) communication devices.
- Pager units.

Only when a perioperative team truly converts to a single and shared digital surgery schedule will modern software be able to fully support the perioperative process. If paper versions of the schedule continue to be used (the paper schedule is always immediately out of date), or if elements of the perioperative team use their own “off schedule” versions of planned cases, it is a clear indication that either the software is not yet sophisticated enough to support clinicians’ needs, or the perioperative process is not yet fully converted to a digital shared format. Either way, what support software can achieve is limited.

Safety is increased by monitoring vital signs in the OR. Similarly, safety can be improved by monitoring the flow of patients and documentation through the perioperative process. Reporting and analysis can be improved if they are based on newly designed longitudinal perioperative databases. Current systems need to be redesigned to integrate data from multiple sources. This increases safety by eliminating transcription errors and duplication of effort.

Table 2. Opportunities for informatics-based perioperative improvements

- Perioperative documentation templates.
- Assessment and improvement of clinical vocabularies to optimally support perioperative requirements (e.g., CPT, SNOMED, others).
- Creation of cases in perioperative staff use of technology.
- Creation of models to assess the effects of new technology designs and standards on the perioperative process and patient outcomes.
- Perioperative workflow design and optimization.
- Software design and usability studies focused on perioperative requirements.
- Creation and maintenance of surgical knowledge bases.
- Inference engine (knowledge base) deployment strategies.
- Surgical case longitudinal database design.
- Interoperability of clinical equipment and clinical software: design, standards, testing.
- Surgery command-and-control techniques and systems.
- Perioperative data analysis.
- Perioperative case registries and outcome studies.
- Perioperative error analysis and trending.
- Optimal training strategies: ensuring that perioperative staff are optimally trained in the use of software and technology.
- Meta-analysis of peer-reviewed literature on surgery and perioperative use of technology.
- Others.

It is critical to focus reporting and analysis with a process-based approach that analyzes key process steps, cycle time, backlogs, rework, and errors. If measures of quality, productivity, service, cost per unit of service, and patient/clinician satisfaction can be created along the entire perioperative process, historical mysteries about hard to solve problems can be illuminated and resolved. The goal is to utilize software to support the optimal perioperative process, and once sophisticated workflow-enabled software is deployed, to utilize real-time measurement to constantly track and improve how work is defined, how process steps are staffed, and how resources are utilized. Ongoing process course corrections or fine tuning should be encouraged and expected.

Newly discovered medical evidence can take years to become incorporated into general practice. However, new practice guidelines or measurements—such as perioperative beta-blockade, prophylactic antibiotic administration, and normothermia maintenance—can be incorporated into the online knowledge deployed with perioperative software. Software must be designed to assist clinicians in utilizing clinical guidelines and evidence-based “best practice.”

Expert systems and predictive alerting engines should be designed to assess data in real time for potential unsafe or error conditions before patients are harmed. Expert systems could also be used much more extensively to assess digital patient data and create evidence-based treatment suggestions at relevant points in the perioperative care process. Knowledge-aware software becomes a tool both to promote evidence-based practice and to report compliance with "best practice" and new research findings.

A key question for the designers of future perioperative systems is: Should perioperative surgical software applications be designed to be stand-alone (niche), or should they be designed to be part of larger application suites? The primary advantage for the niche design is a more specific focus on the needs of perioperative-based clinicians. However, these systems typically have not been designed to interoperate with other applications that are used within the perioperative process, or outside the process, to share relevant information. As clinical software uses more online clinical knowledge and software tools (e.g., inference engines) to manage that knowledge, it will become even harder to interoperate at the level required.

Larger clinical application suites often include perioperative applications, but these do not provide the depth of function or the usability needed in the perioperative environment. Thus, they have been poorly accepted to date. Given the inherent difficulty of achieving a high level of software interoperability, well-designed integrated "suites" of clinical applications might provide the best future foundation for delivering sophisticated clinical support function. However, they ultimately must be able to deliver the level of function needed by clinicians and staff in the perioperative care process that is so far available only from the niche applications.

RFID Technologies

To support the real-time surgery schedule and enable perioperative process-support software to be "aware" of the many key elements of surgical cases, the use of radio frequency identification (RFID) holds significant promise to bring dramatic improvements in sophistication to perioperative software.

To make use of RFID and positioning technologies, a ubiquitous sensor environment or network must be deployed throughout the perioperative environment. In the past, this involved deployment of new and proprietary radio frequency sensors, but many products now support the more traditional 802.11 wireless networks that are already in use in many hospitals and clinics. With this system, important items that are "tagged" with RFID chips can be located and identified by the radio frequency network; the precise location can be noted, and in some cases, the movement (e.g., an object going into or leaving a surgical suite) can be recorded.

The RFID tags or chips can be "passive" with no power needed by the chip and provide simple identification. They also can be "active"—that is, driven by a power source and able to interact with the network to infer events, task completion, or relevant movement. Data about tag locations and movement are written in real time into a database, and unique visualization software is used to transform highly specific location data into a map or image that personnel can use to track key events or issues. For example, once the architectural layout of the surgical department is scanned into the visualization software, after a one-time special setup

programming, the location of relevant tag-provided data becomes visible on a computer rendering of the department.

The possibilities of using RFID tags in the perioperative process are many and varied. For example, they would permit:

- Visualization of the exact location of a piece of surgical equipment or a case cart.
- Automation of time fields of patient entry into or exit from the OR.
- Notation of which clinicians are present in an OR suite during a surgical case.

RFID chips are not all the same; some are less sophisticated and provide only a rough location of a tagged object (e.g., accurate to within 15 feet). This low level and low cost degree of location precision is fine for some items, such as the location of a piece of equipment. However, more precision would be needed for certain other functions, such as surgical instrument management, a critical and very difficult task. Electronic tagging through barcoding or RFID tagging and tracking technologies could be designed to individually identify surgical instruments, which can then be tracked from operation to operation, making sure all the correct instruments are in the correct place at the correct time. Proper instrument quality assurance procedures could also be enabled through tracking the history of each surgical instrument. Items that need repair or are at the end of their useful life would be electronically flagged and could be taken out of circulation prior to delivery to an OR.

The promise of more sophisticated function using RFID networks and chips is called "co-location." This capability depends on higher functioning, and higher cost, RFID chips that have the ability to note a much more exact geographic calculation of location to within 12 to 18 inches. Once a more precise location of two items can be calculated—for example, the RFID tag on a patient and a tag on a perfusion machine used on that patient during surgery—the two tagged items can be "co-located" and recorded in a database. In this scenario, if a patient and perfusion machine were within 3 feet of each other for more than 15 minutes, a software application would note the event and enter the serial number of that perfusion machine into the patient's surgical case history. Should there ever be a recall or problem with that specific piece of surgical equipment, all patients on whom it was used could be quickly located in the database for any necessary followup.

In a similar manner, blood safety could be improved by tagging blood products, and "co-location" technology could be used to assess whether the blood product (e.g., blood type A+) matches the blood type of a patient (as recorded in the electronic medical record) who is located within a predefined distance of that blood product. If the blood product does not match the patient's blood type, an alarm sounds. These are just a few of the possibilities of how tagging and "co-location" could be utilized to greatly enhance efficiency and patient safety.

Implementation

Adoption of HIT in the perioperative process has often been slow, expensive, and difficult. Integrating even well-designed and workflow-enabled software into the perioperative workflow is not easy. Clinicians have little tolerance for systems that do not work as claimed, even when the systems are clearly an improvement over the former noncomputerized versions. Because they

are reluctant to change current work patterns, the value of new software and process changes must be clearly demonstrated and delivered to gain clinician acceptance. Workflow for clinicians must be made easier and faster, not more complicated and slower. It helps when key clinical and administrative leadership within the perioperative process champion the perioperative system. Second only to patient safety, the bottom line for clinicians is what the software can do to deliver improvements that would justify investments in new software and technologies—for example, streamlining workflow, increasing efficiency, supporting more cases, increasing revenue, and improving time management.

As in the successful adoption of any technology, especially in a clinical environment, providing resources for the training of all affected clinicians is critical. Successful training in the perioperative environment is especially challenging, since hours available for training for surgeons, anesthesiologists, nurses, and OR support staff are typically limited and costly. It is a challenge to provide technology training without negatively affecting the surgery schedule.

A larger OR suite might require several iterations of the same training session due to the large number and variety of shifts. To help with the training time burden, new systems must also be designed to be intuitive to those using the system so training can be minimized. Web-based training materials can provide a significant value, since they can be accessed by staff at home or at other locations.

An important design approach is to deliver training in smaller content increments that support interruptions while training materials are learned. Furthermore, smaller content increments can be revisited for “just-in-time” rereading when needed. Additional reference materials, designed for adults who might not be experts in clinical software usage, should be offered to perioperative staff.

The most important time to support perioperative staff is when new software is deployed. A large number of extra clinical, technology support, and vendor staff should be available to help if any problems or questions arise during implementation. This period during which extra support is required could last for weeks or months after new software is deployed, and the cost of providing this critical higher level of support is not trivial.

Implementation does not end with the installation of the hardware and software. A significant part of the original technology investment must be allocated each year to support ongoing software and technology needs. It is common for clinical software to have one or two major new versions released each year. These new versions should be approached as smaller scale deployments, not as consuming as the original software deployment, but not trivial either, and resources must be allocated. It is important for the software used in the perioperative environment to be kept as current as possible. It is not advisable to fall too far behind the current software release, as bugs and other problems with the current version will not be fixed, and new functions will not be available if the software is not kept current.

Installing computer workstations in the perioperative environment also is not a trivial task. Due to the space limitations of most OR suites, system designers need to be creative about using mounting hardware that provides access to the computer workstation when it is in use and also takes minimal space when the workstation is not in use. Like all equipment in the perioperative environment,

such equipment has special requirements, such as the need for thorough cleaning and electrical safety. New microcomputers and communication devices are now available with cases made from materials with embedded antimicrobial agents that provide protection against a broad spectrum of bacteria, mold, and fungi. Technology products should be at least semi-waterproof and have the ability to be wiped clean for disinfection. Examples include the Vocera® wireless communications badge with embedded BioCote® silver-based antimicrobial agent (Vocera Communications, Inc., San Jose, CA), and the Motion C5 tablet computer from Motion Computing, which can be washed using many chemical disinfectants (Motion Computing, Inc., Austin, TX).

As with all patient care environments, ethical and legal issues demand that privacy rights be respected. Thus, the placement of computer hardware in publicly accessible areas must be limited to systems for which access can be controlled or which display data only in a format that is consistent with privacy rules, such HIPAA regulations. Special care should be taken to locate all computer/equipment view screens in a way to prevent patient-identified information from being accessed by nonauthorized people. This includes the installation of large computer monitors used to support patient tracking information—tracker boards—similar to those in airports that display flight information. Tracker boards can still be utilized and can be very valuable, but data on them should be displayed to support privacy standards. For example, the software can be made to display the patient's initials instead of their full name.

Focus on Technology Use in Health Care: Inclusion of Perioperative Requirements

Government agencies, health care systems, and professional organizations have now realized the importance of creating sophisticated HIT systems. Incentives are being planned in terms of reimbursement increases and other incentives for implementing HIT systems.[4] The Office of the National Coordinator for Health Information Technology (ONCHIT) was created on executive order of President George W. Bush. The national coordinator of Health IT, who reports to the Secretary of Health and Human Services (HHS), has focused on implementing the president's vision for widespread adoption of interoperable electronic health records (EHRs) within 10 years. Toward this goal, major efforts have been undertaken to support patient data sharing, improve health care IT standards, and foster improvements in health care software to meet clinicians' needs.

Significant resources are now being allocated for the development of sophisticated regional and national capabilities to share clinical information at the community level. In October 2005, HHS awarded three contracts totaling $17.5 million to public-private groups that will accelerate the adoption of HIT and the secure portability of health information across the United States.[5] HHS and ONCHIT have also supported the relatively new Certification Commission for Healthcare Information Technology (CCHIT) with a $7.5 million contract awarded in October 2005. It is critical that the data and clinical requirements of the perioperative care process be included in this vision and in the infrastructure that is now being created.

CCHIT has taken an approach similar to the Underwriters Laboratories (UL), where products are put through rigorous testing and have to prove they function and that they comply with relevant standards. CCHIT has created standards for ambulatory and inpatient EHRs and is now working

on standards for networks that share clinical data. For the first time, health care software vendors must actually prove they comply with industry standards and deliver specific items in the areas of function, interoperability, and security. Many vendors have now put their products through the CCHIT testing process and have earned the right to use the CCHIT symbol on their products, verifying that the products deliver mandated levels of function.

CCHIT is now beginning to focus on more specific areas of IT health care support, including child health, cardiovascular medicine, and the emergency department. The effort to create standards and testing scripts for more specialized areas starts with the creation of an expert panel and formulation of goals and standards. Given the unique issues facing perioperative and surgical medicine, an important step would be to create a CCHIT work group in this area.

Conclusion

The challenges in perioperative and surgical care are daunting. While many approaches and technologies hold great promise for perioperative care, incremental change and use of new technologies will not be enough. To fulfill the promise of new informatics and technology approaches, a dramatic change is needed in how technology is designed, deployed, and supported within the perioperative environment.

Technology that is designed expressly for and adequately tailored to the demands of the perioperative care process and requirements will result in optimal clinical adoption and outcomes. Through the design and implementation of such systems, the perioperative process can help maximize improvements to safety, patient and clinician satisfaction, and ultimately the success of this highly complex and financially important area of clinical care.

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Appendix: Abbreviations and key terms

Acronym	Description
IT	Information technology
CPOE	Computerized physician order entry
CIT	Clinical information technology
HIT	Health care information technology
DICOM	Digital imaging and communications in medicine; the standard for distributing and viewing any kind of medical images
PACS	Picture archive and communications system; technology to store and view clinical images
HL7	Health Level 7; the standard for electronic interchange of clinical, financial, and administrative information among health care-oriented computer systems
MIB	Medical information bus; the standard to connect critical care equipment at the beside to health information technology software applications
CPT	Current procedural terminology; defines and describes medical, surgical, and diagnostic services and is supported by the American Medical Association (AMA)
SNOMED CT®	Systematized nomenclature of medicine-clinical terms; a systematically organized computer processable collection of medical terminology that defines most areas of clinical information, including diseases, findings, procedures, microorganisms, and pharmaceuticals
PDA	Personal digital assistant
VoIP	Voice over internet protocol; technologies to make voice calls over a broadband internet connection
RFID	Radio frequency identification
802.11	Standards for wireless local area networks developed by the Institute of Electrical and Electronics Engineers (IEEE). The 802.11 standard has many different protocols, including “a,” “b,” “g,” and “n,” each with different speeds and attributes
ANSI	American National Standards Institute
CCHIT	Certification Commission on Health Information Technology
HER	Electronic health record
ONCHIT	Officer of the National Coordinator for Health Information Technology
HHS	Department of Health and Human Services

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

Emily M. Campbell, RN, MS; Hong Li, MD, MSPH; Tomi Mori, PhD; Patricia Osterweil, BS; Jeanne-Marie Guise, MD, MPH

Abstract

Objective: Implementation of health information technology (HIT) is a national priority to improve patient safety, yet little is known about how electronic charting affects workflow and patient care in busy, fast-paced hospital units. Labor and delivery units are high-risk and high-cost environments in which failures in data transmission or delays in patient care can have tragic consequences. We evaluated the impact of the introduction of an inpatient electronic health record (EHR) on clinical workflow in a high-volume labor and delivery unit in a large university hospital in the United States. **Methods:** A work-sampling study was performed before and after implementation. Objective observers recorded workflow activities for 3.5-hour periods over nine work shifts (day, evening, night) during 2-week study periods before and after EHR implementation. Activities were standardized to counts per shift and compared using Wilcox two-sample tests. **Results:** For all health care workers, after introduction of an EHR, direct patient care activities increased from a mean of 12.0 to 15.4 ($P = 0.004$); computer activities increased from 1.9 to 8.5 ($P < 0.0001$); and personal/idle time decreased from 3.1 to 1.4 ($P = 0.0002$). **Conclusion:** The introduction of an EHR into a busy labor and delivery setting did not reduce time spent in direct patient care activities; instead, direct patient care activities increased.

Introduction

In 1999, the Institute of Medicine (IOM) brought the world's attention to the patient safety vulnerabilities of the U.S. health care system and emphasized the need for widespread adoption of electronic health records (EHRs) as a fundamental component of a new health information technology (HIT) infrastructure designed to improve health care quality.[1] Little research has been done on the impact of HIT, such as EHRs and other interventions, on patient care and safety in obstetrics. Given that childbirth is the leading reason for hospitalization in the United States, comprising over 4 million hospital discharges each year, pregnant women and infants are particularly at risk for safety issues,[2] making evaluation of the impact of EHRs on obstetric care especially timely.

EHRs have yet to be widely implemented in the United States,[3] but data on the impact of these systems on patient safety are conflicting. The use of EHRs with embedded clinical decision support (CDS) can improve adherence to clinical care guidelines,[4] shorten the length of in-hospital stay,[5] and improve overall clinical documentation completeness, legibility, and understandability when compared to traditional paper-based medical records.[6, 7] However, a recent, large study suggested that EHRs are not associated with better quality of care.[8]

Additionally, significant barriers have been identified as limiting ready adoption of these systems. The most commonly cited barriers include high implementation costs, poor integration with legacy systems, fear of technology failure, potential for new kinds of errors, and strong physician resistance due to concerns that practice disruption and loss of clinical productivity are inevitable, regardless of the gains in safety and efficiency the technology might afford.[3, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20]

Relatively few studies have evaluated EHRs with respect to their impact on clinical work when compared with the larger body of work on the effects of EHRs on physician and/or patient satisfaction, medication error reduction, clinical guideline compliance, risk reduction, and patient outcomes.[21, 22, 23] Of the studies that have evaluated the impact of EHR implementation on clinical work, the systems under evaluation were found to support both ordering and charting activities, but the studies did not report on time utilization specific to clinical documentation alone.[24, 25, 26, 27, 28] In addition, although there is a growing body of research on how EHRs impact nursing care activities, very few studies have focused on how EHRs affect the amount of time physicians spend in direct patient care activities.[21, 25, 29, 30] Finally, we can find no research on the implementation or use of EHRs in the obstetric setting, an area noted to be lagging behind other specialties in EHR adoption.[31] The aim of the larger patient safety health information technology (HIT) study[a] is to systematically evaluate the value of incremental advancements in HIT integration for patient safety and clinical care. This study focuses on the impact of an inpatient electronic obstetric charting system on clinical workflow in a fast-paced, high-volume labor and delivery (L&D) unit.

Methods

Setting

This study was conducted in a large U.S. teaching hospital L&D unit between March 2005 and August 2006 with approval of the hospital Institutional Review Board. The onsite hospital clinics manage over 34,000 prenatal ambulatory clinic patient visits per year. The 450-bed hospital handles over 2,600 deliveries each year from the outpatient clinics, outlying health departments, and transfers. Care on the L&D unit is provided by nurses, obstetrics and family medicine residents, and faculty (including maternal fetal medicine fellows and faculty) and certified nurse midwives.

Prior to this study, all obstetric clinical care documentation was handwritten as free-text progress notes or by using specialized forms for inclusion in the official, paper-based patient record. In June 2005, after this study had begun, all inpatient obstetric charting (including triage, admission, delivery, and discharge) was entered exclusively in a hospital-developed, inpatient electronic, obstetric charting system, referred to as “STORC.” By December 2005, outpatient laboratory data were integrated into STORC, so that this important information would be available when women arrived for delivery. Full outpatient data integration occurred in March

[a] Funded by the Agency for Healthcare Research and Quality (AHRQ), No. HS015321.

2006. The completion of this outpatient STORC implementation meant that all obstetric data were now collected and displayed in a single, integrated system that was available to clinicians providing care at any point during a woman's pregnancy.

Our study examined inpatient work practices before the initial implementation of STORC in March 2005, when all documentation was paper-based, and in August 2006, 5 months after the full integrated release, when all documentation was completed electronically.

HIT Intervention

STORC is a comprehensive obstetric charting system designed with the concurrent goals of facilitating clinical care, enabling clinical outcomes data collection, and promoting patient safety. Incremental advances in systems and data integration were released in series to enable evaluation of value enhancements with each release. In its final, fully integrated form, STORC:

- Integrates existing, disparate data sources into a single point-of-care clinical application (e.g., laboratory results reporting and admission, outpatient and inpatient integration, discharge, and transfer data).
- Pulls key clinical (i.e., pregnancy dating; medical, surgical, and obstetric history; allergies), laboratory, and demographic data collected during prior visits or from hospital systems directly into note fields for editing.
- Provides clinical decision support relevant to obstetrics.
- Provides shortcuts and other tools to speed up care activities (e.g., default values, tailored pick lists, calculators to estimate gestational ages).
- Prints documents in standardized formats.
- Prints patient educational materials and discharge instructions in English or Spanish.
- Keeps clinicians apprised of current clinical studies and patient qualifications for enrollment and more.
- Does not provide clinical order entry functionality.

Figure 1 shows an example of the STORC interface, and Figure 2 provides an example of STORC documentation output for the paper medical record.

Study Design

Work-sampling. Work-sampling studies seek to identify the tasks clinicians perform at predetermined, discrete time intervals, so that inferences can be made regarding the overall time a clinician engages in these activities during a given time period. We adapted the work-sampling approach utilized by Fontaine, et al.,[32] because this method allows a single researcher to make multiple observations; it works well in clinical settings where staff work is generally restricted to a single physical location (e.g., an inpatient obstetric unit); and it allows researchers to "blend in" more readily in the practice environment, thus reducing the potential for performance bias.[33] Table 1 describes the formal observations and abstractions we used to identify clinical workflow activities.

Observations. Observational sessions took place in 2-week blocks on the L&D Unit. A single researcher conducted three, 3.5-hour observation sessions during each of three standard work

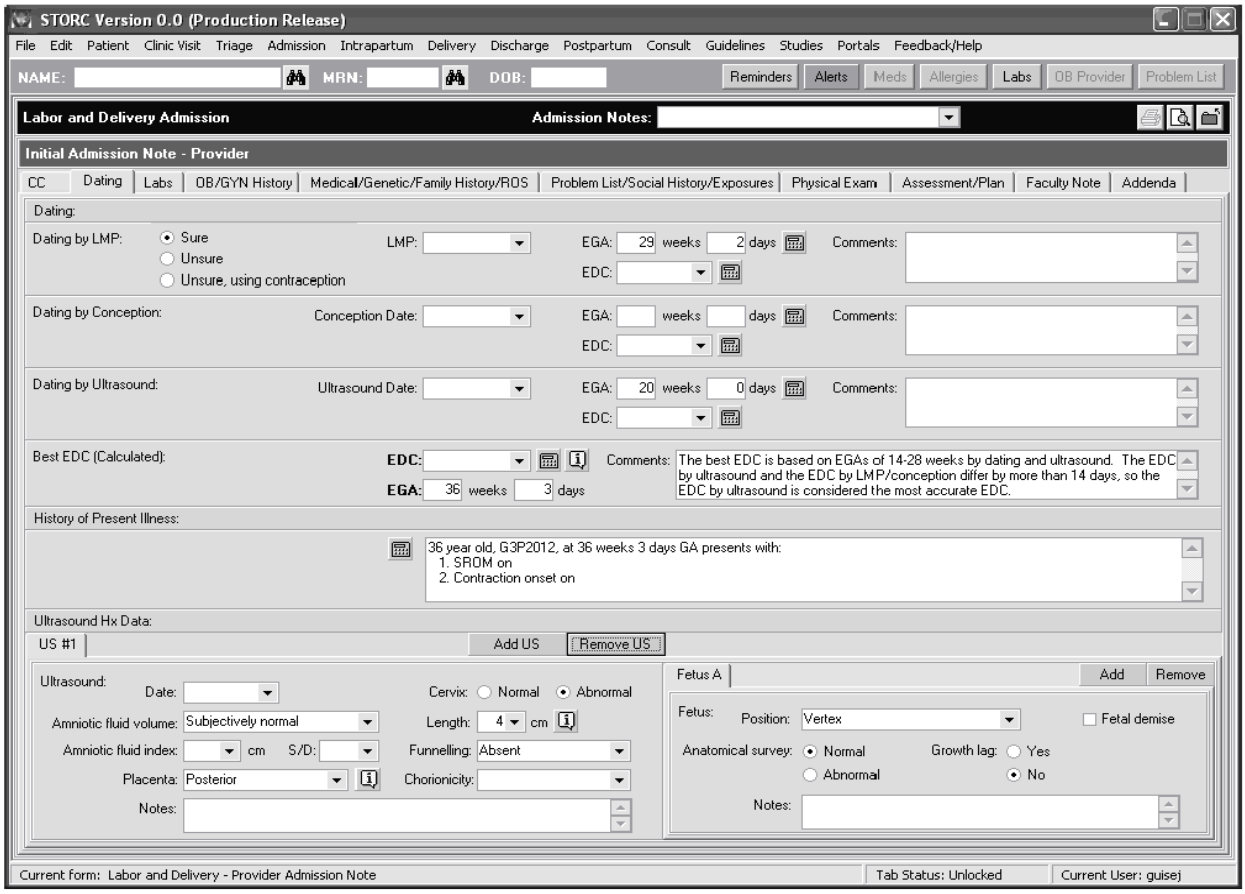


Figure 1. Example of STORC interface.

shifts (i.e., 7 am-3 pm, 3 pm-11 pm, and 11 pm-7 am) for a total of nine observation sessions during each 2-week block. Use of a single researcher eliminated interobserver bias; the observational periods were spread across the three daily shifts to assure collection of a comprehensive and representational set of work tasks.

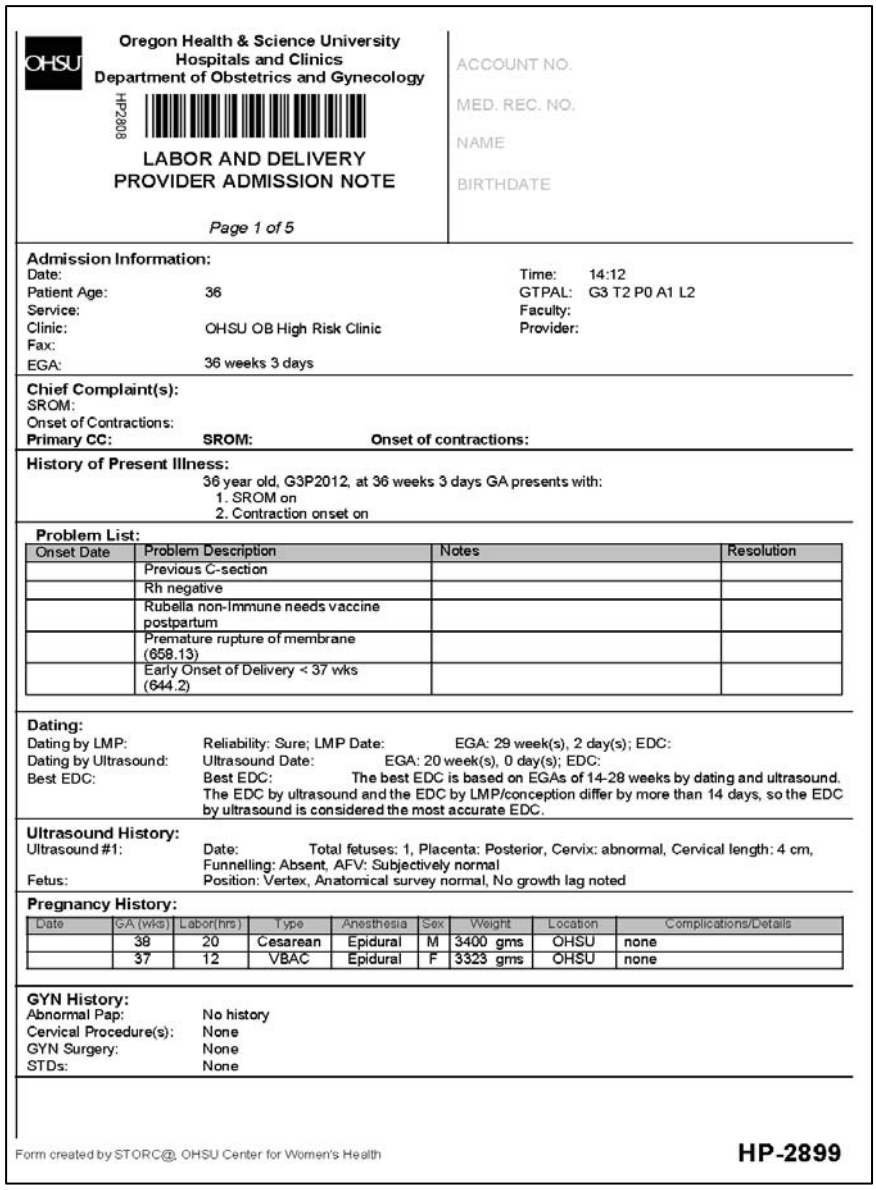
At the start of each sampling session, the researcher obtained a list of the health care providers (i.e., nurses, medical residents, medical faculty) scheduled to work during that period. Nurse midwives were excluded from this study because they have a lower volume of patient care and would not be expected to be on L&D many times, if at all, during the observation period. All providers on duty were randomly assigned observation times throughout a 3.5-hour observation period.

The researcher cycled through the list, observing the work activities of each provider every 10 minutes, using an obstetric workflow abstraction form to record the observations. When the next provider could not be located in any L&D room, the activity was listed as “off floor,” and the next provider on the list was located for observation. Providers had the option to decline observation; in these cases the observation for that provider for the specific time interval became “declined participation.” When providers were in patient rooms, the provider was assumed to be involved in direct patient care activities and recorded accordingly. When a provider was involved in simultaneous activities, one of which involved direct patient care (e.g., talking with a patient’s

family member while on hold on the telephone), the researcher recorded the direct patient care activity as the primary activity.

Statistical Analysis

The main outcome of interest for this study was the counts of clustered clinical activities prior to the implementation of STORC in the inpatient setting and 1 year after STORC was fully operational. All analyses were performed using SAS®/STATS software release 9.2 (SAS Institute, Cary, NC). Provider type and the ratio of nurses to patients (used to assess unit workload) in the two observational periods were compared using Chi-square and Wilcox two-sample tests.



Oregon Health & Science University
Hospitals and Clinics
Department of Obstetrics and Gynecology

HP2808

LABOR AND DELIVERY
PROVIDER ADMISSION NOTE

ACCOUNT NO.
MED. REC. NO.
NAME
BIRTHDATE

Page 1 of 5

Admission Information:

Date:		Time:	14:12
Patient Age:	36	GTPAL:	G3 T2 P0 A1 L2
Service:		Faculty:	
Clinic:	OHSU OB High Risk Clinic	Provider:	
Fax:			
EGA:	36 weeks 3 days		

Chief Complaint(s):
SROM:
Onset of Contractions:
Primary CC: **SROM:** **Onset of contractions:**

History of Present Illness:
36 year old, G3P2012, at 36 weeks 3 days GA presents with:
1. SROM on
2. Contraction onset on

Problem List:

Onset Date	Problem Description	Notes	Resolution
	Previous C-section		
	Rh negative		
	Rubella non-Immune needs vaccine postpartum		
	Premature rupture of membrane (658.13)		
	Early Onset of Delivery < 37 wks (644.2)		

Dating:

Dating by LMP:	Reliability: Sure; LMP Date:	EGA: 29 week(s), 2 day(s); EDC:
Dating by Ultrasound:	Ultrasound Date:	EGA: 20 week(s), 0 day(s); EDC:
Best EDC:	Best EDC:	The best EDC is based on EGAs of 14-28 weeks by dating and ultrasound. The EDC by ultrasound and the EDC by LMP/conception differ by more than 14 days, so the EDC by ultrasound is considered the most accurate EDC.

Ultrasound History:

Ultrasound #1:	Date: Total fetuses: 1, Placenta: Posterior, Cervix: abnormal, Cervical length: 4 cm, Funnelling: Absent, AFV: Subjectively normal
Fetus:	Position: Vertex, Anatomical survey normal, No growth lag noted

Pregnancy History:

Date	GA (wks)	Labor(hrs)	Type	Anesthesia	Sex	Weight	Location	Complications/Details
	38	20	Cesarean	Epidural	M	3400 gms	OHSU	none
	37	12	VBAC	Epidural	F	3323 gms	OHSU	none

GYN History:

Abnormal Pap:	No history
Cervical Procedure(s):	None
GYN Surgery:	None
STDs:	None

Form created by STORC@, OHSU Center for Women's Health

HP-2899

Figure 2. Example of formatted output from STORC.

Recorded activities for each provider were treated as independent observations and standardized to activity counts per 8-hour shift. Activity differences between the before- and after-implementation study periods were compared using the Wilcox two-sample test. Workload-adjusted activity on direct patient care was analyzed using analysis of covariance (ANCOVA) with a generalized linear model.

Table 1. Work activity categories and their operational definitions

Work activity	Operational definition
Off floor	Provider to be observed cannot be located during observation period
Declined participation	Provider declines to participate in the scheduled observation
Talk/phone (internal)	For telephone calls internal to OHSU. Includes the time from picking up the phone to hanging up the phone for voice calls. Does not include the time spent on the phone on-hold or during faxing
Wait/phone (internal)	For telephone calls internal to OHSU. Includes the time from when the clinician is put on-hold to when the other party reconnects or the clinician hangs up. The clinician may be engaged in another task at the same time
Talk/phone (external)	For telephone calls external to OHSU. Includes the time from picking up the phone to hanging up the phone for voice calls
Wait/phone (external)	For telephone calls external to OHSU. Includes the time from when the clinician is put on-hold to when the other party reconnects or the clinician hangs up. The clinician may be engaged in another task at the same time
Fax	Initiated when the clinician first engages fax forms and ends when the clinician completes use of the fax machine. During fax transmission of longer documents, the clinician may be engaged in another activity while the fax is completing
Direct patient care	Includes any face-to-face interaction with the patient, in our out of the exam room. This may include interactions with the patient's family
Talk/person	Involves talking to anyone other than the patient or the patient's family
Read/paper	Includes reading or viewing anything on paper, including, but not limited to, the paper medical record, printouts, reference materials, etc.
Write/paper	Includes writing information onto any paper and/or writing on the L&D unit patient management "white board"
Personal	Includes any non-work-related activity, such as scheduled and unscheduled breaks, personal phone calls, interactions with nonemployees, non-work-related interactions with co-workers, etc.
Read/computer	Includes any form of viewing or reading data on a computer screen, or making printouts
Write/computer	Includes any form of entering data into the computer, whether by keyboard or mouse
Gather/check	Includes time spent gathering and checking information, supplies, or medications needed for the delivery of care. This includes work with the medication-dispensing machines, evaluation of fetal and/or maternal monitoring strips or displays, checking the L&D "white board," etc.
Listening/recording	Listening to information recorded on a cassette recorder or Dictaphone
Talk/recording	Dictation for transcription
Environmental maintenance (nonclinical)	Organizing nonclinical work areas: arranging documents, replacing printer toner, maintaining other office equipment, etc.
Environmental maintenance (clinical)	Cleaning or setting up patient encounter areas
Travel	Time spent in transit from one work area to another
Other	Any activity that cannot be classified in one of the above categories

Results

Basic Study Characteristics

Table 2 describes the basic characteristics of the study, including the number of observations for each type of provider and the unit workload (estimated by the ratio of nurses to patients). A total of 195 observations were obtained over the two study periods: 61.5 percent of observations involved nurses; 31.8 percent involved residents; the remaining 6.7 percent involved medical faculty.

Table 2. Characteristics of observational period

Factors	STORC EHR		Comparison *P-value*
	Before	After	
Observation times			
Duration (weeks)	2	2	
Hours/shift	3.5	3.5	
Shifts			
Total	9	9	
Day/evening/night	3 / 3 / 3	3 / 3 / 3	
Observations	**N (%)**	**N (%)**	
Nurse	61 (61.0)	59 (62.1)	NS
Resident	32 (32.0)	30 (31.6)	NS
Attending physician	7 (7.0)	6 (6.3)	NS
Total	100	95	
Workload			
Nurses/patients (mean ± SD)	0.98 ± 0.31	1.00 ± 0.37	NS

As shown in Table 3, both the counts of computer-related activities (1.9 vs. 8.5, $P < 0.0001$) and direct patient care (12.0 vs. 15.4, $P = 0.004$) increased significantly following STORC implementation. Similar patterns were observed for nurses and residents.

It is also notable that counts of nurses' activities related to gathering and checking medical records (1.5 vs. 3.0, $P = 0.002$) increased after STORC EHR implementation. Although comparisons for faculty were not statistically significant due to small sample size, activity counts for computer work (0.3 vs. 4.2), direct patient care (7.8 vs. 8.8), and talking to nurses or residents (8.2 vs. 11.4) all increased after the implementation of STORC. Because talking to other workers is a vital component of direct patient care, we grouped direct patient care activities and talking with other workers together under the header "patient-related work" to more fully assess the impact of STORC on these activities. Patient-related work activities increased significantly (20.1 vs. 23.9, $P = 0.001$) overall, with residents having the greatest activity count increase (21.3 vs. 25.8, $P = 0.005$), followed by nurses (13.0 vs. 16.1, $P = 0.02$).

Although the amount of paperwork did not seem to decrease (4.3 vs. 4.5 counts per shift), personal/idle waiting time decreased from 4.1 to 1.8 counts per shift. Activity counts for other recorded activities—such as telephone/fax use, recording, environmental maintenance, and traveling—were very low before STORC implementation, and no significant difference was detected (data not shown).

Table 3. Working pattern by provider type

Provider/activity	STORC Before Mean[a]	STORC Before ±SD	STORC After Mean[a]	STORC After ±SD	Comparison *P*-value[b]
Overall					
Total observations	100		95		
Computer work	1.9	3.8	8.5	5.6	<0.0001
Direct patient care	12.0	8.3	15.4	8.8	0.004
Talk to other workers	8.1	5.6	8.5	5.8	NS
Paper work	3.9	3.3	4.2	3.8	NS
Personal/idle waiting	3.1	3.9	1.4	2.3	0.0002
Nurse					
Total observations	61		59		
Computer work	1.5	2.9	9.7	5.7	<0.0001
Direct patient care	13.0	8.5	16.1	8.8	0.06
Talk to other workers	6.9	5.0	7.3	4.7	NS
Paper work	4.3	3.5	4.5	3.9	NS
Personal/idle waiting	4.1	4.5	1.8	2.7	0.0007
Gather and check medical records	1.5	2.0	3.0	3.0	0.002
Resident					
Total observations	32		30		
Computer work	3.1	5.3	6.9	4.7	<0.0001
Direct patient care	10.9	6.8	15.4	9.2	0.05
Talk to other workers	10.4	5.1	10.4	6.8	NS
Paper work	3.2	3.2	4.1	3.7	NS
Personal/idle waiting	1.3	1.7	0.7	1.2	0.07
MD attending					
Total observations	7		6		
Computer work	0.3	0.9	4.2	5.3	0.06
Direct patient care	7.8	11.6	8.8	3.7	NS
Talk to other workers	8.2	9.5	11.4	7.4	NS
Paper work	3.3	2.2	1.9	2.3	NS
Personal/idle waiting	0.7	1.1	0.4	0.9	NS

a Mean count/8-hour shift.

b Adjusted for unit workload (ratio of nurses to patients).

Direct Patient Care Activities

Comparisons of direct patient care activity counts before and after STORC implementation are summarized in Figure 3. Even after adjusting for workload, direct patient care activity counts showed a statistically significant increase for nurses (13.0 vs. 16.1, $P = 0.04$) and residents (10.9 vs. 15.4, $P = 0.02$). Although activity counts for attending staff increased, these differences were not significant. Overall, direct patient care activity increased significantly ($P = 0.03$) following implementation of STORC.

Discussion

Our results suggest that an EHR can be successfully implemented in busy, fast-paced, procedure-oriented hospital units without negatively affecting activities directly involving patients. We believe this finding is very important to patients, providers, hospitals, and policymakers, particularly during childbirth, when fetal status can change in minutes, but the experience leaves a permanent memory for families.

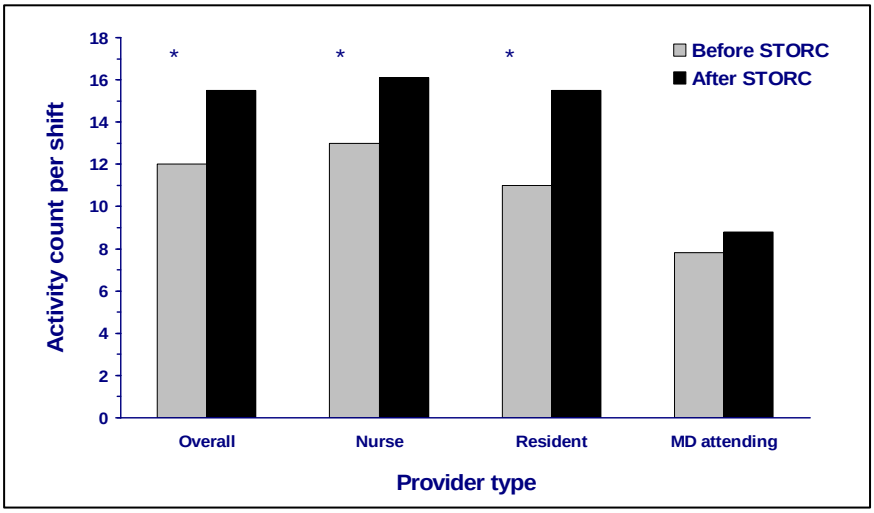


Figure 3. Direct patient care before and after STORC implementation. (* P <0.05)

We expected computer work to increase with the introduction of an EHR because the system marked the formal shift from pen-and-paper documentation to the computer. However, we were pleased to discover that this increase did not appear to come at the expense of direct patient care work. In fact, direct patient care activity counts significantly increased for nurses and medical residents, suggesting that EHRs, like STORC, might improve practice efficiency in other areas, despite the greater time spent at the computer. For example, direct importing of laboratory, prenatal visit, and scheduling data into the electronic patient record might have reduced the amount of time clinicians spent locating and collating this information from disparate sources in order to compile and synthesize sufficient data to provide care. Additionally, embedded calculators for determining due dates (estimated dates of conception), Bishop's scores, and preconfigured selections (e.g., pick lists, menus) may have led to time savings for clinicians.

Finally, the amount of time spent repeatedly transcribing these data points from one form to another may have been significantly reduced. This is because STORC is designed to pull data forward as collected, so that once the information is recorded, it populates all forms where this information is required (while allowing editing).

The increase in activity counts for gathering and checking medical records might have resulted from STORC's lack of order-entry functionality. This means that clinical orders were still written into the paper medical record, requiring providers to locate the paper record. In addition, this EHR had not implemented the unit "white board" electronically. The white board was updated frequently to reflect the most up-to-date, at-a-glance information for all patients in the unit, and thus required constant management.

The EHR implementation also coincided with the introduction of a new maternal/fetal monitoring system on the L&D unit. The new work associated with this system (e.g., reading monitoring strips, documenting interventions) is most likely reflected in the increased time spent processing these new data and interacting with the monitors.

The reduction in idle waiting activity counts likely resulted from the improved availability of patient information in a single electronic source. For example, prior to STORC implementation, when a woman arrived for an unscheduled delivery, the L&D staff spent significant time locating the paper prenatal record or contacting the ambulatory clinics to have copies of the record faxed to the unit. Because this information is now collected electronically, it is available immediately when the woman arrives for delivery, eliminating this often frustrating search for important historical clinical data.

Overall, the shifts in types and amounts of work activities were reasonable with the introduction of the computerization of clinical documentation. The time-saving improvements with the technology (e.g., single source of information, prenatal visit information available at the time of delivery) did not entirely offset the increased time required to document patient care. However, these changes did not appear to negatively affect total direct patient care activities, despite concerns to the contrary.

We believe this study provides an important view of the positive value that HIT interventions can have on clinical care for high-reliability units if they facilitate integration of data across systems, saving clinicians time and ultimately improving patient care and safety.

Study Limitations

This study has some limitations. The brief observational periods used for evaluations and small sample size (particularly in observations of medical faculty) might have affected statistical significance. It is difficult to determine if longer observation periods would have affected these results.

As previously mentioned, STORC is a clinical documentation system that does not provide order-entry functionality. It is possible that some changes in workflow might not have been as dramatically affected had order entry functionality and this documentation system been combined. Because order-entry systems are known to slow down the ordering process, it is possible that additional order-entry functionality might increase computer activity.

Most importantly, the results reflect an EHR designed to accommodate workflow on a busy L&D unit. It is possible that a study of a more general EHR (e.g., one not specifically tailored to the work practices of the specific unit or clinical specialty) might not yield similar results.

We believe that by taking this unique opportunity to assess the work activities of clinical staff during incremental data integration into an EHR, the significant benefits of data integration in general and its potentially positive impacts on patient safety are demonstrated. Furthermore, measurement in a high-volume, fast-paced L&D environment offers substantial reassurance to other high-acuity units for the potential benefits of adopting EHR systems.

Future Work

Regardless of time savings or loss, it is important to consider whether we are actually improving the quality and completeness of the information collected and recorded for perinatal care. Clinical information systems can promote standardization in data collection, prompt providers to document information they might otherwise forget or ignore, and crosscheck information for consistency across documentation. In addition, if the system is carefully designed with research needs in mind, the data can be collected and stored in discrete, retrievable fields, such that clinical research is more readily supported, obviating the need for traditional chart reviews. The shift to an EHR certainly provides a ripe opportunity to determine if clinical care documentation actually improves quality and comprehensiveness, and if in turn, this can be related to improved patient outcomes through data availability for research.

Conclusion

The introduction of a clinical information system into a busy L&D setting did not reduce the total count of direct patient care activities. This study may assuage physician fears about the potential for loss of direct patient care time due to documentation time spent on electronic systems. Although overall computer work increased, this was not to the detriment of patient care. The increase in computer work is an unavoidable by-product of the technology age. This is not to say that the shift from paper to computer is seamless, effortless, or easy. The shift does require that clinicians rework their routines, which alone can cause strong emotional reactions and resistance to change. Happily, we see an overall increase in patient-related work, which we believe translates directly to higher quality care in the obstetric setting.

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

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Abstract

The traditional, film-based radiology system presents serious limitations for patient care. These include forcing clinicians to make decisions based on information that is often less than optimal and making transfers of films and prior studies to other facilities more complicated than they need to be. Picture Archiving and Communication Systems (PACS) address these issues by allowing for acquisition, storage, display, and communication (e.g., transportation) of images in a digital format. Although PACS has been shown to improve patient care, many rural health care organizations have found obtaining these systems cost-prohibitive. The Consolidating Imaging Initiative (CI-PACS) in Maine provides an alternative way to offer this technology to rural hospitals. Through CI-PACS, a tertiary care hospital and its health care system have implemented a shared, standards-based, interoperable PACS in two rural hospitals (one belonging to the larger health system and one not). In this article, we discuss how the regional system works, and how it will be sustained. We also highlight the unique challenges associated with implementing a regional system.

Introduction

Over the last few years, the health care system has increasingly focused on obtaining health information technology (HIT), especially electronic medical records (EMRs). Although the number of health care providers adopting HIT has increased, there continue to be significant barriers and challenges to acquiring this technology.[1, 2, 3] Hospitals identify cost as the major barrier to adopting HIT, including initial and ongoing costs of maintaining the systems.[2] Other important challenges include issues with interoperability with other systems, medical staff support and usage of HIT, difficulty building a strong business case for adoption, availability of IT staff, and privacy and security of patient information.[1, 2, 3]

Rural health care providers have many of the same challenges as urban providers, but these challenges can affect rural providers to a greater extent. In rural settings, where salaries are lower, hospitals and other providers have difficulty attracting and retaining IT staff to implement and maintain HIT. Rural physicians may be less technologically savvy and more resistant to HIT adoption. Rural providers also may face unique challenges. For instance, they may find it more difficult to obtain needed network bandwidth or may face higher transmission costs than their urban counterparts.[2, 4]

Health information exchange (HIE) allows different health information systems to share clinical information electronically among health care organizations. Therefore, HIE helps health care providers access and retrieve patient information across the continuum of care.[5] With the development of Picture Archiving and Communications Systems (PACS), health care providers have a new opportunity to exchange radiology information across organizations. PACS is a digital radiology system that acquires, stores, displays, and communicates (transports) radiology images in a digital format.[6] Many rural hospitals want to move to a filmless system, but the startup and ongoing costs and the technologic challenges of maintaining large and complex information systems are onerous. Most rural hospitals have considered filmless systems and recognize that they will ultimately be necessary, but few believe that these challenges are currently surmountable. Participating in a shared PACS not only allows rural hospitals to obtain a PACS, but may provide them with additional benefits beyond purchasing their own stand alone PACS.[7, 8]

Sharing a PACS among multiple providers is not necessarily a new concept. However, most attempts involve organizations that all belong to the same health system and share the same technology infrastructure, patient identifiers, information systems, and support staff. They also share the same organizational structure, which reduces or even eliminates issues of trust, cooperation, persistence, and dedication to fundamental change. On the other hand, a shared PACS must integrate multiple organizations in order to make each hospital's system compatible with the shared system. They also must gain the trust and cooperation of independent radiologists.

In February 2001, MaineHealth, Maine Medical Center (MMC), and other health care providers developed the Consolidated Imaging Initiative (CI-PACS) to explore ways to allow multiple organizations to archive radiology images through MMC's PACS and to retrieve and display those images throughout each organization's clinical enterprise. With the support of an Agency for Healthcare Research and Quality (AHRQ) HIT Implementation Grant, the CI-PACS began implementing a shared system with two rural hospitals, Franklin Memorial Hospital (FMH) and Miles Memorial Hospital (MMH).

Prior to implementation, the involved hospitals anticipated three major benefits: one, cost savings; two, improved quality of care; and three, improved access to radiologists. By eliminating film, film storage needs, and the need for an archive, the two rural hospitals expected to save money in the long term. MMC could also benefit by distributing their costs for PACS across multiple organizations. With a shared system, each hospital would have access to the other hospitals' radiology information. Having access to relevant prior images and reports has been shown to improve the interpretation of radiology exams.[7, 8]

Lastly, many rural hospitals have difficulty recruiting and retaining radiologists. They also require a limited amount of a radiologist's time. Since MMC employs the radiologists of Spectrum Medical Group, an independent physician group, if one of the rural hospitals were to lose its radiologist, they would have the potential to hire someone from the group. Miles Memorial Hospital, which already hired a Spectrum radiologist, expected CI-PACS to help make coverage for nights, weekends, and vacations more efficient. Without the shared PACS, these

radiologists would have to travel about an hour to Miles Memorial Hospital. However, with the PACS, the radiologists at Spectrum could remain in Portland to review the exams.

As part of the AHRQ grant, an evaluation was conducted. The evaluation focused on two objectives: documenting the implementation process and lessons learned and assessing the impact of a shared PACS on cost and quality.

In this paper, we focus on the implementation process and lessons that were learned from the project. We describe the organizations involved and the phases of implementing a shared PACS. We then discuss the implementation challenges faced by the rural hospitals and the benefits that participants perceived as being realized by these hospitals.

Creating a Shared PACS in Maine

Organizations Involved

Figure 1 provides a map that identifies each organization involved and the distance of the two rural hospitals from MaineHealth, Maine Medical Center, and Spectrum Medical Group (all located in Portland). Maine is a large, mostly rural State. As illustrated in Figure 1, the hospitals participating in CI-PACS are separated by considerable distance. Because MMC is Maine's largest tertiary system, these and other hospitals refer many of their patients to MMC.

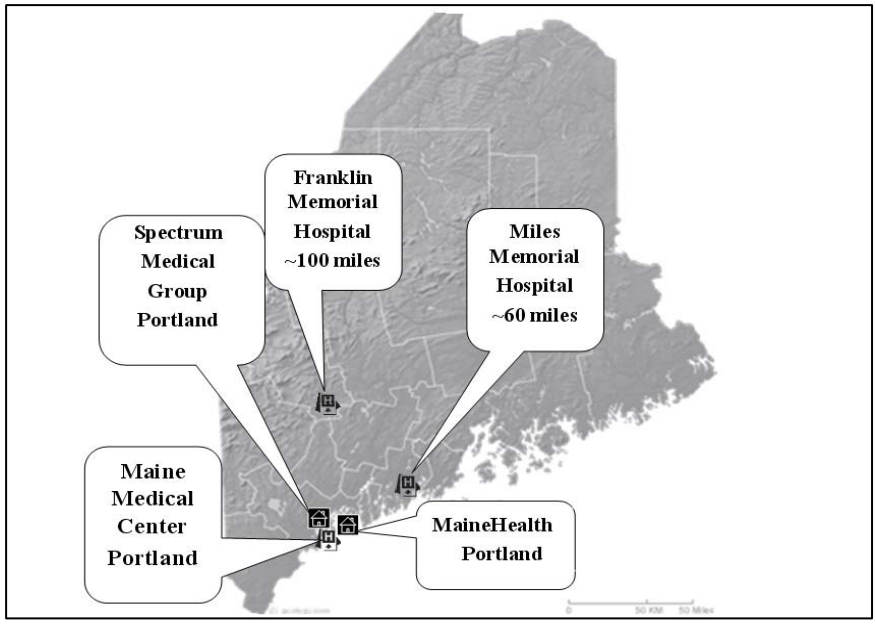

Figure 1. Location of organizations involved in CI-PACS

MaineHealth. MaineHealth is a not-for-profit integrated health care delivery system that serves approximately three-quarters of the State's population (1.2 million). MaineHealth provided the leadership to develop the partnerships needed to implement CI-PACS. Members of this system, including MMC and Miles Memorial Hospital (MMH), are owned by MaineHealth, while affiliated organizations are independently owned. MaineHealth offers a wide array of benefits and services, which are voluntary for members and affiliates.

Maine Medical Center. MMC, owned by MaineHealth, is the largest hospital in Maine, with 600 beds. MMC acts as a Level 1 trauma center and a tertiary referral and teaching hospital. The department of radiology performs over 180,000 exams per year and has 25 diagnostic radiologists. These radiologists are members of the Spectrum Medical Group, described later.

MMC's radiology informatics team, located within the radiology department, has developed expertise in radiology workflow and integration of radiology systems. They managed and carried out the implementation of CI-PACS at the two rural hospitals.

Miles Memorial Hospital (MMH). MMH, a MaineHealth member, has 46 beds, including 22 medical/surgical, 8 intensive care, 8 day surgery, and 8 obstetrical beds. Approximately 82 percent of the hospital's revenues come from Medicare and Medicaid, forcing the hospital to depend on fundraising and grants to purchase new equipment or systems. The radiology department has only one full-time radiologist, who is contracted from Spectrum Medical Group in Portland. They offer CT, ultrasound, mammography, x-ray, and mobile MRI services. The majority of their referrals are sent to MMC.

Franklin Memorial Hospital (FMH). FMH is not a MaineHealth member or affiliate. The hospital has 70 beds and serves approximately 40,000 individuals in 23 predominately rural communities in northwestern Maine. FMH has developed its own health network, which includes four other organizations: a behavioral health provider, a community public health coalition, a multi-specialty group practice, and a physician hospital organization. The radiology department is staffed by two radiologists who are independently employed, representing 1.5 full-time equivalents. They currently perform 42,000 images a year. FMH refers its patients to MMC in Portland and to Central Maine Medical Center in Lewiston.

Spectrum Medical Group. Spectrum Medical Group (Spectrum) is Maine's largest physician-owned and -led multi-specialty practice. The group includes over 140 board-certified or eligible providers, including radiologists. These radiologists perform over 600,000 diagnostic exams or interventions each year and provide subspecialty expertise. Spectrum designated 25 percent of a radiologist's time to work on the implementation of CI-PACS. This work included optimizing the clinical work and service environment, streamlining radiologists' workflow, enhancing the function and usefulness of the PACS, and working with the other hospitals' staff while implementing CI-PACS. Spectrum also contributed $100,000 for a diagnostic workstation at MMH, which allowed the radiologist to perform softcopy interpretations for CT, MRI, and ultrasound.

Functioning of the System

Through CI-PACS, MMC stores all images taken at MMH and FMH on the MMC servers. Storing images on a single server allows the hospitals to access their own and other organizations' images through wide-area network (WAN) connections to MMC and eliminates the need for each hospital to have its own server. MMC also implements and maintains the PACS at each facility, provides IT support, and installs upgrades. The rural hospitals pay for new radiology equipment (e.g., computed radiography), network connections, and data transmission costs. Although the AHRQ implementation grant provided the funding needed to buy equipment and install the system in the hospitals, MaineHealth and MMC have created a way to sustain the system, using a per-exam fee schedule to cover MMC's costs.

Implementing CI-PACS: The Major Phases

The implementation process consisted of seven phases, with each being critical to success. They are described in the approximate order in which they were accomplished, but some phases overlapped. Each phase description focuses on the high-level tasks.

Phase 1: Pre-implementation preparation. A CI-PACS management team was created to develop implementation plans and oversee the implementation process. The management team consisted of radiology personnel from MMH, FMH, and Spectrum and the Director of Radiology Informatics from MMC. Administrative, clinical, and information systems staff joined the team when needed.

The management team first conducted a workflow analysis, which assessed the current and future states of workflow in each radiology department. Conducting a workflow analysis was essential in determining how best to implement CI-PACS at each hospital. While the system can typically adjust to differences in workflow, some differences cannot be addressed without changing the workflow process. Therefore, this analysis also identified when workflow needed to be changed to fit the system.

Also during this phase, the team assessed DICOM (Digital Imaging and Communications in Medicine) conformance and infrastructure needs. DICOM is an application network protocol that allows for the transmission of radiology images. A DICOM standard was designed to ensure the interoperability of radiology systems. For DICOM conformance, the team evaluated the conformance of each modality (e.g., CT, MRI) to determine the level of interoperability of MMH's and FMH's modalities with MMC's PACS. Non-DICOM-compliant systems required unique solutions to make them conform to the system.

To implement CI-PACS, FMH and MMH needed to upgrade their local area networks (LANs) and WANs. During the pre-implementation phase, the team determined the time needed to obtain the network bandwidth, connectivity, and quality of service enhancements. Obtaining network connectivity and required network bandwidth has often been difficult for rural communities. Infrastructure changes included designing reading room configurations and determining equipment and lighting requirements.

Lastly, the team created a training plan to encompass both functional use of CI-PACS workstations and the changes in workflow. The training plan focused on radiology staff and other clinicians to ensure optimal usage and image review frequency. The team used a train-the-trainer model, with MMC's radiology informatics staff training one or two "super users" at each hospital and then having these "super users" train their own staff. Each hospital used group training sessions, while FMH also used one-on-one training as new parts of CI-PACS were implemented.

Phase 2: Establish network connectivity. Ensuring adequate network bandwidth represented the key technologic challenge during implementation. Only FMH needed to establish a WAN connection, but both hospitals had to obtain the necessary bandwidth. Although the hospitals and management team worked closely with their community's telecommunications provider to establish these connections, obtaining the necessary bandwidth took both hospitals at least a

year. The costs of WAN for MMH and FMH have been $30,000 and $50,000 per year, respectively.

Phase 3: Demographics/radiology order flow. The PACS-Radiology Information System (RIS) interface provides the CI-PACS with patient demographic and radiology order information. A RIS is a computer-based system that allows a radiology department to store and maintain patient radiology data and images. Most systems provide patient registration, appointment scheduling, patient tracking, results entry, and reports. The interface between the PACS and RIS serves a number of additional functions, including:

- Linking PACS imaging information and Hospital Information Systems (HIS)/RIS clinical information.
- Connecting all studies for a given patient.
- Providing the necessary order information to enable automatic retrieval of relevant prior exams.
- Updating patient demographics, when the information is updated or changed.
- Associating radiology results in the RIS to the images archived in PACS.
- Providing new and prior reports to clinicians via the PACS and Web-based access.
- Providing the link between the digital dictation system and PACS.

The accession number or exam identifier allows the CI-PACS to associate all images for a particular study to an order and all its associated patient and clinical information in the HIS and RIS. Without a valid accession number, the validation process—which ensures that all human data entry errors are corrected before the study is archived—cannot occur. Therefore, the images would note be available for the radiologist to interpret or for clinical distribution.

An important decision that each hospital had to make was how to integrate CI-PACS with MMH's and FMH's Meditech systems. Meditech is a vendor that provides HIS and RIS products. The order information could be manually entered in CI-PACS through the Cerner RIS (MMC's RIS), or an interface could be developed between the MMH and FMH Meditech systems and the MMC RIS. Interfaces also needed to be created to connect result reporting and transcription. Ultimately, both hospitals chose to keep their own HIS and RIS, requiring the creation of interfaces.

Phase 4: Computed radiography implementation. Both rural hospitals installed a computed radiography (CR) unit to enable direct digital capture, storage, and display of images. CR provides physicians and radiologists with images ready for interpretation almost immediately after the technician validates that the exam was performed correctly. To provide some redundancy should the CR unit fail, the hospitals implemented a high-volume and a low-volume unit.

Phase 5: Modality connectivity and digital archiving. Based on pre-implementation analysis, modality connectivity required upgrading each modality, as needed, to ensure full DICOM compliance. The implementation team also provided each hospital with diagnostic-level digitizers, which allow for the conversion of films to digital images. Once network connectivity

was established and patient demographic and radiology information was available in the MMC RIS, images were ready to be archived. By archiving images, the images can be stored, routed, prefetched, and softcopy reviewed. Also during this phase, the workflow re-engineering process occurred, and training began with radiology and clinical staff.

Phase 6: Diagnostic softcopy reading. The activation of softcopy reading on a PACS workstation depended on several steps, including:

- Installation of radiology workstation(s).
- Configuration of the CI-PACS to forward studies to the local workstation.
- Creation and customization of each user's account.
- Installation of appropriate digital dictation equipment and interfaces.
- Training all radiologists on the use of CI-PACS workstations.
- Training other radiology staff in new soft copy reading workflow.

At this point, only radiologists were able to view images. Web access, implemented in the final phase, provided access to other clinicians.

Phase 7: Web access rollout. Implementing Web-based access to digital images expanded the softcopy review to additional clinical areas. Before full implementation of Web-based access, the implementation team needed to demonstrate high levels of system performance and reliability and completion of the hospital network implementation. Softcopy access was provided through Agfa Corporation's Web1000™ tabletop processor, using Web-based review stations positioned in the emergency department and other high-use clinical areas. These workstations provided clinicians with diagnostic-quality images and image manipulation. In addition, the system allowed remote sites and physicians' offices access to images as long as they had a connection into the hospital's CI-PACS network. With these connections, the implementation team hoped that FMH and MMH could reduce their reliance on hardcopy films by at least 90 percent, providing cost savings that could be used to help sustain the CI-PACS implementation.

Implementation Challenges

Information on challenges was obtained through onsite interviews with hospital management, radiology staff, and IT staff. These interviews focused on the planning and implementation process, satisfaction with the process, challenges and how they were overcome, and lessons learned. Our discussion is focused on the challenges faced by the two rural hospitals. The challenges are presented in three major categories: technical, inter-organizational, and human resources and training.

Technical challenges. There were several technical challenges during the implementation of the shared PACS, including WAN connections, higher transmission costs, responsiveness from Agfa and MMC, and creating a master patient identifier. Both rural hospitals had significant problems obtaining their WAN connections and adequate bandwidth from their local telecommunications provider. They each waited at least a year for these needs to be met. However, since the study began, the ability of rural communities to obtain these connections has improved, potentially making it less of a problem in the future. FMH and MMH also paid higher transmission costs per

year than urban hospitals, with FMH paying $50,000 per year, and MMH paying $30,000 per year. Although it is too early to assess results, MMC and the rural hospitals expected that cost savings obtained from reducing the need for film-based images would help to cover these transmission costs. Similar to the WAN connectivity problem, transmission costs have decreased over the last 3 years, making this less of an issue. Some staff felt that IT and system support were not as quick or effective as they expected. One hospital had to wait 2 weeks for the vendor, Agfa, to respond to a problem.

MMC faced a significant challenge in developing a master patient identifier across the organizations participating in CI-PACS. With separate patient identifiers for each hospital, it was essential to develop an effective approach to sharing clinical and administrative data from these disparate systems. MaineHealth created a master patient index which conducts a behind-the-scenes matching of the same patient, using demographic information. However, the system does not work perfectly, due to errors in the data and people changing their names or moving. In these situations, a person has to manually process these matches and might need to make phone calls to verify that the records are for the same person. The manual process often results in a delay in accessing relevant prior exams when they are needed.

Interorganizational challenges. There were several inter-organizational challenges during the CI-PACS implementation, including differences in knowledge and differences in workflow. Rural and urban hospitals function very differently. Urban hospital staff are highly specialized, whereas rural hospital staff tend to be generalists. Although the management team conducted a workflow analysis within each radiology department, some rural staff felt the implementation team did not understand how their radiology department worked. While rural hospitals have a strong understanding of how their hospital and radiology department operate, they might not have much expertise in PACS. On the other hand, MMC has significant expertise in PACS but might know very little about how rural hospitals work. Given this problem, rural staff found it difficult to communicate what they wanted in a PACS, while urban implementation staff had difficulty determining what PACS components would work best for each rural hospital.

In addition, unexpected differences in workflow could not be changed at FMH. Prior to PACS, the transcription process at FMH identified and placed urgent or emergency cases at the top of the list. For these cases, transcriptionists were provided information on whom to call immediately after the report was completed. On the other hand, the transcription system used by MMC placed urgent or emergency cases at the top of the list but did not identify them as urgent. Therefore, they appeared just as the next report to transcribe, and transcriptionists did not know to rush a particular case. The system also did not include information about who to contact when the report was completed. Initially, FMH tried MMC's transcription system but decided that they could not change this portion of their workflow. To resolve this problem, MMC's IT staff is creating new interfaces to ensure that the different transcription system will work under CI-PACS. Until completed, FMH's radiology reports are unavailable on CI-PACS.

Human resources and training challenges. The two rural hospitals approached IT support and project management in different ways. One hospital decided they needed an IT support person onsite. Fortunately, they had a radiology technician who also had an IT background. The hospital felt that having this person allowed them to look out for their hospital's interests, assist in project

management, and address day-to-day issues during PACS implementation. The other hospital did not hire its own IT support staff or a project manager. Instead, they relied on an IT staff person provided by MaineHealth, which they had to share with another rural hospital. The director of radiology took on the responsibility of managing the radiology department and the implementation process. In retrospect, the director believes that the implementation process would have gone more smoothly if they had hired a staff member dedicated to the CI-PACS implementation.

They also approached training and obtaining clinician buy-in differently. One hospital involved their radiologists, physicians, and others in the planning phase. By doing this, they were able to identify physician champions, making it easier to get buy-in from other clinicians in the hospital. The other hospital did not take this approach and found it harder to get physicians to buy-in to the new system. At one hospital, they not only informed staff before a new phase would be implemented, they also provided group training and one-on-one training the first time a clinician dealt with the new technology. The other hospital provided only group training, possibly making it harder for staff to learn the new technology and potentially affecting staff's willingness and comfort with using the system.

Perceived Impact of Shared PACS

The hospitals involved in CI-PACS anticipated that the shared PACS would bring additional benefits over a stand-alone PACS, including greater access to relevant prior exams, cost savings, and assistance with radiology coverage. As part of the evaluation of CI-PACS, we wanted to know whether hospital staff actually felt they had achieved these benefits. Through interviews with hospital management and radiology and IT staff, we found that overall, the staff at both rural hospitals felt that the shared PACS had achieved the expected impact. Radiologists found that they had improved access to relevant prior exams, allowing them to base their diagnoses on better information. However, a few staff thought the drawbacks of a shared system did not outweigh its benefits. They stated that the shared PACS was slower than a stand-alone PACS because they needed to transmit images over long distances, while they had only a small percent of cases where they needed a relevant prior image from another organization. One staff member suggested that being able to make hospitals' different stand-alone systems interoperable would be more effective and efficient.

While the hospitals have not had enough time to assess the actual cost savings due to CI-PACS, all staff expected to save money over the long term. In addition, as more organizations have come into CI-PACS, the per-exam fee has decreased, making it more likely that cost savings will increase over time. The only concern among the staff was how they would cover the transmission costs after the grant period was over.

MMH has a radiologist from the Spectrum Medical Group, which means other Spectrum radiologists can assist him. This radiologist found that if he became too busy or could not come to work, Spectrum radiologists could provide the hospital coverage by reading exams remotely. This not only benefited MMH, it also allowed Spectrum radiologists to provide coverage more efficiently, not needing to drive to MMH. Although not used to its full potential, both hospitals found consultation from other radiologists, especially subspecialty radiologists, to be an important benefit from CI-PACS. With these consultations, they could determine whether a

patient needed to be transferred to MMC or another facility and to confer with another radiologist in difficult cases.

Conclusion

The Consolidated Imaging Initiative developed by MaineHealth and Maine Medical Center can provide other rural and urban hospitals with a blueprint for developing systems within their own communities. Most staff at the rural hospitals thought the implementation process went well overall and was probably easier and faster than if they had implemented a stand-alone PACS. They have already perceived an impact of the shared system on their radiology departments, especially for access to relevant priors from other organizations.

However, there were technical, interorganizational, and human resources and training problems during the implementation project. Some of the technical problems have been easily resolved, while others will take more time. Over the last 3 years, rural communities in Maine have attained improved access to needed network bandwidth and lower transmission costs, making this less of a problem for future projects. Shared PACS requires either a master patient identifier or a manual process of matching exams to patients with different identifiers at each organization. With the development of the Enterprise Master Patient Identifier by MaineHealth and MMC, other organizations might find creating a unique patient identifier a little easier. A national patient identifier could virtually eliminate the problem, but there are still privacy and security concerns with this approach.

The inter-organizational problems related to differences in knowledge and workflow could be resolved in several ways:

1. The rural hospital could hire an IT person with experience in rural radiology systems and PACS.
2. The urban hospital could hire an individual or consultant with knowledge about how rural hospitals work.

At FMH, a radiology technician with a background in IT was already on staff, which made the implementation process easier at that hospital. Rural hospitals considering a shared approach should consider hiring an IT person with experience in PACS or rural radiology systems. Unfortunately, this approach might be difficult for rural hospitals, since they frequently have problems recruiting and retaining IT staff, especially more specialized IT staff members. A more realistic approach might be to have the urban hospital hire a consultant with knowledge about how rural hospitals work. The consultant could act as a liaison between the rural and urban hospitals to better communicate workflow issues and other needs.

The availability of human resources and the need for training approaches were also identified as challenges during the implementation process. Rural hospitals might improve the implementation process by hiring their own IT support staff, even if part time, and a project manager to deal with day-to-day implementation issues. The IT support position, especially one with rural hospital experience, would ensure a smoother implementation and more effective communication between the urban and rural hospitals. The project manager would prevent the

director of radiology from being overwhelmed. Radiology directors should also involve physicians and other clinicians that need to use the system in the planning phase and identify physician champions to help convince reluctant physicians of the benefits to their practices of a shared PACS.

Participating in a shared or regional PACS might provide rural providers with an alternative approach to acquiring a filmless radiology system. Many rural hospitals and providers cannot afford or support a stand alone PACS. The Consolidated Imaging Initiative brought two rural hospitals access to PACS and provided potential cost savings, improved access to relevant priors from other organizations, and more secure access to radiologists.

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Personal Health Records to Improve Health Information Exchange and Patient Safety

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Abstract

The personal health record (PHR) is proposed as an innovative solution to the problems of fragmented communication and lack of interoperability among diverse electronic medical record (EMR) systems. It provides a single source (the patient's PHR) for authentication and remote access of the health information data from all EMR systems. A voluntary survey was offered to selected patients, caregivers, and health providers of the Willmar, MN, PHR project to determine if a PHR was useful to these stakeholders, and if so, what aspects of a PHR would be most helpful in caring for patients. The survey responses revealed nearly universal interest by both patients and health providers in using the PHR regularly for accessing and exchanging health information, including medication and medical history reconciliation and patient education. The highest utilization would result from a community-based PHR implementation that was owned and controlled by the consumer and was portable among providers, plans, and employers.

Introduction

Health information exchange through electronic interoperability of electronic medical records (EMRs) allows a person's health information to be immediately accessed by any approved health provider and would improve the safety and quality of health care, particularly during emergency care. The Institute of Medicine's report, *Preventing Medication Errors 2007,* states that poor communication and exchange of medical information at transition points for patients from one provider to another are responsible for many medical errors and adverse drug events.[1]

There are substantial barriers, however, to the exchange of health information through the electronic interoperability among EMRs. Such an exchange would require extended technical and political processes and involve standardization and modification of current information systems. Electronic exchange of health information also raises questions about policies and procedures regarding confidentiality, security, and identity management. Many health providers are reluctant to give up confidentiality of their records, and many EMR vendors have found the process of creating complex algorithms to convert one database to another to be costly and time consuming.

As a result, only limited health information—such as demographics and immunizations—can be accessed through data exchange among information systems available today. To achieve the many benefits of interoperability—such as improvements in quality, safety, and the costs of

health care—new solutions are needed to integrate and exchange health information between different health care providers and consumers.

One solution involves the use of electronic personal health records (PHRs) as the center of a person's health information exchange. PHRs are considered by many to be an important part of this initiative.[2, 3, 4, 5, 6, 7, 8] A PHR is a personal and secure set of online tools that connect consumers to their EMRs and empower them to manage their health, health care, and health care costs.[1, 3] Various types of PHRs include those tethered to an EMR or health plan database, as well as those that are nontethered, independently hosted, and owned by the consumer.[2-7] The nontethered PHR is proposed as an innovative solution to the problems of fragmented communication and lack of interoperability among diverse EMR systems by providing a single source for an individual patient (the patient's PHR) for authentication and access to health information data from all EMR systems.

A patient's PHR could include utilities for translating EMR databases into a standard format to allow health providers secure HIPAA-compliant electronic access. It also could include online educational tools and information to help consumers make the best decisions to improve the quality and cost of their own health care. The goal of interoperability of health data and its reconciliation into one source, the patient's PHR, can be achieved with a simple, inexpensive, and expedient process.

However, the PHR is a new concept that has yet to be fully developed and implemented. First-generation efforts have been an important initial step in testing the utility of PHRs, but their adoption by consumers has been slow. For example, despite considerable publicity, PHRs tethered to a health care plan have been used by less than 2 percent of the plan's members.[7] The low initial utilization by consumers could be explained by several reasons, including slow adoption of new technology by consumers, lack of perceived ownership and transportability by the consumer, concerns about privacy and security issues, and lack of research into the utility and features that engage consumers.

This article discusses the implications and processes involved in using PHRs for health information exchange and presents the results of a study that evaluated the PHR features that drive utilization and improve health care safety and quality.

Methods

This project was initiated with funding from the Minnesota Department of Health, Stratis Health, and Avenet Web Solutions to implement PHRs in a defined population of congestive heart failure (CHF) patients who were involved in a collaborative CHF rehabilitation initiative in the rural community of Willmar, MN. The goals of the project were to improve participating clinics' ability to access patients' medical records through the PHR, improve health information exchange, and provide online education for patients.

A PHR was defined as a nontethered, consumer-owned, personal and secure set of online tools that connect consumers to their health information and provide e-tools to help them manage their health, health care, and health care costs. The study selected for development features of a PHR

that were of interest to consumers and had been studied previously.[7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19]

A voluntary survey was mailed to all CHF patients, caregivers, and health providers involved the CHF collaborative, followed by mailed reminders to complete the survey. The participants were asked to determine if a PHR was useful to them, and if so, what aspects of a PHR would be most helpful in their own care. The sampling frame for the health providers included health care providers in the two practices that make up the Affiliated Community Medical Center and Family Practice Medical Center and the hospital health providers who had patients involved in the CHF collaborative. It also included all patients and identified caregivers who were involved in the collaborative between the hospital and clinics. A total of 440 surveys were mailed to patients and caregivers, and an additional 80 surveys were mailed to health care providers for a total sample of 520 surveys.

The features identified in the survey were then used to develop the PHR that best fit the needs of these stakeholders. Survey development was based on the results of focus groups with patients and providers and was approved by the University of Minnesota institutional review board (IRB) for research with human subjects. The purpose of the survey was described in a letter, which also asked participants to complete the survey and to answer questions about the features and functions of the myHealthfolio® PHR from Avenet Web Solutions (Figure 1).

Figure 1. Summary of features and functions of the myHealthfolio® PHR from Avenet Web Solutions. (Reproduced with permission from Avenet Web Solutions, St. Paul, MN.)

The survey had two specific goals:

1. Ascertain the general level of interest and support from patients, caregivers, and health providers in using a PHR.
2. Determine which features would best motivate regular use of the PHR by this group.

The questions in the survey described each potential feature in the myHealthfolio and asked questions designed to elicit information about the following issues:

- Whether participants would use the feature.
- How often myHealthfolio would be used and, if not used, why not.
- General comments and concerns about myHealthfolio.
- Demographic and computer use characteristics of the survey participants.

Results

Of the 520 surveys mailed out, 182 were returned, including 84 patients, 49 caregivers, and 49 providers, for a response rate of 35.1 percent. The mean ages of respondents were 75.7 years for patients and 67.9 years for caregivers.

The Willmar survey results showed overwhelming interest in the use of the PHR by all groups, including the senior population (Tables 1 and 2). Health providers indicated the strongest interest, with 96.7 percent indicating interest in at least monthly use, and 67.4 percent indicating they would use it every week; 83.8 percent of caregivers and 78.1 percent of patients indicated they would use it at least monthly (Table 2).

Table 1 identifies the specific features of myHealthfolio in which respondents expressed the greatest interest. In general, respondents showed strong interest in PHR features, with interest in use ranging from 33 to 93 percent. The general features in which respondents indicated the most interest included:

- Organizing health records, including medication reconciliation (91 percent).
- Availability of online calendars and reminders (74 percent).
- Personalized health education (71 percent).
- Access to community services (69 percent).
- Online health communication with providers and health plans (60 percent).
- Health care cost management (57 percent).

All three groups expressed high interest in accessing and exchanging health information, including accessing doctor, laboratory, and hospital records (90.6 percent); organizing current health history, immunizations, registration, and health plan information (91.2 percent); and organizing medications (90.5 percent). This interest was across the board, with doctors, patients, and caregivers all expressing strong interest in accessing health information. There were no significant differences among the groups.

Table 1. Percent of patients, caregivers, and doctors/staff who indicated interest in using various PHR features

Would you use or recommend use of this PHR feature?	% (95% CI) responding "Yes"			Total
	Patient	Caregiver	Doctor/staff	
Order prescriptions from online pharmacies	42.9 (0.3, 0.6)	33.3 (0.2, 0.5)	65.2 [a] (0.5, 0.8)	47.1[a]
Most current medication list that has been reconciled by the patient and doctors	85.3 (0.8, 1.0)	94.9 (0.8, 1.0)	91.3 (0.8, 1.0)	90.5
Check adverse effects, safety, and medical history conflicts of medications	78.5 (0.7, 0.9)	81.6 (0.7, 0.9)	73.3 (0.6, 0.8)	77.8
Access doctors' summary, imaging, and laboratory reports, and hospital records for a specific patient	87.9 (0.8, 1.0)	92.3 (0.8, 1.0)	91.5 (0.8, 1.0)	90.6
Access patient's most current health history, registration, and health plan information	88.1 (0.8, 1.0)	92.1 (0.8, 1.0)	93.3 (0.8, 1.0)	91.2
Give new doctors permission to access medical records	83.1 (0.7, 0.9)	92.1 (0.8, 1.0)	68.2[a] (0.5, 0.8)	81.1[a]
Health directives, e.g., end-of-life care, living wills	79.1 (0.7, 0.9)	76.3 (0.6, 0.9)	69.6 (0.5, 0.8)	75.0
Confidential doctor-patient e-mail, including online consultations	52.3 (0.4, 0.6)	58.8 (0.4, 0.8)	45.5 (0.3, 0.6)	52.2
Doctor-finder with contact information and background	70.8 (0.6, 0.8)	81.1 (0.6, 0.9)	43.2[a] (0.3, 0.6)	65.0[a]
Communicate with health care plans about claims, eligibility, benefits, and prior authorization	75.8 (0.6, 0.8)	78.9 (0.6, 0.9)	52.3[a] (0.4, 0.7)	69.0[a]
Online patient support groups for health issues	42.9 (0.3, 0.6)	37.8 (0.2, 0.6)	41.8 (0.3, 0.6)	40.9
Receive e-mail about health, drug, and implanted device alerts	51.6 (0.4, 0.6)	59.5 (0.4, 0.8)	59.1 (0.4, 0.7)	56.7
Health care fees for clinics, hospitals, and procedures, e.g., MRI scans, surgeries	67.2 (0.5, 0.8)	59.0 (0.4, 0.7)	45.7 (0.3, 0.6)	57.3
E-mail reminders for when and why to complete important preventive tests and conduct regular health care routines	84.8 (0.7, 0.9)	92.3 (0.8, 1.0)	45.7[a] (0.4, 0.7)	74.3[a]
Online self-management action plans for specific illnesses	75.8 (0.6, 0.8)	71.8 (0.6, 0.8)	67.4 (0.5, 0.8)	71.7
Online community services available for patients	73.8 (0.6, 0.8)	64.1 (0.5, 0.8)	69.6 (0.5, 0.8)	69.2
Frequency of using online resource for health information in the past year?	19.4 (0.1, 0.3)	46.2 (0.3, 0.5)	87.5[a] (0.8, 1.0)	51.0

* Significant difference between groups, $P \leq 0.05$

Table 2. Estimated frequency (%) of personal health record use of selected features by survey participants

	Daily	Weekly	Monthly	Never	Total
Patient	4.7	20.3	53.1	21.9	64
Caregiver	5.4	21.6	56.8	16.2	37
Doctor	37.0	30.4	28.3	4.3	46
Total	15.0	23.8	46.3	15.0	147

Note: Selected features are identified in Table 1.

The feature of second highest interest to participants was patient education and empowerment. All groups expressed strong interest in receiving information on how to self-manage using personalized action plans for a specific illness, such as heart disease (mean, 70.1 percent). Patients and caregivers also indicated strong interest in receiving reminders for important diagnostic tests, medical checkups, and health routines (88 percent); doctors expressed significantly less interest in this feature (45.7 percent, $P < 0.05$).

All groups also expressed interest in having access to medication safety information (77.8 percent); documenting personal health directives, such as end-of-life care and living wills (75.0 percent); and accessing online information about community services available to patients (69.2 percent). Patients and caregivers indicated significantly more interest than health providers and doctors in online communication with patients or caregivers, health plans, or referring doctors ($P < 0.05$).

Discussion

Although the respondents represented a population of patients, caregivers, and health providers who were self-selected and most likely had more interest in health information than the broader population, the survey identified those features of the PHR that have the best potential to engage interested patients, caregivers, and health providers. Despite the fact that less than 50 percent of the population had ever accessed online health information previously, 85 percent had interest in doing so; accessing their own health records with their own PHR was the feature with highest interest.

These results support the conclusions of the two earlier PHR studies commissioned in 2003 and 2006 by the Markle Foundation and other PHR research.[2, 20, 21] In a 2003 survey of a broad profile of 1,246 consumers, only 1.5 percent of respondents managed their health records on a computer, and 0.5 percent of respondents maintained their records online.[2] However, over 60 percent of respondents were interested in using at least one feature of an online medical record database now or sometime in the future. Additionally, 35 percent of respondents said they would use a complete online medical record (i.e., using 7 or more of the suggested 15 tools) if it were available to them.

A study of patients with irritable bowel syndrome found that the usefulness of patient-based information and communication technology had a theoretical framework that included promotion of a sense of illness ownership, patient-driven communication, personalized support, and mutual trust.[20] The authors state that simply providing access to electronic medical records has little usefulness on its own, but integrating this information into a patient-centered framework, such as the PHR, would go farther toward improving health care quality and health outcomes.

The 2006 Markle study[21] of 1,003 adults nationwide using random digit dialing (RDD) probability sampling demonstrated continued interest in PHR and the ability to access consumers' own medical records. Two-thirds of respondents (65 percent) were interested in accessing their own personal health information electronically. Most respondents (88 percent) said that online records would be important in reducing the number of unnecessary or repeated tests and procedures they undergo; 90 percent said it would be important for them to be able to track their symptoms or changes in health care online. However, respondents also expressed strong concern that their information could be used for purposes other than their own care, including identity theft or fraud (80 percent) or the possibility that their information might get into marketers' hands (77 percent).

Despite privacy concerns about keeping medical records online, studies show that consumers still recognize the benefits of having medical records online so they can access medical information and improve safety and quality of care. One of the most commonly cited needs by health care providers and patients alike in the Willmar project involved the need for accurate medication and medical history reconciliation. This refers to identifying the most accurate list of all medications a patient might be taking at any point in time—including the name of each drug, dosage, frequency, and route—and using this list to provide correct medications for patients anywhere within the health care system. Reconciliation involves comparing the patient's current list of medications against the physician's or other health provider's orders.

Poor communication of medical information at transition points is responsible for as many as 50 percent of all medication errors and up to 20 percent of adverse drug events.[1] Each time a patient moves from one clinic or setting to another, clinicians need to review previous medication orders alongside new orders and plans for care and then reconcile any differences. If this process does not occur in a standardized manner that is designed to ensure complete reconciliation, medication errors could lead to adverse events and patient harm.

Although medications are ordered through physicians and noted in a patient's medical record, and prescriptions are filled by pharmacies, patients ultimately are the final source of information about which medications they are currently taking (including prescribed and over-the-counter drugs), which health care providers have prescribed them, and which pharmacy filled the prescriptions. Thus, the PHR can play an important role in medication reconciliation, particularly, if medication data from multiple EMR sources can be transferred and integrated into the patient's PHR and then reconciled by the patient.

Once stored in a PHR database, medication lists can be integrated and patients can periodically review them to determine the status of their medications at any point in time. This reconciled

medication list in the PHR also can be viewed by health care providers to confirm and update the status of specific medications. The same process can occur with medical history items.

There were problems in the deployment of the PHR in our study. For example, the policy issues of determining which health information from EMRs should be routinely available to patients and how best to secure that information were controversial. Although many physicians acknowledged the importance of patient access to health information, they indicated a greater interest in routinely sharing laboratory, imaging, and medication data but not progress notes or consultation reports. EMR vendors' reluctance to share the costs of developing common health information exchange interfaces with a PHR was a financial obstacle that would need to be overcome. Finally, the lack of use of the computer by 80 percent of the patients became an issue as implementation progressed. However, in most cases in this study, the burden of collecting, conveying, and using health information was often seen as the responsibility of health care providers and caregivers, thus explaining the stronger interest in these groups in the use of the PHR.

Deployment of a PHR has great potential for improving health education, personal health empowerment, health and wellness for consumers, and ultimately lower health care costs.[22] For this reason, the Minnesota e-Health Initiative has a stated goal for Minnesota that all residents will have access to a personal health record that is secure, portable, standards-based, and consumer controlled by 2015.[23]

The processes associated with developing and selecting features of the PHR are critical to whether it will be successful in engaging consumers sufficiently to improve their health and reduce health care costs. Although first-generation efforts have been an important beginning in testing the utility of PHRs, their adoption by consumers has been slow. The low initial utilization by consumers might be attributed to several reasons, including:

- Slow adoption of new technology by consumers.
- Lack of ownership and transportability by the consumer.
- Privacy and security issues.
- Poor application of health literacy principles in consumer interfaces.
- Lack of research in the utility and features that engage consumers.
- Inclusion of features that do not engage consumers.
- Low ease of use with low level of intuitive and personalized features.
- Little inherent motivation and incentives.
- Lack of interoperability with medical records and use by health providers.

There are several options for facilitating wide use and broad implementation of PHRs. The results of this study suggest that a community-based implementation that allows the PHR to be owned and controlled by the consumer and be portable among providers, plans, and employers would be better utilized. Other characteristics that are attractive to both patients and health providers included:

- User-controlled access to the PHR, including which parts of the PHR can be accessed, by whom, and for how long.
- A permanent lifetime health information portal that is interoperable with electronic medical and dental records from all providers.
- Tools to improve health decisionmaking regarding care and cost by the consumer.
- Privacy, security, and HIPAA compliance.
- "Transparency," i.e., possible to see who entered each piece of data, where it was transferred from, and who has viewed it.
- Ease of use, personalized, and intuitive with an appropriate level of health literacy.
- Community-based efforts to support a regional health information organization that permit easy exchange of information with other health information systems and health providers as approved by the owner.
- Accessible from any place at any time.
- Training on how to maximize its use.
- Incentives to use the PHR to improve consumer health and health care costs.

Conclusion

This study demonstrates overwhelming interest in the use of PHRs by patients, caregivers, and health providers alike. It also identified the features that have the best potential to engage patients, caregivers, and health care providers, and it supported previous research in the field. There was nearly universal interest in using the PHR regularly for accessing and exchanging health information, including medication, medical history reconciliation, and patient education and empowerment. It is recommended that a community-based implementation allow the PHR to be owned and controlled by the consumer and be portable among providers, plans, and employers to create high utilization. Future research is needed to determine the impact PHRs might have on actual health behaviors and health care costs and to address larger questions regarding financial issues of implementation and use, including documentation of cost savings and expenses related to PHR use.

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

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Abstract

The purpose of this paper is to describe potential improvements in patient safety resulting from design decisions in the development of a computerized decision support system (DSS) for managing opioid therapy for chronic noncancer pain. ATHENA-DSS is an automated decision support system developed in a collaboration between Stanford University and the U.S. Department of Veterans Affairs (VA) to increase guideline-adherent prescribing and to change physician behavior. Based on data in patients' computerized medical record and knowledge of the clinical domain encoded in a knowledge base, the system gives patient-specific recommendations to primary care providers at the point of care. ATHENA-Opioid Therapy is based on a previous system, ATHENA-Hypertension, and is designed to follow the VA/Department of Defense clinical practice guideline for the management of opioid therapy for chronic noncancer pain. We describe the rationale for development of decision support system elements and a graphical user interface to increase patient safety during primary care treatment for chronic pain. The ATHENA-Opioid Therapy system focuses on reducing patient risk in four main ways by: (1) identifying patients with comorbidities or concurrent prescriptions that raise risk for overdose and recommending more conservative dosing; (2) identifying patients with mental health problems that increase risk of medication abuse and recommending referral to psychiatric care and close monitoring; (3) assisting doctors with complex pharmacologic calculations to reduce the risk of mistakes when initiating, titrating, or switching medications; and (4) presenting relevant information to clinicians in an easy-to-use format. We describe a system evaluation plan that we believe is essential to ensure that deployment of ATHENA-Opioid Therapy leads to improvements in patient safety and increases in guideline-concordant prescribing, and we discuss the limitations of this system for patient safety efforts.

Introduction

As stated in the Institute of Medicine (IOM) report *Crossing the Quality Chasm*, information technology is widely recognized as an important means to improve patient safety in the health care setting.[1, 2] Computerized clinical decision support systems are one method of addressing patient safety in the outpatient setting. These systems can highlight absolute and relative contraindications to drug therapy; alert about the presence of comorbidities or laboratory results that warrant consideration; make patient-specific, evidence-based recommendations; summarize patient data in easy-to-review graphical displays;[3] and provide relevant information that is

integrated into the clinician's workflow. The clinician receives and reviews the information while making clinical decisions, such as during the clinic visit.

Introducing information technology can, however, create unforeseen errors.[4] For example, a study by Cheng and colleagues[5] examined the effects of computerized prescription order entry on workflow in an intensive care unit (ICU). Deployment of this order entry system increased workload on the health care team and raised the likelihood of new errors, such as those resulting from using a new graphical user interface and entering data incorrectly. In order to improve patient safety with a decision support system and prevent errors resulting from the technology, thoughtful development and careful testing of the system must occur before deployment, as well as monitoring after deployment.

ATHENA-DSS is a computerized decision support system (DSS) that can improve patient care and has been extensively tested for errors.[3, 4, 5, 6, 7, 8, 9] It was initially deployed to improve management of hypertension (ATHENA-Hypertension) by providing patient-specific, evidence-based recommendations to primary care clinicians during the outpatient encounter. ATHENA-Hypertension is currently being deployed and studied in a large multisite randomized controlled trial.[6]

The ATHENA-DSS system integrates seamlessly into VistA—the electronic medical record (EMR) used at the U.S. Department of Veterans Affairs (VA)—and its user interface, the Computerized Patient Record System (CPRS). When an appropriate provider selects a patient in CPRS for whom ATHENA-DSS has a recommendation, the ATHENA-DSS displays a pop-up window in front of the CPRS cover sheet. This display is easily minimized or closed when the physician wants to view CPRS.

ATHENA-DSS consists of a knowledge base that allows knowledge engineers to codify and translate portions of a clinical practice guideline into a computable format and a reasoning engine; this, in turn, generates patient-specific recommendations by processing the patient data with the guideline knowledge in the knowledge base.[10] Using patient data from VistA, ATHENA-DSS is able to reason about a patient's condition and issue guideline-based recommendations to improve care.

In 2004, the VA funded an additional ATHENA-DSS project to improve management of chronic noncancer pain using opioid therapy. Chronic pain is an important public health problem. It is estimated that half of VA patients are diagnosed with at least one type of chronic pain, and approximately one-third of these are prescribed at least one opioid pain medication.[11] The management of opioid therapy for chronic pain by primary care physicians presents a significant clinical problem. First, these providers tend to be undertrained in opioid therapy, and second, there is a high prevalence of substance use disorders and other psychiatric comorbidities that complicate opioid therapy in some patient populations.[12, 13] Physician "best practice" must balance the need for pain relief against the risks of adverse effects and opioid misuse.

The VA/Department of Defense (DoD) Clinical Practice Guideline (CPG) for the Management of Opioid Therapy for Chronic Pain[14] provides much needed guidance to physicians, but it is being underused. With the help of expert clinicians and authors of the guideline, we codified and translated the guideline into the ATHENA-Opioid Therapy knowledge base. ATHENA-Opioid

Therapy delivers patient-specific, guideline-based recommendations to primary care providers at the point of care and will be studied in a pilot implementation at the VA Palo Alto Health Care System.

In this paper, we examine the potential improvements to patient safety that can result from having primary care providers use ATHENA-Opioid Therapy. We also examine methods for identifying and addressing new potential errors when introducing a computerized clinical decision support system into the clinical workflow.

Elements of Athena-Opioid Therapy Designed to Increase Patient Safety

ATHENA-Opioid Therapy has been constructed specifically to address issues related to patient safety (Figure 1). ATHENA-Opioid Therapy focuses on reducing patient risk in three main ways: (1) identifying patients with physical conditions that raise risk for overdose and recommending more conservative dosing, (2) identifying patients with mental health problems or other risk factors that increase the likelihood of medication abuse and recommending close monitoring and referral to psychiatric care, and (3) assisting doctors with complex pharmacological calculations to reduce risk of mistakes when initiating, titrating, or switching medications. Furthermore, we designed the graphical user interface of ATHENA-Opioid Therapy to prioritize the display of information and to enhance patient safety features.

Reducing Risk of Overdose or Medication Abuse

Opioid overdose may be fatal due to respiratory depression. Several populations of patients are at risk for overdose, including: (1) patients with substance addiction or abuse problems who may overconsume medication; (2) patients with dementia or psychosis who may lack the mental capacity to take their medication as prescribed; (3) patients with lung, liver, or kidney problems who may have a greater sensitivity to opioid medication; and (4) patients on other medications that may amplify the effects of opioid medication.

ATHENA-Opioid Therapy identifies these patients based on three sources of data:

- Patients at risk because of diagnosed conditions (e.g., substance dependence, dementia, COPD) are identified based on diagnosis codes, ICD-9, in their medical records.
- Patients receiving prescriptions for medications that may increase their risk of overdose in combination with opioids (e.g., benzodiazepines, barbiturates) are identified using pharmacy records.
- Patients with suggestive laboratory results (e.g., positive drug screens for cocaine or opioids) are identified based on laboratory records.

For patients at risk due to mental health or substance use disorders, ATHENA-Opioid Therapy makes recommendations to the primary care provider to ensure that opioid use is closely monitored through urine drug screening, more frequent followup, use of patient contracts, and education of caregivers. The DSS also makes recommendations for appropriate referrals,

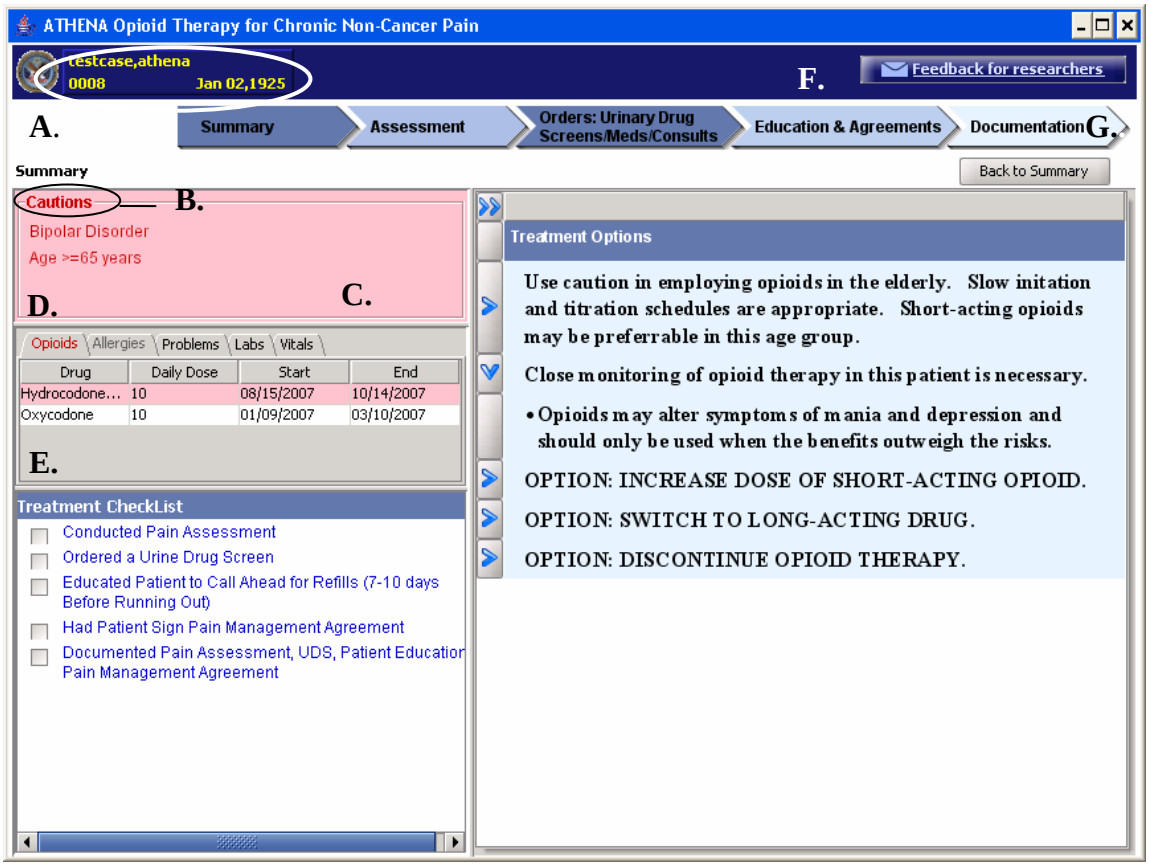

Figure 1. ATHENA-Opioid Therapy for chronic noncancer pain pop-up. Highlights of patient safety features in ATHENA-Opioid Therapy.

A. Patient identifiers: The graphical user interface (GUI) shows two identifiers: name and social security number, to help ensure information on the correct patient is presented.

B. Cautions: Important patient characteristics that are relevant to opioid prescribing are highlighted in red with a pink background to draw the provider's attention to the area.

C. Treatment options: Patient-specific recommendations are issued. These provide information and recommendations relevant to patient characteristics highlighted in the cautions table, as well as detailed instructions for possible general treatment options the provider may be considering.

D. Data tables: Potentially relevant information on history of opioid prescriptions, allergies, diagnoses, labs, and vital signs are presented in tabular form. Information of clear relevance to opioid prescribing is highlighted in pink (e.g., a current active prescription for an opioid medication).

E: Treatment checklist: Recommended chronic pain care practices that should be carried out at all visits are listed for the provider to check when completed.

F. Feedback for researchers: This button provides a text box where comments to the research team can be added.

G. Drop-down tools: These drop down menus include tools to assist the primary care physician with chronic pain management. Tools include a structured pain assessment, instructions for conducting urine drug screens and making patient referrals to specialty care, a conversion calculator, patient education materials, a template for an opioid contract, and information about useful community resources.

assessment of prescriptions from providers outside the system, alternative or adjuctive therapy, and proper documentation of treatment.

For patients at risk because of medical conditions or concurrent prescriptions, the system recommends a modified opioid dosing schedule, including slower medication tritration, lower initial starting doses, and more conservative conversions when switching medication, based on the patients' risk factors.

Reducing Risk of Prescription Errors

To reduce risk for prescription errors, two tools have been provided: (1) specific doses and schedules for titration and discontinuation and (2) a calculator for opioid conversion. Based on available information in VistA, the system issues specific medication dosing schedules for initiation, titration, and discontinuation. For example, if a patient has respiratory, kidney, or liver disease or is over age 65, the system recommends smaller and slower dose changes when escalating or reducing opioid levels.

Patients may also be harmed by errors in dosing calculations when physicians attempt to switch a patient's medication. To address this issue, ATHENA-Opioid Therapy has a conversion calculator that is easily accessible and usable (Figure 2). This calculator provides equianalgesic doses and instructions for medication titration during conversion from one opioid medication to another. The conversions have been reviewed by two experts in opioid therapy. Our preliminary studies on usability of the conversion calculator suggest that it is usable and will help avoid conversion errors.

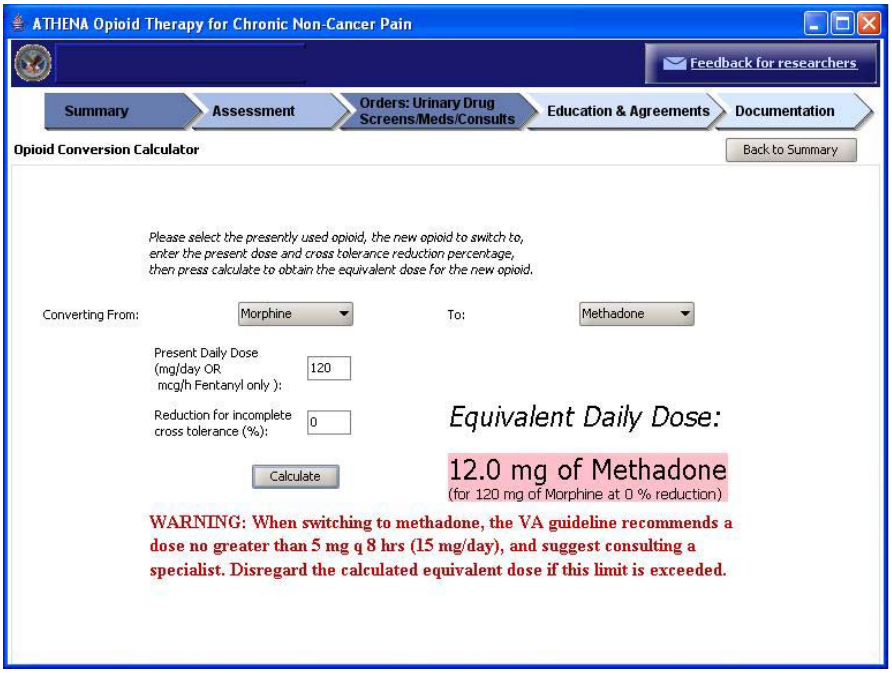

Figure 2. ATHENA-Opioid Therapy conversion calculator.

Graphical User Interface Elements to Improve Patient Safety

Just providing information to the clinician in his or her busy workflow will not necessarily influence clinical management of opioid therapy. It is necessary to provide information in a way that can capture the clinician's attention. The information has to be selective and organized in order to facilitate readability. The ATHENA-Opioid Therapy team made choices of what information was essential at the first layer, how to group such information, and the format for display. We relied on a "Less is more" paradigm, focusing first on highlighting risks to prevent medication error/abuse and second on providing general information to improve assessment, education and documentation of chronic pain management. Features of our graphical user interface (GUI) to improve patient safety are depicted in Figure 1 and include:

Cautions box. ATHENA-Opioid Therapy presents a cautions box which identifies patient-specific characteristics that may impact a doctor's prescribing decisions regarding opiate therapy for chronic pain (Figure 1). This box displays conditions that increase the risk of opioid prescription but might not be obvious to the primary care provider from reading the patient's health record. For example, clinicians are alerted if a patient has a diagnosis of a substance use disorder, a positive urine drug screen, or an elevated creatinine value.

Patient-specific recommendations. The system issues patient-specific recommendations that are tailored to the patient's conditions and current treatments. The recommendations are meant to encourage guideline adherance and address patient safety. For example, if a patient has a substance use disorder, the system will alert the physician that it is necessary to closely monitor the patient and provide information on referrals.

Detailed prescribing recommendations for general treatment options. Once the clinician has decided on a general treatment plan—such as initiating a short-acting opioid, switching from a short-acting to a long-acting medication, or discontinuing opioid medication—the system provides detailed recommendations for the choice of opiate and dosing schedule. Following these recommended dosing schedules should reduce risk of overdose, side effects, and withdrawal symptoms. The system would also alert the provider if a patient has an allergy to an opiate and he or she should not recommend that drug.

Data tables. Using a data table format, the system presents and highlights prescriptions, labs, allergies, vital signs, and medical conditions that are potentially relevant to opioid prescribing decisions. The system highlights relevant information that contributes to patient-specific recommendations in red, thus bringing important data about patient characteristics and treatment history to the provider's attention.

Pain management tools. Numerous tools that facilitate guideline-adherent opioid prescribing practices are included in drop-down menus on the user interface. These include the above mentioned conversion calculator, templates for opioid contracts, patient education materials, and instructions for addressing medication side effects. These tools are designed to assist and encourage primary care clinicians to communicate with their patients about their opioid therapy plan, set goals and boundaries for prescribing, and ensure that side effects are minimized.

We have also developed templated assessment tools and checklists to help clinicians thoroughly and correctly assess and document the pain condition being treated and treatments tried

previously. Clinicians are given the option of having these assessments written back into the patient's medical record as a structured note. By encouraging good documentation practices, we hope ATHENA-Opioid Therapy will improve care coordination among members of the treatment team.

Two patient identifiers. To clearly identify the patient for whom the recommendations are being generated, the patient's name and social security number appear in yellow with a dark blue background at the top level of the window. This was an institutional requirement.

Text feedback box. We realize that timely interaction with clinicians using the system is needed to ensure patient safety in ATHENA-Opioid Therapy. For example, if a clinician identifies an unexpected problem with the accuracy of the recommendations, it is important that this information be quickly reported to the development team so that it can be promptly corrected. For this purpose, we created a feedback button that allows clinicians to send us text feedback about any issues they encounter using the system. This feedback is reviewed frequently, and responses are sent to clinicians. The importance of early detection of unexpected problems cannot be overstated to ensure the generation of correct recommendations.[15]

Redundant information. Patient information that is relevant to opioid prescribing is repeated many times in the GUI. For example a history of substance abuse will appear in red in the "Cautions" area, be highlighted in the patient data table, and be used in patient-specific recommendations, such as "Patient has a history of cocaine abuse. Consider referral to addiction specialist to manage pain." This helps to emphasize relevant clinical information for opioid management for busy clinicians.

Testing of the Athena-Opioid Therapy System

Before ATHENA-Opioid Therapy is deployed into general use it will have undergone extensive testing. Our testing will consist of three main phases:

Phase 1: System Testing. In addition to standard tests of the interoperability, functionality, VA integration, and performance of the ATHENA-Opioid Therapy system, specialized testing of the clinical information provided by the system is crucial to ensuring patient safety. Towards that end, we developed several methods for this testing.

To test the clinical algorithm, all elements of the algorithm encoded in the knowledge base were written into a "rules document." This rules document was iteratively reviewed by three members of the expert consensus panel that wrote the VA/DoD clinical practice guideline for the management of opioid therapy for chronic pain. It was revised based on their clarifications and corrections until consensus was reached. The knowledge base was then updated to match the consensus rules. As a further check of the accuracy of the ATHENA-Opioid Therapy recommendations, system recommendations for real patient cases are being reviewed by clinicians with expertise in the treatment of chronic pain, substance use disorder, and mental health problems, and identified errors are being corrected in the knowledge base.

Phase 2: Usability Testing. Clinical recommendations are only useful if they are viewed and followed by primary care physicians. To ensure that ATHENA-Opioid Therapy is designed so that primary care physicians can easily and reliably use the system without extensive training, we

are conducting usability testing with sample patient cases viewed in a laboratory setting. Volunteer providers are briefly trained on the elements of the system, and they then provide feedback on their understanding of these elements, their usability in clinical practice, the likelihood that they would use them with their patients, and their suggestions for system improvement. Providers then walk through an assessment of several patient cases using the system with a study team member to demonstrate how they would use the system during patient care. Based on usability testing, we have redesigned our GUI and altered the level of detail offered in initial recommendations. We will continue usability testing on the redesigned system with additional providers.

Phase 3: In-clinic testing. Once the system has passed initial system and usability testing, ATHENA-Opioid Therapy will be deployed into real-time practice with volunteer primary care physicians at the VA Palo Alto Health Care System. These clinicians will use ATHENA-Opioid Therapy with real patients and provide feedback on the accuracy, usability, and helpfulness of the system in four ways:

- Clinicians are encouraged to use the feedback button on the GUI, where they can enter comments about a specific patient case or the system in general as they interact with ATHENA-Opioid Therapy. These comments will be evaluated by the study team every 2 days.
- We will telephone volunteer clinicians monthly for a brief interview about their recent experience with the system, problems encountered, and recommendations for improvement.
- We will shadow volunteer primary care providers in the clinic to observe their use of the system during visits.
- Volunteer physicians will complete standardized assessments of software usability and user satisfaction, so that ATHENA-Opioid Therapy can be compared to similar decision support systems. We expect this in-clinic testing to improve patient safety by ensuring that the system provides accurate recommendations and information during real clinical use, does not interfere with the patient visit or distract from other patient care and safety issues, and fits with clinical workflow such that it is used regularly by primary care providers.

Discussion

The ATHENA-Opioid Therapy system has the potential to increase guideline-concordant prescribing, improve documentation of patient management, reduce misuse or abuse of opioids, and improve patient outcomes. Because of the inherent risks related to opioid prescription, we have designed a system that can help maximize patient safety and improve management of chronic noncancer pain.

Our ability to design patient safety features in ATHENA-Opioid Therapy has been limited by several factors. A substantial limitation is a lack of reliable, easily extractable, patient health information in VistA. In order to make appropriate decisions about whether to increase, decrease, maintain, or discontinue opioid therapy in a patient, a provider must monitor changes in chronic pain and social, emotional, and physical functioning over time and during trials of medication. While providers are supposed to enter this information in CPRS, we found that chronic pain

management plans are poorly documented in the medical record. When documented, this information is often written in free-text notes, making automated data extraction difficult.

Additionally, VistA contains data only on patient care received in the VA. Some patients receive care from non-VA providers who also may prescribe opioids or develop chronic pain management plans. While we have not been able to completely overcome this substantial limitation, we have made several design decisions to reduce the impact of this problem:

- We included structured chronic pain assessment templates among the system tools, and providers are encouraged to use them. These assessment tools will be written back to VistA in a structured format that will allow for later data extraction to inform clinical recommendations. Thus, we hope the system will not only improve documentation of pain management plans, but also ensure that information is available in a computer-accessible format.
- We provide recommendations and instructions to clinicians to ask patients about care and prescriptions received outside the VA.
- We acknowledge that the limitations of the patient data do not allow us to reliably make decisions about whether it is best to increase, decrease, maintain, or discontinue opioid therapy in a particular patient. Instead of presenting a "best guess," the system presents physicians with detailed instructions on how to proceed once a treatment option has been chosen. Thus, we try to make optimal use of the ability of ATHENA-Opioid Therapy to make dosage and medication recommendations, while encouraging the provider to communicate with the patient to make decisions about the course of treatment.

The system is also limited by lack of specificity in the clinical practice guidelines. Although opioid therapy for pain is by no means a new treatment, there have been surprisingly few well-designed clinical trials on which to base clinical practice recommendations. Therefore, the current guidelines are based primarily on expert opinion, and we have had little empirical information to use when operationalizing the guideline recommendations. To address this limitation, we developed a protocol that included iterative review by clinical experts and guideline authors to ensure that the clinical algorithm encoded in the ATHENA-Opioid Therapy system accurately represented the expert consensus. We expect that recommended practices will change over time and that this will require updates to the knowledge base. Positively, the ATHENA-Opioid Therapy knowledge base is relatively easy to modify as knowledge evolves. The system is flexible enough to grow with the base of clinical evidence.

Clinician time constraints also limit the impact of the decision support system on patient care and patient safety. Primary care visits are short, and VA primary care patients typically have multiple disorders that require attention. Thus, primary care clinicians often have only minutes to devote to chronic pain management. In order to be helpful within this time frame, recommendations and tools must provide quick, concise information to guide decisionmaking. To balance the need to present detailed information to ensure patient safety with the reality of primary care practice, we display short objective recommendations to clinicians, supported by drop-down boxes with detailed information and clinical instructions, should the clinician require more information. Nevertheless, given the time constraints and competing interests found in the real-life clinical setting, we await empirical evaluation to assess whether ATHENA-Opioid Therapy can effectively modify clinician practice.

We met a specific patient safety challenge when trying to develop recommendations for the use of methadone for treatment of chronic pain in primary care. Methadone is an excellent, long-acting analgesic. It is substantially cheaper than other comparable opioid medications, costing up to 100 times less than other long-acting options for an equianalgesic dose. Thus, our local health care system encourages use of methadone and has recommended its use for treatment of chronic noncancer pain.

However, methadone can be difficult and dangerous to initiate and titrate up, as medication levels build up over the course of days and may not reach steady state for up to a week. A dose that is optimally analgesic on day one could build up to blood levels that could induce accidental overdose and death in subsequent days. Indeed, as use of methadone for chronic pain has increased in the recent past, rates of accidental overdose have increased. For example, a study in Utah from 1997 to 2004 found that, in conjunction with a 727-percent increase in number of methadone prescriptions, accidental methadone-related deaths increased 1,770 percent.[16]

An analysis of adverse events in Medicaid administrative claims data suggests that, compared to prescription of other opioid medications, methadone prescription is associated with greater risk of overdose symptoms.[17] To address the conflicting goals of providing cost-effective pain management and minimizing serious adverse events related to opioid prescriptions, we have worked closely with our expert team and the head of primary care at our medical center to balance the benefits of the low cost and effectiveness of methadone with its patient safety risk. Thus, ATHENA-Opioid Therapy recommends conservative dosing practices for initiation, titration, and conversion to methadone, and it provides additional warnings about overdose risk when methadone is prescribed or recommended.

In addition to the more direct benefits of highlighting at-risk patients and preventing prescribing errors, we hope that ATHENA-Opioid Therapy will positively contribute to patient-provider communication. Pain and substance addiction can produce strong emotional reactions, leading both patients and providers to feel threatened, uncomfortable, and/or mistrustful during discussions about opioid prescribing. ATHENA-Opioid Therapy has the potential to encourage these discussions by initiating interactions about uncomfortable subject matter, depersonalizing concerns about substance use problems or mental health status, ensuring that the provider is aware of previous treatment plans, and outlining the proper practices of pain management for the clinician.

Conclusion

ATHENA-Opioid Therapy provides a model for the development of decision support systems to improve patient care by improving clinical guideline adherence with a focus on patient safety. Through a combination of careful design, multilevel iterative testing, and consideration of the realities of the clinical practice setting and the current medical record system, we developed a decision support system with a potential for reducing patient risk associated with opioid prescribing. Evaluation of the effectiveness of this system for improving clinical practice and reducing opioid overdose, side effects, and adverse events will determine the extent to which ATHENA-Opioid Therapy achieves this potential.

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

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Abstract

Electronic health records are thought to improve quality of care; computerized provider order entry (CPOE) systems are believed to reduce medication errors. Yet, research suggests that implementation of new technologies revises existing sociotechnical systems and introduces unpredicted and unintended consequences, including the generation of new types of errors. We narrate development and implementation of a CPOE system—specifically a homegrown, e-prescribing system—in a community-based, integrated health care system. We describe the strategies used and lessons learned that enabled successful adoption: buy-in starts at the top of the organization; ongoing communication is key; a team-oriented culture is critical to success; iterative implementation is a useful strategy; ongoing and readily accessible training is necessary; involvement of clinicians achieves buy-in and contributes to ongoing improvements; and workflow redesign is an integral facet of implementation. These strategies and lessons were used to minimize unintended consequences and to maximize the potential of e-prescribing technology to improve medication safety.

Introduction

A recent systematic review of the impact of health information technology (HIT) on the quality of medical care revealed that HIT interventions—primarily electronic health records (EHRs)—improve quality by improving medication safety, increasing adherence to guidelines, and providing tools to enhance disease surveillance.[1] Most research that documents these benefits describes a few systems implemented in the inpatient setting, primarily in academic medical centers.[2, 3, 4, 5, 6, 7] Less work has been conducted in the ambulatory setting, where volumes and complexities are greater.[8] Much of this work describes the benefits of computerized provider order entry (CPOE) systems, which have been studied as a proxy for EHRs.[9]

The limited body of literature describing the benefits of EHRs reflects the fact that in the United States, adoption of EHRs has been slow in both inpatient and ambulatory settings.[10] The perceived barriers are many: increased workload for clinicians; unfavorable impact on workflow and communications; negative emotions; changes in power structures; and importantly, generation of new kinds of errors.[10, 11, 12, 13] Research suggests that the implementation of new technologies revises existing sociotechnical systems, creating behavior changes that cannot be fully predicted from the individual social or technical components.[14] These changes result in

unintended consequences, called latent or silent errors. Indeed, the social organization of medical work is now widely recognized as an important aspect to consider when designing and implementing HIT solutions to improve health care.[14]

Use of a CPOE System to Improve Medication Safety

The Everett Clinic prioritized implementation of a CPOE system, specifically an e-prescribing system, primarily to improve medication safety by reducing medication errors. Further, embracing the philosophy that unintended consequences can originate from unexpected sources—such as system design, implementation strategies, or the organizational culture associated therewith—The Everett Clinic paid careful attention to these overarching aspects during e-prescribing implementation and documented the strategies and lessons learned. In this report, we provide a chronologic narrative of e-prescribing implementation, weaving throughout a description of the strategies that enabled successful implementation. We also present a comprehensive list of lessons learned and highlight the importance of these lessons in minimizing unintended consequences and improving medication safety. Separately, we have conducted quantitative evaluations of the impact of the e-prescribing system on medication errors and on the time-intensity of e-prescribing. The results of these studies are being reported separately.

Setting

Founded in 1924, The Everett Clinic (the Clinic) is a vertically integrated, multispecialty physician group practice that provides comprehensive, community-wide health care for the northern Puget Sound area. Over 250 physician-owners deliver care to 225,000 patients in 14 ambulatory locations. Facilities include eight urgent care clinics, two outpatient surgery centers, comprehensive laboratory services, an advanced imaging center, four retail pharmacies, and a cancer center. A hospitalist team from the Clinic admits to the single hospital in the local market and provides continuity of care between the ambulatory and inpatient settings.

The culture of the Clinic includes a stable leadership team that embraces a culture of safety, efficiency, and continuous quality improvement of clinical care. A high priority is implementing programs aligned with the six aims for improving health care in the 21st century, as promulgated by the Institute of Medicine, which include effective use of information technology (IT) and re-engineering care processes.[15]

The Clinic maintains a full array of HIT services through its wholly owned IT subsidiary. From 1995 through 2007, these IT professionals were responsible for developing and implementing the Clinic's homegrown EHR and e-prescribing system. In late 2006, in the interest of long-term sustainability of the EHR, the Clinic's board of directors made the deliberate decision to transition to a vendor-purchased EHR, purchasing Epic® (Epic Systems Corporation, Verona, WI) in 2007. The Clinic is now in the process of customizing the Epic® system with features of its homegrown system, particularly its e-prescribing system. The strategies used and lessons learned from implementing the Clinic's homegrown systems are proving useful in the Epic® rollout.

Developing and Implementing the Homegrown e-Prescribing System

Context

At the outset, a physician advisory board was appointed to guide implementation of clinical IT initiatives. The homegrown EHR was launched in 1995, with additional features and functionality added over time (Table 1).[16]

Several times during these years, leadership conducted market evaluations of commercially available EHR products, but at each juncture, they found that available systems were expensive, cumbersome, and not well-accepted by users, and they were thought to decrease workflow and productivity. Thus, until 2006, the Clinic returned to development of their homegrown system. Throughout the development process, the developers paid close attention to meeting national standards as codified (e.g., Health Level 7[17]), and to maintaining compliance with requirements of the Health Insurance Portability and Accountability Act (HIPAA).[18]

Since its inception, a detailed log has been kept of every user transaction, which has provided a rich source of data for making improvements in safety and quality.

Lessons learned. The advisory board is of pivotal importance in

Table 1. Timeline for the development and implementation of the electronic health record

Year	Activity or feature developed/implemented
1995 - 1997	• IT subsidiary formed • Intranet developed • Practice management system converted to Web platform
1997 - 1998	• Development of comprehensive, homegrown EHR prioritized by leadership • Transcription system for chart notes and radiology reports
1999	• Patient profile added to transcription system: demographics, problem list, surgeries, medication list, allergies
2000	• Laboratory system
2000 - 2002	• Integration of practice management, transcription and laboratory systems create true EHR • Features added: physician schedules, health maintenance information, immunizations, reference laboratory reports, radiology images, pathology reports, and electrocardiograms • Links added for access to patients' insurance plans, patient educational materials, drug information and disease management guidelines, and patient registry information • Security system developed: single sign-on required; electronic signatures added • Hospital admit and discharge summaries; hospital images • Remote access from off campus
2002	• E-prescribing module prioritized, with the goal of improving medication safety
2003 - 2005	• Development and rollout of e-prescribing system (see text)

EHR = electronic health record; IT = information technology

setting priorities in an organization where competing priorities are the norm, for example, making investment decisions and ensuring that projects stay on track.

E-Prescribing Development and Testing

The e-prescribing module was prioritized in 2002. The Clinic purchased the Multum® drug database (Cerner Multum, Inc., Denver, CO) and, using it as the backbone, spent several months developing the e-prescribing module. Two clinical pharmacists led the effort on the clinical side, working closely with the IT professionals. Their task was to ensure that the drug database used to populate the module was accurate and relevant and that screens were easy to use and involved minimal manipulation. The resulting e-prescribing system is Web-based and includes point-and-click functionality. Medications, strengths, doses, and directions are selected from drop-down menus. When a prescription is written electronically, it is saved on the mainframe computer and can be printed and handed to the patient or automatically faxed (auto-faxed) to a retail pharmacy of the patient's choosing. (Prescribing software does not currently allow for full electronic transfer to retail pharmacy order entry software.) The printed prescription is maintained by the retail pharmacy as part of the patient record.

The Clinic developed an e-prescribing system that includes basic clinical decision support (CDS) features,[19] reasoning that it was best to start simply and to not overwhelm users with too much information. Features included from the outset were basic dosing guidance, formulary decision support, and duplicate therapy checking. Fearful of causing "alert fatigue"[20] due to the display of clinically insignificant alerts, the conscious decision was made to delay implementation of drug-allergy and drug-drug interaction checking.

During development, Clinic leadership educated all prescribers and staff about the upcoming change from paper-based to electronic prescribing. A mascot representing the change was designed and introduced to facilitate buy-in: a "superhero" named "MedMan," short for Medication Management. MedMan was used to convey the important information that one of the primary goals of the e-prescribing system was to improve medication safety. The term proved quite popular among physicians and staff, and MedMan became synonymous with the e-prescribing system. One clinic was selected to pilot the e-prescribing module; this was an internal medicine site with six prescribers who were enthusiastic about the prospect. Training was provided, and the module went live on July 1, 2003 (Day 0).

Lessons learned. Each feature added must be easy to use and require minimum effort to navigate. Quality and efficiency must be built in with every step. Extensive user interviewing and testing are necessary—not just feature-specific testing but also testing of component integration. Testing becomes more complex as the system matures, and adequate time must be allocated. Perception differs among users, and testing efforts should accommodate as many user styles as possible. Feedback should be encouraged from all, incorporated, and used to facilitate system improvements, enhancements, and error corrections. A helpful tactic is to decide what is "mission critical" with each new release, withholding launch until these elements are perfected.

Training and Implementation

Five months after Day 0, the average number of prescriptions leaving the internal medicine site weekly was 625, a small number but a sound start. The early success story at the pilot clinic was

championed at site-specific, clinic-wide, and board of directors meetings. Implementation at other sites proceeded according to a strategic plan, created based on the culture and provider mix at each site; primary care sites preceded specialty sites. Site-specific launch meetings were provided in the group setting; buy-in was achieved by providing advance education. The old adage, "Tell them what you are going to tell them; tell them; tell them what you told them," held true for implementation.

Clinical pharmacists and IT professionals provided training, one on one, at the point of care, with a minimum of two subsequent "check-ins." Training continued on an as-needed, just-in-time basis, with the IT professionals and the clinical pharmacists serving as the "help desk," monitoring backend utilization, and responding to telephone calls and e-mails about software/ hardware or clinical issues, respectively. Training during implementation was divided into two phases: authorizing prescription refills, followed by writing new prescriptions. Use of the system was encouraged but remained voluntary.

The speed of adoption varied widely. Previous computer experience ranged from novice to expert and from positive to negative. Each factor influenced adoption beliefs. Early adopters served as trainers. Late adopters were encouraged by addressing their perceived barriers in one-on-one meetings. Although prescribers at one site voiced strong opposition to e-prescribing, leadership listened to their concerns, assisted them in realizing the benefits of the system, and proceeded with implementation. Newly hired prescribers were expected to use the system from the day they joined the practice.

Eighteen months after Day 0, 110 prescribers were using the e-prescribing system for at least some of their prescribing, resulting in over 6,000 e-prescriptions transmitted to pharmacies, weekly; 24 months after Day 0, 200 of the 225 prescribers were prescribing electronically. The final site to go live was the ophthalmology clinic, which went live 51 months after Day 0. Maintenance was provided, and enhancements were made throughout this time, with vigilant monitoring and constant attention paid to improvements. Over time, lists of prescribers' favorite medications and drug laboratory checks were added. These provided additional medication safety features and proved popular. A list of over 225 retail pharmacies to which prescriptions could be auto-faxed was added. At present 5,000 new e-prescriptions leave the Clinic daily, 95 percent of the total number written.

Lessons learned. Including IT and clinical personnel as members of testing and implementation teams results in a more robust product, facilitates buy-in, and helps streamline rollout. Key to our success was the iterative process by which new features were introduced and implemented. Coupled with this was the deliberate decision to slow implementation until users became accustomed to new features already released. This approach prevented widespread resistance or even potential rebellion, and it allowed the necessary time to make small course adjustments without abandoning the entire project.

Gradual development and implementation kept the system affordable and prevented substantive reductions in productivity during rollout. Sharing with clinicians the preliminary results of our quantitative evaluations—which have revealed a reduction in medication error rates and the time-neutrality of e-prescribing—further facilitated buy-in.

Training provided “just in time” and 24/7 minimized user frustration and provided opportunities to educate users about appropriate use. In vigilantly monitoring the backend of the system, the pharmacists found many opportunities for clarification, retraining, and identification of database or programming errors, thus minimizing the occurrence of prescription-related medication errors. The trainers also found that users adopt technology at widely varying rates; and although users might not ask questions, full understanding could not be inferred by the lack of questions. Demonstrations were highly effective; understanding was assured when the user could repeat the demonstration using the mouse him/herself.

Using early adopters as trainers was well received. Peer pressure created an incentive for adoption. Negative first impressions expressed by reluctant users were frequently overcome with acknowledgment of their concerns and familiarity of use. One year after implementation, the group that was initially resistant admitted to liking the system and to seeing the benefits. The new physician-owners have embraced the use of the system from the moment they joined the practice.

When training, the team realized that physicians have never been trained to handwrite prescriptions. Many prescribers were unfamiliar with units of measurement used to accurately prescribe medications (e.g., teaspoons vs. milliliters). A review of the necessary components was undertaken prior to transitioning to e-prescribing. This greatly helped ease the transition from paper to electronic prescribing and reinforced best prescribing practices to maximize medication safety.

Network

E-prescribing adoption proceeded more quickly than leadership had anticipated. An unanticipated problem was that the IT infrastructure (i.e., facsimile servers, stability, and redundancy) was unable to keep up with adoption. As prescription volume increased, network speed to facilitate auto-faxing became important. The Clinic engendered the cooperation of the local utility company to solve the problem of the long “fax queue” of prescriptions to dispensing pharmacies. Several receiving retail pharmacies also agreed to add additional fax machines to ease the backlog. Development was sometimes postponed to allow time for more robust infrastructure development. System upgrades caused slowdowns, of which clinicians were intolerant. One system upgrade caused speed-related user complaints to increase from 10 to 150 calls per week.

Lessons learned. Sufficient up-front investment in the infrastructure is necessary to support rapid adoption. Speed is dictated by the type of cable used by the local utility company; fiber optic cable is faster than microwave. Keeping the network functioning well requires constant vigilance by IT professionals. Also important is the development of a sound plan that can be activated when the system becomes unavailable. Downtime procedures should include processes for patient registration, patient charting, and handwritten prescribing and for incorporating these into the EHR when it again becomes functional.

Retail Pharmacies

At the time of implementation, retail pharmacies that served clinic patients were not accustomed to receiving electronically written prescriptions via auto-fax. Leadership educated members of

the Washington State Board of Pharmacy regarding the benefits of e-prescribing and walked board members through the process of prescription verification. Rules for electronically transmitting prescriptions were developed and approved by the State Board prior to launch. Prescription legitimacy is now verified by setting both the sending and receiving fax machines to display the corresponding telephone numbers.

Lessons learned. Educational efforts conducted by the Clinic for retail pharmacists and State Board members facilitated the e-prescribing process. This, in turn, improved patient care by decreasing wait times at the pharmacy and by eliminating a step wherein drug diversion could occur. It also provided an opportunity to educate these important stakeholders about the realities of functioning in a medical group and about the emerging trend of e-prescribing.

Clinic Workflow

The most challenging issues involved the hardware and platform on which the EHR and e-prescribing module were housed. Prior to July 2003, users accessed the EHR via desktop computer terminals located in each prescriber's office and at centrally located workstations throughout the clinics. However, the Clinic's goal was to provide each prescriber with his/her own laptop computer and to have all users access the EHR using a clinic-wide wireless network.

Thus, in July 2003, each prescriber at the pilot site was provided with a laptop, with the intent that it would serve as a personal mobile device they could take into the examination room during the day and home at night. The initial strategy for e-prescribing (software) rollout also included the rollout of hardware and networking capabilities. Sites were grouped into three categories for ordered implementation: (1) refills partially adopted/wired desktops, (2) refills partially adopted/wireless laptops, and (3) refills fully adopted/wireless laptops. In the midst of this rollout, the IT professionals realized that the goal of functioning entirely on a wireless network was not feasible in the near term, due to issues of stability, reliability, and robustness. Leadership spent several months exploring solutions, eventually abandoning wireless implementation in its entirety, in favor of hardwiring all 505 examination rooms with desktop computers.

By early 2006, the Clinic was exploring designs for hardwiring examination rooms, with a focus on workflow; two options that were seriously considered were mobile carts and wall mounted systems with flexible arms; the latter option eventually was adopted. Mock examination rooms were configured; users were invited to try them out and provide feedback. A walkthrough was conducted at all 505 examination rooms. Space issues were paramount, and configuration solutions were sometimes unique to each examination room; retrofitting was sometimes necessary. A Web site was created through which stakeholders could express their views and make recommendations. A list of Frequently Asked Questions (FAQs) was posted.

Because of e-prescribing implementation and installation of desktop computers in examination rooms, clinical workflow was re-engineered to standardize processes, increase efficiencies, and integrate care among clinicians and staff. A standard rooming process was adopted, empowering medical assistants to perform several tasks intended to improve care. In addition to rooming each patient and taking vital signs, medical assistants now schedule mammograms and colonoscopies, conduct incentive spirometry checks, prepare laboratory orders, and prompt prescribers about disease management reminders.

As workflow changed, the requirement for increased competence in managing medications became apparent. The clinical pharmacists created an educational module targeted toward frontline clinic staff, which described the top 200 medications that receive refill requests and prompt medication questions from patients. The module includes a crosswalk between brand and generic names, drug indications, and a short list of drug-specific monitoring parameters. The program is delivered through a PowerPoint® presentation, a 20-page handout, and a quiz. Separately, registered nurses, who have historically been required to contact physicians directly to obtain approval for prescription refill requests or to find answers to patient-specific questions, can now send an e-mail on the Clinic intranet system, alerting the prescriber to the situation and the desired outcome. The use of these e-mails, called "patient encounter forms" (PEFs), has streamlined exchanges between physicians and nurses, allowing each professional to prioritize their daily tasks as they see best.

Lessons learned. Determining the adequacy of wireless network speed installations was sometimes delayed for 2 to 3 weeks after installation. Ultimately, it was the physical plant infrastructure that prevented installation of a reliable wireless network.

With hardwiring, Clinic leadership realized early on that re-engineering workflow was necessary and that it would provide an opportunity to increase efficiencies and promote standardization, both of which are integral to successful implementation. Advance preparation for workflow redesign paid off with a smoother transition. Mockups were helpful in achieving buy-in and preventing later reworking. With the decision to install desktops came the realization that the physical area of the examination room of the future might need to be larger to accommodate new technologies and enable efficient workflow. Standards that promote handoffs from staff to provider and that integrate data entry and access among all users were particularly helpful in easing the providers' burden. Asynchronous communication between nurses and physicians has increased efficiencies.

Transitioning from one HIT solution to another (i.e., laptop to desktop) proved challenging. Users immediately compared the two. Anticipating this dynamic would be helpful, the team created a list of benefits of the more recent initiative and shared these when resistance surfaced.

Using a laptop is vastly different from using an examination room desktop, in that the former is used by a single individual, while the latter may be shared by multiple users. With the latter, accommodations were made for information sharing, moving between files, and user verification, as workflow demanded. A cultural shift from "my exam room" to the "standard exam room" was noted. A spike in e-prescription volume was also noted after desktop installation.

Patients have been overwhelmingly positive about the availability of the EHR in the examination room and enjoy looking at their data with the physician. Concerns that the provider no longer faces the patient have not materialized.

Security

Identifying a feasible solution to provide an adequate security system was another challenge. With busy clinicians and staff entering and exiting examination rooms upwards of 20 times daily, it was critical to adopt a system that would protect patient privacy and allow quick access,

while minimally impeding workflow. The Clinic adopted a system that first requires each user to login each morning. This initial login is followed by an unlimited number of secondary logins, using the combination of a swipe card and a short, user-specific password. In preparing for a patient visit, the medical assistant slides the card into a reader and receives access to screens appropriate for his/her level of employment. When the card is removed, the computer is secured and left in a mode that reverts to the queued patient when the provider swipes his/her card.

Lessons learned. Security issues were thought through from both the hardware (device) and software (application) perspectives. Finding a workable security solution took several months. In the end, the use of context-switching and logon/logoff cards was found to be an effective way to both secure work stations and switch between users.

Transitioning to a Vendor-Based Electronic Health Record

Notwithstanding the success of their homegrown EHR and e-prescribing system, adding additional technology began to stress and crash the homegrown system. Moreover, Clinic leadership and the IT professionals kept a pulse on developments in the field of commercially developed EHRs. Initially, the idea of transitioning to a vendor-purchased system was controversial amongst the physician-owners, but by 2006, the market had reached a level of maturity that made such discussions worthwhile.

The rationale for switching was that a commercial product, supported by resources sufficient to sustain ongoing development and evolution, would better position the Clinic for long-term success. It would also improve the safety and quality of care by providing more robust and integrated clinical outcomes data. The board of directors launched an educational campaign that described the benefits and risks of purchasing such an EHR. A Web-based dialogue was initiated. After months of thoughtful discussion, physician shareholders voted to purchase the Epic® system (Medi-Span®, Wolters Kluwer Health, Conshohocken, PA). Additional IT professionals were hired, and customization took place during 2007, with rollout anticipated to take up to 2 years.

Lessons learned. Lessons learned from the homegrown era are being applied. Once again, a clinic-wide dialogue to facilitate buy-in was critical to move the project forward. A pilot site transitioned first. “Super-users” have been called on to assist in implementation.

Customizing Epic®

From the e-prescribing perspective, the Clinic is customizing the Epic® product to incorporate features of its homegrown system that optimize medication use and safety. Team members have painstakingly mapped drugs from Multum® and the homegrown system to the drug database used by the Epic® system (Medi-Span®, Wolters Kluwer Health, Conshohocken, PA), as each database utilizes differing forms of drugs and dosage notations. Corrections are shared with the vendors when discrepancies are found. The clinicians on the team focus on every detail, dosage form, package size, and quantity dispensed, while the IT professionals focus on speed and reliability. The goal is 100 percent accuracy when it comes to prescribing medications; any standard less than this can predispose to patient harm.

The Clinic is creating robust preference lists to improve the clinician-user experience. The focus is on customizing advanced level CDS programming, limiting machine-actionable alerts to only those that are of clinical significance. The Pharmacy and Therapeutics Committee is overseeing the customization of drug-allergy and drug-drug interaction alerts. Epic® uses a 12-level alert system for allergies. The Clinic has decided to "fire" only a portion of these.

Similarly, the team has learned that the classification systems for drug-drug interactions used in the databases provided by the three vendors in the marketplace (Multum, Medi-Span, and First Databank®, San Bruno, CA) are different from the classification systems used in popular drug-drug interaction literature[21]; the former use a three-category system, and the latter uses a five-category system. Mapping these systems from Multum to Medi-Span has been challenging. E-prescribing will become mandatory when the Epic® system is totally implemented and fully functional.

Lessons learned. Customization of the drug database and CDS alerts has been a tedious and time-consuming task. The lack of standardization of classification systems used by vendors of the commercial drug databases has been a finding that was both unexpected and of some concern. The differing, yet complementary, areas of expertise of both clinicians and IT professionals are necessary to deliver CDS alerts that will serve as intended to maximize patient safety. Overall, the team has been enlightened about the amount of work still needed in the field, before CDS alerts can provide the potential benefits for which they are intended.

Discussion

The Everett Clinic has accrued 12 years of experience in developing and implementing an EHR. The major lessons learned are that buy-in starts at the top of the organization; ongoing two-way communication is key; a team-oriented organizational culture is critical to success; iterative implementation is an effective strategy; ongoing and readily accessible training is necessary; involvement of clinicians in every facet of development achieves buy-in and contributes to improvements; and workflow redesign is an integral facet of EHR implementation. A more detailed summary of these lessons appears in Table 2.

The risk of unintended consequences with implementation of EHRs and CPOE systems is great. One expert panel has described nine categories of adverse consequences:[13]

1. More work for clinicians.
2. Unfavorable workflow.
3. Neverending system demands.
4. Problems related to paper persistence.
5. Communication difficulties.
6. Negative emotions.
7. Generation of new kinds of errors.
8. Changes in the power structure.
9. Overdependence on technology.

Table 2. Summary of lessons learned

Category	Lesson learned
Context	• Physician advisory board sets priorities, keeps project on track
System development & testing	• Each added feature should be tested for ease of use • Extensive user interviewing and testing is helpful • Adequate time must be allowed for testing • Both feature-specific and component integration testing are necessary • Feedback from users should be encouraged and used to make improvements and corrections • Launch only features that have been perfected
Training & implementation	• Involving clinical and IT personnel results in more robust product facilitates buy-in, streamlines rollout • Iterative rollout and introduction of new features enhances buy-in, keeps system affordable, prevents reduction in productivity • Training provided one-on-one at point of care, just in time, and 24/7 minimizes frustration; provides opportunities to educate about appropriate use; identifies corrections; and allows further improvements to minimize potential for medication errors • Demonstrations are effective; understanding is assured when user can repeat process • Early adopters make good trainers • Training provides opportunity to reinforce “best practice” techniques for “writing” prescriptions
Network	• Sufficient upfront investment is necessary to support rapid adoption • Fiber-optic cable is faster than microwave • Involving utility company facilitates auto-faxing • System maintenance includes vigilant monitoring and readiness of downtime procedures
Retail pharmacies	• Educating about auto-faxing is paramount for buy-in of this group of external stakeholders
Clinic workflow (transition from wireless laptop to hardwired desktop computers in exam rooms)	• Physical plant infrastructure can prevent adoption of wireless network • Re-engineering workflow is critical to success of this transition • Advance preparation in countering resistance is helpful • Standardizing transitions between staff and providers eases provider burden, creates culture of “shared” examination room • Patients are positive about having computer in exam room
Security	• Approach from hardware (device) and software (application) perspectives • Context-switching log on/log off cards are effective

Table 2. Summary of lessons learned (continued)

Category	Lesson learned
Transitioning to Epic®	• Reaffirm importance of ongoing, two-way, and clinic-wide communication • Customization of drug databases and CDS alerts is tedious • Lack of standardization of vendor-created classification systems creates complexities • Efforts of clinicians and programmers are essential to success of CDS alerts • Much work remains to be done in field of CDS alert development before full potential of CDS alerts can be realized to improve safety and quality of care

Importantly, this panel suggested that CDS features introduce many of these unintended consequences.

Others investigators[22] framed these same concerns as aspects that must be addressed in order to achieve successful implementation and to avoid unintended consequences. They found that organizational issues—such as collaboration, culture, and control—were instrumental in successful adoption. They also noted that clinical and professional issues—such as individual or specialty customization—were important in achieving clinician-user buy-in, and that technical and HIT implementation issues included the need to continually modify the system, conduct usability testing, provide adequate training and support, and ensure that network speed made using the EHR time-neutral. Finally, they found that information needed to be organized in a way that would make intuitive sense to clinicians, rather than to programmers. These characteristics were incorporated into a consensus statement that described considerations for successful CPOE implementation.[10] To avoid the unintended consequences related to medication use, The Everett Clinic has focused on these same issues in developing their e-prescribing system.

The Everett Clinic's experience is unique in that it operates from the perspective of having implemented both a homegrown and now a vendor-purchased EHR. In the former, it is similar to inpatient, academic institutions that have developed their own systems and used them with much success.[2, 3, 4, 5, 6, 7] In the latter, it is similar to other community-based health care systems not affiliated with academic centers, although these systems are more likely to purchase their EHRs without having first developed their own.

For several reasons, we believe the Clinic's experiences with its homegrown system can be generalized to other community-based health care systems preparing to implement EHRs. Many of the barriers and challenges identified by health care systems that are implementing commercially available systems have also been addressed and overcome by The Everett Clinic: identifying core functionalities, conceptualizing the impact of the EHR on workflow, conducting a market analysis, conducting field tests prior to going live, ensuring a functional network, developing software that is user-friendly, and addressing security issues. That the Clinic is

applying the lessons learned in all aspects of implementation to Epic® customization, particularly with e-prescribing, further attests to the generalizability of our lessons learned.

Conclusion

Implementation of EHRs, and particularly CPOE systems, is fraught with the risk of introducing unintended consequences into the clinical environment. The identification of strategies that can aid implementation and minimize unintended consequences is important to realize the full potential of HIT solutions in improving patient care. The Everett Clinic utilized several strategies that enabled successful implementation of their homegrown e-prescribing system and concurrently learned valuable lessons. As EHRs become more widely implemented, applying these strategies and lessons to system implementation can minimize unintended consequences and maximize the quality and safety of patient care.

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Measuring IT Sophistication in Nursing Homes

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Abstract

Objective: Little activity has occurred in nursing home (information technology) IT adoption. The purpose of this study was to describe the range of IT sophistication for resident management processes and explore the association of IT sophistication with nursing home ownership, bedsize, and regional status. **Methods**: This descriptive, exploratory, cross-sectional study used an IT sophistication survey that was adapted for nursing home environments. The survey was administered between December 2006 and August 2007. All 491 nursing homes in Missouri were invited to participate. **Results**: Of the 491 nursing homes asked to participate, 349 initially agreed to complete the survey, but only 199 (41 percent) responded. The degree of functional sophistication adopted was most related to bedsize and location; ownership and location were also factors. IT integration was mostly affected by type of ownership. **Conclusion**: Nursing home administrators have a long way to go before they will be able to achieve the goals suggested by the Institute of Medicine in their report on IT adoption.

Introduction

People who make up the oldest of the old population have more complex health care needs and a higher probability of entering a nursing home, and they are at greater risk for receiving poorer quality of care.[1, 2, 3] There is growing recognition that a stronger information technology (IT) infrastructure is needed to address the complex health care needs of nursing home residents and the quality of care delivered in these facilities.[4]

Technologic strategies designed to improve quality of care in nursing homes must include methods to achieve valid, reliable, and timely care processes.[5, 6] However, technology for nursing homes has been overlooked by most agencies that have advocated for its wider use.[7] The lag in IT implementation has been attributed to such factors as significant cost of infrastructure, lack of onsite IT expertise, variable staff competency levels, and high staff turnover leading to high training costs.[7, 8]

IT development has the potential to improve the safety, quality, and efficiency of health care in the United States.[9] Increasing attention to errors in health care and concern for patient safety have prompted general recommendations for the development of technologies to support clinical decisionmaking, promote data standards, and develop systems that communicate with each other.[10] In acute care situations, sophisticated technology that assists in diagnosis and supports chronic care management can improve clinical decisionmaking, enhance adherence to clinical guidelines, and provide increased focus on patients with chronic disease states.[11, 12] Despite these known benefits, little activity has occurred in nursing home IT.

The purpose of this study was two-fold: (1) to describe the range of IT sophistication for resident management processes for nursing homes in Missouri; and (2) to explore the association of IT sophistication with nursing home ownership, bedsize, and regional status.

IT Sophistication

IT sophistication was derived from Nolan's Stage Theory used to evaluate computer activity and the degree of IT maturation over time.[13] Nolan identified four stages that all organizations follow toward a point at which an information system is considered fully integrated. Nolan's four stages—initiation, expansion, formalization, and maturity—represent growth from early stages when computers were used to meet basic organizational needs to later stages and the full integration of computer applications.[14] Measures of IT sophistication were developed from the early applications of Nolan's Growth Model in business firms.[15, 16]

Recently, IT sophistication has been used to describe the diversity of technologic tools and software used to support three domains of health care, including (1) resident care, (2) clinical support, and (3) administration.[17, 18, 19] Furthermore, three dimensions of sophistication have been defined:[15, 17, 18]

1. Functional sophistication is the extent to which clinical processes are computerized.
2. Technological sophistication is the degree of use of different technologies in the clinical area.
3. Integration sophistication represents the level of internal and external integration among departments and clinical settings inside and outside of a facility.

Dimensions of IT sophistication in acute care have been used to compare the use of computerized systems both nationally and internationally.[18] In nursing homes, the level of use in each dimension of IT sophistication is unknown. What is known is that there is diversity in technology applications in nursing homes. In March 1998, when the Health Care Financing Administration began requiring electronic transmission of the Minimum Data Set, approximately 70 percent of certified nursing home facilities in the United States were using computerized tools to transmit data; 16 percent had a computer system that needed upgrading to meet requirements for transmission; and the remaining 14 percent had no computer at all.[20, 21]

A goal of the research described here was to develop an IT sophistication profile of Missouri nursing homes using a previously tested tool that was adapted from acute care settings for use in nursing homes. This development of IT sophistication profiles is a necessary first step toward benchmarking best practices in information system use across multiple nursing homes.

Developing IT Sophistication in Nursing Homes

Primary uses of clinical information systems are to assist in the delivery, support, and management of patient care; assist in administrative and financial matters; and assist in patient self-management. In 2003, the Institute of Medicine (IOM) identified eight core functions for clinical information systems including:[4]

1. Storage and retrieval of health data.
2. Results management.
3. Electronic order entry.
4. Decision support.
5. Communication and connectivity.
6. Education.
7. Administrative processes.
8. Population health.

Within the IOM report,[4] projections were made addressing the level of diversity and maturity of IT expected for each core function through 2010. These projections described the expected levels of IT sophistication for clinical information systems in nursing homes. For example, in 2010, the IOM projected that nursing homes should have capabilities to use multimedia support for images and scanned forms, such as resident consents. In 2007, nursing homes should have been implementing rules-based alerts and preventive reminders to support resident care.

Additionally diagnoses, signs and symptoms, and procedures should be structured and coded into clinical information systems to improve data quality. The significance of developing IT sophistication profiles across nursing homes is to orient researchers, policymakers, and nursing home leaders to the varying degrees of technological instruments, IT functionality, and degree of integration in each clinical domain of resident care, clinical support, and administration.

Methods

A census of all 491 nursing homes in Missouri was undertaken between December 2006 and August 2007. Initially, 349 homes agreed to participate in the study; eventually, 199/349 homes responded. The responding homes were diverse in terms of geographic location, bedsize, and ownership.

- **Location**. Responding homes were classified according to metro-urban-rural regional status, as determined by combining Beal codes into three county continuum codes for population size.[22]
  - Metro status included total facilities in central, fringe, and metropolitan counties with populations of 250,000 or more.
  - Urban status included facilities that were adjacent to or not adjacent to metro areas in urban counties with populations of 2,500 to 250,000.
  - Rural status included all facilities in rural counties with populations less than 2,500, regardless of their adjacency to metro areas.
- **Bedsize.** Nursing homes were classified into small (<60 beds), medium (60-120 beds), and large (>120 beds) homes.
- **Ownership types.** Nursing homes were designated as either investor-owned (IO) or not investor-owned (NIO).

Recruitment

An administrator for each home was asked to complete the survey or to select a site respondent who had oversight of IT functions within the nursing home facility and who had knowledge of other key IT stakeholders within the organization to complete an IT sophistication profile for the facility. Respondents received a small incentive for their participation, a strategy revealed as necessary to encourage participation in research activities.[23]

Survey Instrument

Methods included a written IT sophistication profile, which had been adapted for nursing homes from a previously tested measure used in acute care hospitals.[24] Two options were provided for each facility to complete the sophistication measure. The first option included the completion of a paper-based sophistication tool mailed to nursing homes willing to participate. A return addressed envelope was sent with the survey and cover letter to respondents at facilities electing to complete paper versions. The second option was to complete the IT sophistication tool online. An online account was established under the name of the principal investigator at http://freeonlinesurveys.com. Each option was thoroughly explained in a cover letter.

Contact information for the principal investigator (PI) was made available in the event there were questions while respondents were completing the survey. To increase response rates, two followup telephone calls were made at 1-week intervals to the administrative directors and/or respondents, and subsequent mailings of the survey were sent, if needed.

The IT Sophistication survey used in this study has been rigorously tested and validated in other health care settings. Cronbach's alpha for functional, technologic, and integration dimensions and for overall sophistication was found to have a high internal consistency (≥0.89). Construct validity was measured using correlations between functional and technologic sophistication in the survey's patient care and clinical support dimensions. Correlations were significant, ranging from 0.77 to 0.84, respectively (P <0.001). Finally, concurrent validity was evaluated for the functional, technologic, and integration dimensions in relation to six variables: (1) IT maturity, (2) annual budget, (3) number of IT staff, (4) IT management, (5) educational level, and (6) IT tenure.[17, 18]

Data Management

After each paper-based measure was received, the PI and research assistant performed a double-data-entry process using Microsoft Excel® 2003 to ensure accuracy of the dataset. Uncertainties and discrepancies in data entry were resolved by agreement between the two independent reviewers. The research staff did not manipulate the facilities' online entries.

Analysis: IT Sophistication Measures

Descriptive methods were used to evaluate the range and distribution of IT sophistication in nursing homes. The clinical IT sophistication domains (resident management and care activities, clinical support, and administrative activities) and their subsections, the three conceptual

dimensions of IT sophistication (functional, technologic sophistication, and level of integration) were evaluated. Findings from the resident care management processes as reported by respondents are discussed in this paper. Resident care management in this study consisted of clinical IT applications that involved admission, discharge, and transfer of nursing home residents and covers systems that track medical records in the facility.

It should be emphasized that descriptive methods are appropriate for this study, but inferential methods are not. Since every nursing home in Missouri was contacted, the study was actually a census. As in any survey, there may be bias in the results, since nonresponders may differ from responders.

Functional sophistication measures identified nursing homes that used computer-based applications to complete specific resident care management processes. Functional sophistication was measured using a binary approach. A score of "1" was assigned for each computerized process used, and a score of "0" was given otherwise. Technologic sophistication explores the extent of technology use in resident care management. The level of sophistication was measured on a 0-to-9 scale, where 0 represents "not available," and 1 through 8 represent "barely used" to "extensively used," respectively; respondents could choose 9 if they were unsure. Finally, each clinical subsection had questions evaluating the level of internal and external integration of the IT systems used by the facility. Integration was measured using a 1-to-7 scale ranging from "not at all" to "very much."[17]

To describe the range and distribution of IT sophistication in nursing homes, the analytic approach included a descriptive analysis of the organizational characteristics of the 199 responding nursing homes, based on ownership, bedsize, and location. Percentages for nursing home respondents having specific computerized processes for resident care management are reported. Specifically, survey respondents indicated if computerization was used for resident care management processes related to admissions, discharges, transfers, waiting list management, or bed availability, or whether none were computerized. Cramer's V was calculated as a measure of the association between IT sophistication for resident care management and the characteristics of ownership, bedsize, and location (Table 2).

To further explore the association of IT sophistication with nursing home ownership, bedsize, and regional status, means are reported which describe the extent of use of technologies and integration level of technology use in resident management processes (Table 3 and Table 4). This part of the survey asked respondents to rate the degree of use of electronic tracking systems for medical records and resident identification, scanning of medical records, and centralized scheduling. The means procedure was used to describe differences between degree of IT sophistication for these resident management processes and ownership, bedsize, and geographic location. A statistic η^2 (eta squared), which determines the proportion of variation accounted for by the differences among the groups, was calculated.

Table 1. Number (%) of resident management processes computerized

Location	Bedsize	Investor-owned	Not investor-owned	Total
		Resident admissions		
Metro	<60			3 (4.5)
	60-120			38 (56.7)
	>120			26 (38.8)
		40 (59.7)	27 (40.3)	67 (100.0)
Rural	<60			2 (9.5)
	60-120			18 (85.7)
	>120			1 (4.8)
		8 (38.1)	13 (61.9)	21 (100.0)
Urban	<60			7 (14.9)
	60-120			35 (74.5)
	>120			5 (10.6)
		32 (68.1)	15 (31.9)	47 (100.0)
		Resident discharges		
Metro	<60			3 (5.3)
	60-120			33 (57.9)
	>120			21 (36.8)
		35 (61.4)	22 (38.6)	57 (100.0)
Rural	<60			2 (10.0)
	60-120			17 (85.0)
	>120			1 (5.0)
		7 (35.0)	13 (65.0)	20 (100.0)
Urban	<60			4 (10.3)
	60-120			30 (76.9)
	>120			5 (12.8)
		27 (69.2)	12 (30.8)	39 (100.0)
		Resident transfers		
Metro	<60			3 (6.0)
	60-120			29 (58.0)
	>120			18 (36.0)
		31 (62.0)	19 (38.0)	50 (100.0)
Rural	<60			1 (7.7)
	60-120			11 (84.6)
	>120			1 (7.7)
		4 (30.8)	9 (69.2)	13 (100.0)

Table 1. Number (%) of resident management processes computerized (continued)

Location	Bed size	Investor-owned	Not investor-owned	Total
Urban	<60			2 (6.9)
	60-120			24 (82.8)
	>120			3 (10.3)
		19 (65.5)	10 (34.5)	29 (100.0)
Waiting list management				
Metro	60-120			8 (44.4)
	>120			10 (55.6)
		7 (38.9)	11 (61.1)	18 (100.0)
Rural	60-120			3 (100.0)
		3 (100.0)	3 (100.0)	
Urban	<60			2 (16.7)
	60-120			9 (75.0)
	>120			1 (8.3)
		4 (33.3)	8 (66.7)	12 (100.0)
Bed availability estimation				
Metro	60-120			18 (60.0)
	>120			12 (40.0)
		16 (53.3)	14 (46.7)	30 (100.0)
Rural	<60			1 (14.3)
	60-120			5 (71.4)
	>120			1 (14.3)
		3 (42.9)	4 (57.1)	7 (100.0)
Urban	<60			3 (15.8)
	60-120			14 (73.7)
	>120			2 (10.5)
		11 (57.9)	8 (42.1)	19 (100.0)
None are computerized				
Metro	<60			3 (23.1)
	60-120			7 (53.8)
	>120			3 (23.1)
		9 (69.2)	4 (30.8)	13 (100.0)
Rural	60-120			6 (100.0)
		3 (50.0)	3 (50.0)	6 (100.0)
Urban	60-120			14 (70.0)
	>120			6 (30.0)
		16 (80.0)	4 (20.0)	20 (100.0)

Table 2. Comparison of IT sophistication for resident management processes by ownership, bedsize, and location

Variables	Bedsize x location[a]	Ownership x location[a]	Bedsize x ownership[a]
Resident admissions	0.265	0.200	0.131
Resident discharges	0.230	0.239	0.090
Resident transfers	0.220	0.232	0.152
Waiting list management	0.415	0.230	0.319
Bed availability estimation	0.287	0.091	0.194
None are computerized	0.341	0.233	0.267

[a] Cramer's V

Table 3. Extent of technology use in resident management processes by ownership, bedsize, and location

	Ownership		Bedsize			Location		
Variables	IO (N=113)	NIO (N=65)	<60 (N=14)	60-120 (N=123)	>120 (N=41)	Metro (N=83)	Rural (N=28)	Urban (N=67)
Electronic tracking of medical records	2.63	3.31	1.64	3.13	2.54	2.66	3.07	3.06
Electronic tracking of resident identification	3.81	4.14	3.36	3.85	4.39	3.63	4.32	4.15
Scanning of medical records	1.28	1.62	1.00	1.51	1.22	1.39	1.31	1.46
Centralized scheduling	1.72	2.91	2.21	2.19	2.02	1.99	2.32	2.28

IO = investor-owned

NIO = not investor-owned

Table 4. Extent of integration among resident management systems

	Ownership		Bedsize			Location		
Variables	IO (N=112)	NIO (N=67)	<60 (N=15)	60-120 (N=124)	>120 (N=40)	Metro (N=82)	Rural (N=29)	Urban (N=68)
Resident management systems (admissions, scheduling, resources availability)	3.00	3.93	3.40	3.28	3.53	3.48	3.14	3.28
Resident management systems, et al, computerized systems (lab, pharm, HR, finance)	3.29	4.06	3.40	3.65	3.43	3.73	3.52	3.41

HR = human resources; IO = investor-owned; NIO = not investor-owned; n = number.

Results

Respondent Characteristics

When initially contacted, 349 of 491 (71.1 percent) of all Missouri nursing homes indicated they would complete the survey; 199 (41 percent) actually completed the survey. Total NIO facilities had a higher response rate (50.3 percent) than IO facilities (34.6 percent). All homes that initially agreed to participate were given the option of completing an online survey or a paper survey; 59.3 percent completed online surveys, and 40.7 percent completed paper surveys.

Characteristics of the facilities responding to the survey were representative of nursing homes in Missouri and across the United States:

- In Missouri, nearly 45 percent of the IO and NIO nursing home facilities are located in metropolitan areas; 24 percent of NIO homes and 13 percent of IO homes are located in rural designated areas.
- The distribution of nursing homes by ownership and licensed bedsize is also very uneven. Of 491 facilities in Missouri, 70 percent are IO facilities, and 30 percent are NIO facilities, including nonprofit and government-owned facilities.
- The majority of NIO facilities with 60 to 120 licensed beds are located in metro-urban areas. This compares to very few larger and smaller NIO facilities located in rural county designations.
- Although the majority of IO facilities range between 60 and 120 beds, these are located mostly in urban regions. Very small and very large IO facilities are generally not found in rurally designated areas.
- These statistics are also representative of nursing homes across the United States; 65.2 percent of nursing homes are investor-owned, and 34.8 percent are not investor-owned.[25] In the United States, 26.7 percent of nursing homes fall into the small category, 44.2 percent are medium-sized, and 29.1 percent are larger facilities.

Range Distribution and Relationship of IT Sophistication to Ownership, Bedsize, and Location

Table 1 organizes the percentages of resident management processes in these Missouri nursing homes that are computerized; the sample is stratified by ownership, bedsize, and location. For each home, respondents indicated whether computerization was present for resident admissions, discharges, transfers, waiting list management, and/or bed availability, or whether none of these have been computerized. Table 2 compares the level of IT sophistication reported for resident management processes to ownership, bedsize, and location.

Resident admissions. The majority of homes that had computerized resident admission processes were located in medium-sized facilities with 60 to 120 beds in metropolitan (56.7 percent) and urban locations (74.5 percent) (Table 1). A higher percentage of IO homes with computerized resident admission processes are located in urban and metropolitan areas. In contrast to more populated areas, nearly two-thirds of rural Missouri nursing homes with computerized resident admissions are NIO.

Among 12 respondents from 18 smaller homes with less than 60 residents, 66 percent indicated that they had a computerized system for resident admissions. Respondents from 32/43 (74.4 percent) of larger homes with more than 120 residents used technology for the same process. When comparing reported IT sophistication levels for resident admissions (Table 2) with ownership, bedsize, and location, the association between facilities comparing bedsize and location was weak (Cramer's V = 0.265).

Resident discharges. Nursing home location appears to be a common variable for determining relationships in use of technology for resident discharges. When bedsize and location are compared, a small relationship (Cramer's V = 0.230) is found among facilities. Similarly, when ownership and area are compared, the relationships are small (Cramer's V = 0.239) (Table 2). The majority of homes that use technology for resident discharges are IO facilities with between 60 and 120 beds and are located in metropolitan regions (Table 1). In rural regions, 17 of 29 respondents (59 percent) had incorporated technology into their resident discharge procedures. Most homes (85 percent) were of medium size (60-120 beds), with fewer smaller and larger homes (15 percent) using technology for this same process.

Resident transfers. When comparing the use of technology during resident transfers, no substantial relationships were detected among facilities stratified by ownership, bedsize, and location (Table 2). Again a majority of homes (62 percent) using technology for resident transfers were IO, located in metropolitan areas (54 percent), and had 60 to 120 beds (72 percent). In rural regions, 11 of 29 (38 percent) of medium-sized facilities (60 to 120 beds) that completed surveys had technology for transferring residents between locations. Additionally, in urban regions, only 40 percent of the facilities reported use of technology for this type of activity.

Waiting list management. Table 2 illustrates a medium relationship (Cramer's V = 0.415) between homes stratified by bedsize and location that reported using technology for waiting list management. Most of the homes using technology for this purpose were NIO, located in metropolitan regions, and had more than 120 beds. Only 3 of 15 homes (20 percent) from rural medium sized facilities responded to this question on the survey. Rural small and large facilities did not respond (Table 1).

Bed availability estimation. A small relationship (Cramer's V = 0.287) was found when comparing frequency of IT sophistication for bed availability estimation in facilities with differing bedsize and locations (Table 2). The majority of homes using IT for this process were IO medium-sized facilities (60-120 beds) located in metropolitan areas. Similarly, 64 percent of medium-sized, urban facilities reported using technology to estimate bed availability.

Computerization availability. A medium relationship (Cramer's V = 0.341) was found for technology use in facilities with different bedsizes and locations. Most respondents reporting no computerization for resident care management were from IO, medium-sized (60-120 beds), urban facilities. Similarly, six of nine (67 percent) of IO, medium-sized facilities reported having no technology for resident care management.

Extent of Technology Use in Resident Management Systems

This analysis compared the extent to which technology is used for resident management systems by facilities that responded to the survey. Table 3 provides some details of the findings. In relationship to the electronic tracking of medical records, medium-sized NIO facilities in rural or urban regions reported greater use of technology for this purpose than other facilities. Regarding the electronic tracking of resident identification, large NIO facilities with more than 120 beds that were located in rural and urban regions reported use of technology to a greater extent to identify residents. Most of the respondents reported very little to no ability to scan medical records. Finally, most facilities also reported use of centralized scheduling to a very low degree; those that do use it are NIO small-sized facilities (<60 beds) in rural areas. The means for level of IT sophistication were compared across facilities that reported having centralized scheduling systems; η^2 was found to be 0.062, which means the proportion of variation in technology use accounted for by differences in the mean between IO and NIO groups using centralized scheduling systems was 6.2 percent.

Integration of Technology in Resident Management Systems

In the final analysis, the extent of integration among resident management systems within the facilities was determined. The range across all facilities in resident management systems associated with admissions, scheduling, and resources was 3.00 to 3.53. Resident management systems were more thoroughly integrated in large NIO facilities (>120 beds) located in metropolitan areas. Differences in the means between facilities with different ownership were found. No substantial differences were found for bedsize and location ($\eta^2 = 0.037$; 3.7 percent of the variability in integration level can be explained by ownership types).

The range of integration for resident management systems and other computerized systems (i.e., laboratory, pharmacy, human resources, and finance) in all stratified facilities was 3.29 to 4.06. The widest range of means occurs between the two ownership types ($\eta^2 = 0.031$; 3.1 percent of the difference in technology integration could be accounted for by ownership types). There were no considerable differences in facilities with different bedsize or locations (Table 4).

Discussion

This study describes the results of a survey of nursing home IT sophistication conducted in the State of Missouri. Overall response rates (41 percent) for this study appear to be adequate for both mailed and electronic survey methods.[26] The online survey method was more efficient without sacrificing survey response rates. Functional sophistication related to resident care management processes differed across nursing homes, depending on identified characteristics. Functional sophistication in admission processes appeared to be lowest in NIO metropolitan locations with a medium bedsize (60-120 beds). Conversely, larger NIO nursing homes (>120 beds), though smaller in number, had a higher percentage of technology usage.

Although rarely reported, nearly half of the respondents from small and large rural nursing homes indicated they had some level of technology related to admission processes. These findings were confirmed by the comparable relationships found among IT sophistication

variables with bedsize and location. It is important to note that although few homes had a high level of functional sophistication, those that did so were beginning to integrate it into the resident management systems on a more regular basis.

Functional sophistication in discharge processes appeared to be less advanced in large and small NIO facilities located in rural and urban areas. More than half of the facilities in rural regions had used technology to assist in discharge activities. Functional sophistication appeared to play a smaller role in patient transfers than in discharge processes in this sample.

Technology may play an important role in identifying and tracking clinical services used by residents living in remote locations. Location appeared to play an important role in the variability of technology use in discharge processes. For example, telemedicine technologies had been extensively used to reach Missouri residents living in rural locations.

The extent of technologic sophistication and integration achieved by the nursing homes in this sample appeared to be affected mostly by ownership of the facilities. Facilities that are NIO tended to have higher levels of technologic sophistication and also to have significantly higher levels of integration of those systems into resident management processes. One possible reason for this difference might be that technology is very costly at the initiation of implementation. IO facilities might be under more pressure to turn higher profits and therefore may be less willing to bear the initial costs of technology implementation. NIO facilities, on the other hand, may have a different set of incentives to measure success and therefore might be more willing to invest in technology that is predicted to lower costs over the long run.

Implications for IT Sophistication in Nursing Homes

Advantages of IT sophistication. Computerized nursing documentation systems assist nursing professionals to make a significant, positive impact in work practices and resident outcomes. Technology has improved computer charting, care planning, information accessibility, and perception of information security in acute care settings.[27, 28, 29, 30] Computerized clinical documentation systems can make a difference in the quality of documentation after implementation of an integrated point-of-care system on hospital nursing units.[31] There was a 13 percent increase in compliance with Joint Commission accreditation requirements during this study. In a similar study, improvements were noted in 11 (34 percent) of Joint Commission accreditation requirements for nursing documentation using technology.[30] In other advanced IT research, clinical decision support systems were shown to significantly improve clinical practice when integrated into clinical workflow; systems provided automated reminders to clinical staff; and recommendations associated with computer-based systems were made at the time and location of decisionmaking.[11, 32]

Few resources are available on the use and effectiveness of computerized records in nursing homes.[7] Abbott[33] suggested that computer use in nursing homes has generally been limited to business applications and management of the federally required Minimum Data Set. In contrast, research on computer implementation in nursing homes identified some facilities using highly sophisticated computerized systems to manage care.[34, 35, 36, 37, 38] However, we have limited knowledge about the extent to which nursing homes are using these sophisticated systems.

Barriers to IT sophistication. Key obstacles recognized for preventing widespread development of nursing home IT include a lack of funding, ill-defined standards, insufficient data transfer between care settings, frequent lack of willingness of long-term care markets to invest in electronic records, and the absence of clear legal definitions.[39] The current economic state of nursing homes plays a large role in the development of IT.[40] Current economic barriers include an increasingly disabled nursing home population, staffing problems, rising wages, and State budget shortfalls.[41, 42, 43]

Limitations

A limitation of this study is the possibility of bias due to the failure of many nursing homes to participate. One concern might be that homes with lower IT sophistication may be reluctant to participate in the survey process. Thus, the true rate of IT use by nursing homes in the State might be lower than it appears based on the results of this study.

Conclusion

The original instrument and key concepts of IT sophistication have been extensively studied in acute care settings. Until this study, the level of IT sophistication had not been evaluated in nursing homes settings. Nursing home administrators in the State of Missouri have a long way to go before they will be able to achieve the goals suggested by the IOM report,[4] which addresses the level of diversity and maturity of IT expected of nursing homes by the year 2010.

The promise of sophisticated IT lies in its ability to transform and achieve certain foundational aims, including safety, effectiveness, patient/family centeredness, timeliness, efficiency, equity, and connectedness.[4, 44] Identification of the current level of IT sophistication in nursing homes will facilitate recognition of more sophisticated nursing homes for further study and disseminate lessons learned from early adopters. This information can then be used as a benchmark to identify best practices in IT use to guide development, new implementations, and quality improvement initiatives.[20]

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

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Abstract

Objective: We report on the first in-home test of "Buddy" assistive technology, which combines PocketPC and Web technologies to support family caregivers. Buddy expands a safety net for dementia patients and family caregivers who choose home vs. institutional care. **Methods**: Six elderly adult volunteers and two spousal caregivers of patients with Alzheimer's disease operated Buddy in their homes for 1 to 4 weeks. Participants recorded information concerning their own physical and emotional status and the events of their day. The two caregivers also recorded patient-related events and behaviors. **Results**: Elderly adults learned to operate Buddy in a home environment without encountering any major technologic hindrances. Web logs provided meaningful information about the home environment. **Conclusion**: This brief trial indicates that elderly adults, including caregivers, could use a hand-held system for documenting important caregiving and personal activities in their homes without experiencing a significant added burden.

Introduction

Adults over 65 years of age constitute about 12.4 percent of the U.S. population—about one in every eight Americans.[1] By the year 2030, this proportion will have increased to 20 percent. Those 85 years and older—the oldest of the old—represent the fastest growing group.[2] Not only are older adults in the United States living longer, but many are also eschewing institutional care and remaining in their homes. The U.S. Bureau of the Census has reported that more than 55 percent of older adults live at home with their spouses.[3] Older adults who prefer to age at home, rather than in an assisted living facility, cite independence and social interaction as being critical to their well-being.[4, 5]

One side effect of this rapidly expanding older adult population is a significant increase in caregiving responsibilities being performed by family and friends. Fifty-seven percent of the adult population in the United States currently provides or has provided unpaid caregiving services to family or friends. Moreover, family caregivers perform 80 percent of all long-term-care services.[6]

Other societal trends compound the burden placed on these unpaid caregivers. By 2030, the average number of children per family will be about two, compared to three in 1990.[3] Smaller family sizes, along with geographically dispersed family members, make it difficult to provide

long-term care without some type of external support system. These demographic trends highlight the need for innovative support systems for family members and their caregivers.

Role of Assistive Technology

The Administration on Aging defines assistive technology as any service or tool that helps the elderly or disabled perform activities they have always performed but must now do differently.[7] Telecommunication equipment, computers, access systems, tools for independent living, education, and mobility aids are all considered assistive technologies. Access to these technologies often determines whether an elderly adult will be able to live independently or must move to an institutionalized environment.

The National Council on Disability found that 80 percent of older adults who used assistive technology were able to reduce their dependence on others.[8] Assistive technologies may not only support the aging adult but also their family and friends who serve as caregivers. Devices that increase the independence of an older adult commonly decrease the time required for caregiving assistance.[9] Assistive technology and home modifications have been found to provide caregivers immediate relief, reduce their stress, and help them provide care more easily and safely.[10]

Two types of assistive technology currently being developed to promote aging in place illustrate different approaches that are based on the individual's category of impairment. Becker and Webbe's[11] "Buddy Coordinated Healthcare System" and Scott and Gabrielli's[12] "Ho'alauna ('Good Neighbor') Tablet" permit intervention in the homes of older adults who manifest mild-to-moderate levels of impairment. Their aim is to utilize technology to promote independent functioning in both home and community environments. These projects are considered "noninvasive" in that the proposed technologies allow the individual to control data gathering and dissemination.[13]

Other research projects, such as the Digital Family Portrait[14] and the CareNet Display,[15, 16] would support more severe levels of impairment through a home-monitoring environment that utilizes sensors to gather information about daily living activities. Such detection provides the means to keep members of a support network (e.g., family, friends, and health care personnel) informed of the older adult's daily activities. These types of "invasive" technologies do not provide the older adult full control over data gathering and dissemination activities.

One significant difference between the Buddy Coordinated Healthcare System (BCHS) (Figure 1) and some other emerging technologies is that the former focuses on older adult caregivers of patients with Alzheimer's disease (AD). More than 4 million older adults in the United States suffer from cognitive impairments due to AD; most of these individuals live at home with an aging caregiver.[17] Caregivers endure increasing emotional and physical stress as they assume responsibilities that include managing daily routines and making important medical decisions.[18] Because of these responsibilities, caregivers become increasingly homebound and isolated as the disease progresses in their loved ones. Technologies that support caregivers directly, or indirectly by aiding the one cared for, occupy the forefront of development and support for addressing the growing needs related to Alzheimer's care.[19]

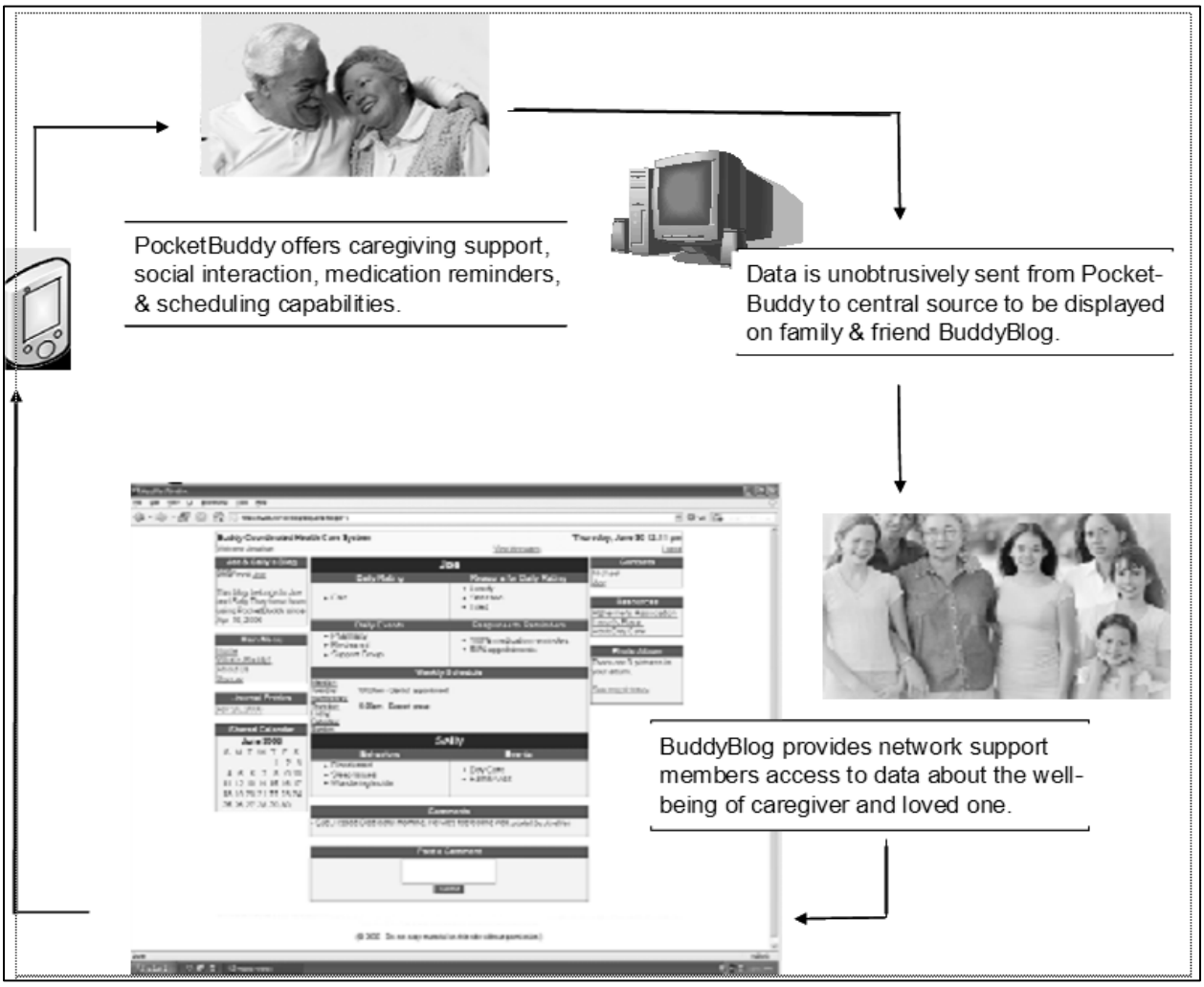

Figure 1. Buddy Coordinated Healthcare System (BCHS) framework

Our virtual network of support proposes the use of handheld, database, communication, and Web-based technologies in the framework shown in Figure 1. The intention of this support network is to transcend both physical boundaries associated with geographic location and time boundaries associated with work schedules and personal commitments.

PocketPC Technology

The PocketPC technology, called PocketBuddy, is used by an older adult caregiver. PocketBuddy can be used to record patient behaviors and the emotional well-being of the caregiver, document daily activities and events, and schedule appointments and personal events, among other features. The PocketPC is used in this project because it is relatively inexpensive, lightweight, and portable and has the potential for both wireless and wired communication. It offers multimodal capabilities, such that audio can be used to support textual display of information. It has a landscape mode for horizontal presentation of screen objects and information content.

Initial research into the use of handheld devices, including Personal Digital Assistants (PDAs) and PocketPCs, shows great promise for their use by older adults. In a study of the use of PDAs by older adults as a memory aid, organizational tool, and communication device, Sterns[20] found that older adults could readily use the technology in supporting a medication-reminder program that was specifically designed for seniors.

Clearly, more research is needed than the initial trials cited above. To address this need, we have initiated a study of novel user interface designs for the PocketPC, taking into account normal aging factors. As an outgrowth of our research, a unique user interface design called the Senior Electronic Pocket Assistant (SePA) was developed to help promote the usability of the PocketBuddy component of BCHS.[11] Design recommendations for senior-friendly Web sites put forth by the National Institute on Aging[21] and other sources have served as important starting points for our interface conceptualization.[22]

These guidelines propose that the good use of color and appropriate font sizes and styles improve the ability of older adults to use the Web. These and other guidelines have been incorporated into SePA. In order to directly support caregiving activities, SePA applications are the only ones accessible on PocketBuddy. Figure 2 shows the Main Menu screen used to access PocketBuddy applications.

Figure 2. Main Menu screen used to access PocketBuddy applications in 12-point font.

This design approach has two major rationales. First, older adults do not have to be familiar with a Windows-based operating system in order to use PocketBuddy, thus eliminating the complexity associated with use of the desktop features and navigational structure of Windows.

The second reason relates to the input mechanism associated with PocketPC use. Existing software applications, as part of the Windows Mobile™ 5.0 interface, most often require the use of a stylus pen for navigation, object selection, and data entry. The stylus pen provided with the PocketPC is very small in both diameter and length. As such, it is difficult to use for people with degraded vision and motor skills associated with aging. By eliminating the need for a stylus pen, loss of the input device becomes a less important issue. In addition, potential usability barriers (e.g., shaky hands or impaired vision, making it difficult to accurately click on objects) are minimized.

Landscape Mode

All SePA applications are displayed in landscape mode in order to use the screen space more effectively. This design allows for object enlargement and novel navigation schemas that could not be readily supported in portrait mode.

Landscape mode accounts for normal aging factors (e.g., vision and motor skills) that may pose barriers when manipulating smaller objects and tiny pull-down menus typically found in portrait mode applications on a PocketPC. The use of landscape mode also allows the older adult to hold the device in both hands while manipulating screen objects. It was noted during usability sessions that older adults utilized fingers and thumbs to manipulate screen objects when holding the device in both hands. Objects appearing on the peripheral of the screen could be manipulated by a thumb tap. This reduced the potential for mistakes associated with object manipulation when holding the device in one hand and using the other to tap the screen.

Button Lists

In order to eliminate the need for a tiny scroll bar to manipulate objects in a list, the SePA interface utilizes an innovative design. A large button object on the screen is used to represent each item in the list. The user simply taps on a button to select it. The side navigation bars are used to scroll forward and backward through the list. In the Behaviors list presented in Figure 3, each button represents a particular behavior that the user could press to describe their loved one for that particular day.

Figure 3. Patient's behavior list items in 12-point font size

Cues

Cues built into the handheld device's user interface help promote usability by older adults. The SePA interface has been designed such that the user can activate a button by tapping it with a finger or thumb. The button is highlighted in a dark color as a cue that it has been successfully tapped. Tapping it again de-highlights the button to show that it is no longer selected.

Buttons also can be programmed to sound personally selected audible cues. The user has the option of selecting specific tones associated with a button tap, error message, and other design features. When navigating through a list by tapping a side navigation bar, the buttons appearing

in the list flash once. Thus, the user receives a cue regarding the display of a new section in the list.

Help and Text Resizing

To enhance usability, each screen, with the exception of the keyboard, has both a built-in help feature and text-resizing feature. The help feature is accessed by pressing the question mark button at the top left corner of the screen, which displays Help content.

The text resizing feature is accessed by tapping the "A" button, which is also located at the top left corner of the screen. The three resizing options include 10-, 12-, and 14-point font sizes (Figure 3).

Customized Keyboard

The SePA interface does not utilize the PocketPC's built-in keyboard. Instead, a soft keyboard was developed to replicate typewriter technology. As shown in Figure 4, the keyboard is displayed in landscape mode in order to enlarge the keys and space bar.

Pressing the "keys" produces an audible cue that resembles the sound of a typewriter, thus further promoting usability.

Figure 4. SePA keyboard facilitates data entry via finger taps, which produce typewriter click-like auditory feedback

Generic and Personal Checklists

The user has the option of using a preset checklist or creating a personal checklist. These checklists support daily living activities associated with caregiving. A built-in checklist, for example, helps a caregiver put together a loved one's personal items in preparation for time spent at a day care center.

Database Technology

BCHS has two database components to support the caregiver and members of a family-and-friends network. PocketBuddy contains a localized version of the central database, which is used to store data entered by the caregiver. The central database receives data gathered on the PocketBuddy via the Internet and stores the most recent as well as historical data. The current day's data can be shared in detail with the support network through the family-and-friends Web site (known as the "BuddyBlog"). Future versions will allow all historical data to be mined for

health and safety trends associated with both the loved one who is being cared for and the caregiver. The BuddyBlog may provide controlled access to data such that members collectively can make decisions related to the well-being of both the caregiver and the loved one.

In order to maintain the integrity of both databases, transparent synchronization is required so that data are merged correctly. Synchronization is accomplished without intervention by the aging caregiver or members of the support network. For example, the shared calendar feature would require the merging of data from PocketBuddy and the BuddyBlog to avoid the possibility that the caregiver or a member of the support network might overwrite a previously scheduled event with a new one.

Communication Technology

A unique aspect of the Buddy system framework is the use of the Internet to retrieve data captured on PocketBuddy. The older adult caregiver does not have to be familiar with Internet use nor have any significant Web experience. What is needed, however, is network access through a traditional telephone line or cable service. Once a server connects to the PocketPC device through a wireless modem placed in the home, data can be transmitted to the server unobtrusively, allowing it to be shared with members of the support network.

E-mail and text messaging capabilities, which are optional components of PocketBuddy, are simplified. The messages are transmitted (not in real time) along with other PocketBuddy data when an Internet connection is made by the server.

Web Technology

Two Web interfaces associated with BCHS are made available to the caregiver's support network. One interface allows for the customization of PocketBuddy (e.g., entering new or revised prescriptions and instructions for taking them). The other is the BuddyBlog, which provides daily information about the caregiver and loved one that is retrieved from the PocketBuddy database. The customized blog provides summary data about the day's events (e.g., Dad went to day care. Mom had a doctor's appointment at 3 pm); the caregiver's well-being (e.g., Mom rated the day as "Fair" and felt "Tired"); and the patient's behaviors (e.g., Dad experienced "sundowning" and was "hiding objects"), and other data.

Purpose

Our research had two objectives. The first objective was to provide lifelong engagement for the aging caregiver through the use of a virtual support network. Lifelong engagement can be viewed as instrumental in allaying the onset of isolation, depression, and cognitive disabilities for older adults.[23] To accomplish this objective, we developed handheld technology to be used by an aging adult to assist in caregiving activities, monitor the well-being of both the caregiver and the person being cared for, and capture information on the home environment for virtual linkages.

The second objective was to foster sharing of the responsibilities associated with caregiving by electronically linking family and friends to aging family members. Too often, family and friends are not as actively involved as they would like to be due to geographic distance and work,

children, and other commitments. Through the use of our “Buddy” system, members of a support network can be distant or local. Regardless of geographic location, they can be actively involved in the daily life of the caregiver and his or her chronically ill loved one.

The Buddy system components had been tested previously in the laboratory, where potential usability issues were identified and the user interface had been refined.[11] This process of usability testing and refinement continues as part of an iterative design approach. We report here on the first in-home tests of the PocketBuddy unit and the transfer of information into the BuddyBlog display.

Methods

Participants

Eight older adults (aged 65-89 years), including two spousal caregivers of AD patients, volunteered to learn and use the PocketBuddy in their homes for 1 to 4 weeks. Non-caregiver volunteers were recruited through advertisements in senior centers and older adult organizations. The caregivers were recruited through the East Central Florida Memory Disorder Clinic in Melbourne, FL. They had occupied the role of caregiver since the time of diagnosis. All participants were informed fully about the study and provided their consent according to the procedures approved by the Florida Tech and HealthFirst Health Systems Institutional Review Boards.

Materials

The Buddy System has been described in detail above. The participants were given the PocketPC unit along with a charging cradle. Participants who did not have Internet service received a wireless link to the telephone, and a no-cost Internet service provider was used to transmit data. Participants who had broadband network access received a standard wireless router to transmit data between the PocketPC and cable modem. This allowed the research team to test both types of Internet technologies in the transparent transfer of data to the subject’s Web log.

The PocketPC platform used in this study was the Dell Axim X51, which runs Windows Mobile 5.0 on an Intel XScale processor running at 416 MHz. The 3.5-in display incorporated a touch-sensitive, 16b-bit, TFT color screen with a resolution of 240 x 320 pixels. Physical dimensions were 4.7 x 2.9 x .0.7 in, with a weight of 5.9 oz. With a shelf price of $299, the X51 was an economical choice. The X51 communicates remotely via Wi-Fi.

Procedure

All participants were interviewed by a research psychologist upon initial enrollment in the study, at which time informed consent was obtained. The two caregivers were interviewed more fully by a clinical psychologist and social worker. Prior to instruction on use of PocketBuddy, one of our clinical team members assessed the status of the home, investigated cleanliness, hygiene, and safety issues, including placement of the Buddy technology in safe locations. All aspects of the study and informed consent were discussed with the participants for a second time during this assessment.

Software specialists from our technology team were matched with each caregiver-patient dyad. After installing the technology, they visited the homes regularly and were also on 24-hour call in the event that technical difficulties arose.

Participants were trained in the use of the PocketBuddy, which required one 2-hour session. All key strokes and button pushes made when entering data into the Buddy system were captured for analysis. A clinical team member interviewed the participants following the in-home trial in order to document their experiences and record their evaluation of the system's usability and the level of additional burden placed upon them.

The volunteers used the PocketBuddy at home over a 1- to 4-week period to assess usability, the transfer of their data into the central server, and the distribution of their data into the various portions of the BuddyBlog. Data were recorded on each device in terms of a timestamp and buttons tapped. PocketBuddy was used to gather daily information about the user and the patient (or a fictitious loved one for the non-caregivers).

Results

All participants learned to operate PocketBuddy to master criteria within the 2-hour training session. Following installation of the information and communication technology (ICT) systems in the home and the introduction of PocketBuddy, no major technical problems were encountered with PocketPC operation. The two types of data transfer technology, dial-up and broadband, worked appropriately and transferred data to the central server flawlessly.

Each participant used the PocketBuddy regularly, with a mean of 1.4 daily entries. Figure 5 illustrates the types and frequency of PocketBuddy functions that were used on a daily basis. Participants rated their day, selected one or more events from a predetermined list that contributed to the daily ratings, used the built-in keyboard to enter comments about daily events and activities, and used other features as recorded on daily blog pages.

For example, "Peggy" may have entered that she had had a "very good day" and then selected the reasons/events that contributed to her day. "Charlie" may have indicated that his wife, for whom he was caring, was aggressive, wandered, and did not eat. Participants entered other journal information and created lists and timers for

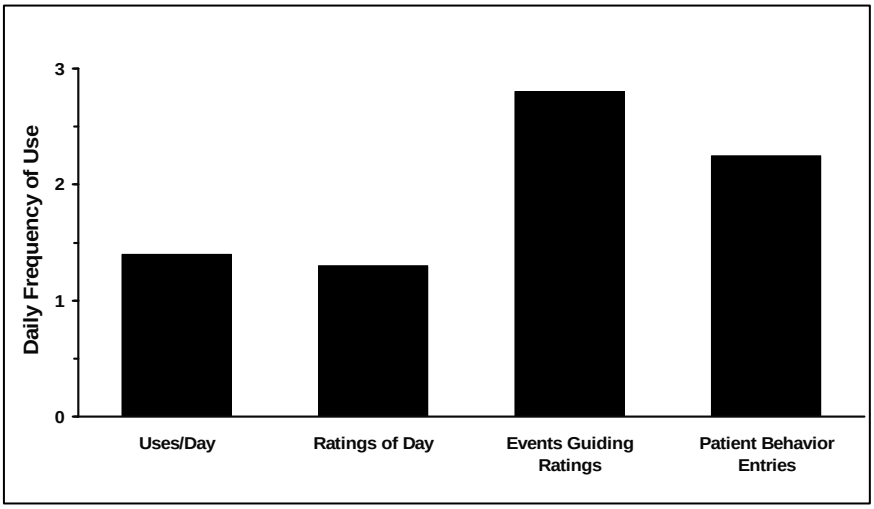

Figure 5. Categories of in-home PocketBuddy use.

events, reflecting the ease of use associated with the novel keyboard, whereby a fingertip or fat stylus pen may be used to enter messages. Most typically, the participants entered all categories of data once per day, the time varying among the individuals. Some participants greatly elaborated their daily activities by entering lengthy descriptions via the soft keyboard.

Prior to study onset, we had determined that we needed clear and unambiguous communication with the participants (particularly the caregivers) regarding their need to maintain normal contacts with their physicians and other health care professionals. During the course of the trials and afterwards, we continued to encourage caregivers to consult their personal physicians. This turned out to be important, as one caregiver had assumed the technology would permit him to relax his communications with his physicians.

A clinical team member also visited the caregivers at home during the trials to ensure that the research protocol did not appear to be increasing the caregiver's burden, interfering with care, or creating other safety concerns. Weblogs were also monitored to insure that the technology was not interfering with caregiving activities.

Of the two caregivers, one gave access to their blog to family members. Clearly, she had a known audience for her data input. The other caregiver had no immediate family. Nevertheless, he input data through PocketBuddy for the 2-week duration of this phase. Indeed, his entries, which expressed considerable frustration and depression, alerted the Aging with Dignity team to extend him offers of additional social service assistance. We see this as a clear demonstration of the Buddy system's utility for intervening when blog entries reflect concerns of care and safety.

Evaluation

The in-home volunteers completed post-session written interviews as well as less formal oral interviews. These served to determine their sense of satisfaction with the project goals, recommendations for modifications of software or hardware, and their estimate of the utility of the Buddy technology for assisting AD patients' caregivers.

We measured caregiver perception of burden due to technology implementation directly through their self-report in followup interviews and through the data that they entered into the PocketBuddy that was then uploaded into the Weblog.

User Satisfaction

Caregivers expressed satisfaction with the system overall, with the PocketBuddy's data collection and alerting functions, and with the potential usefulness of the data presentation in WebBuddy to themselves, their family, and their health care professionals. One usability volunteer, who had recently lost her spouse to AD, took the time to write us as follows:

Dr. Webbe and Others,

Thank you for allowing me to help in the testing of the PocketBuddy. I was very impressed, and I do hope it will be on the market soon. It's a wonderful device that will be a tremendous benefit to any caregiver. I only wish something like that had been available when I was a caregiver. I feel honored and privileged that I could be a part of the experiment, and if I can help in any way I will be glad to do so.

Good luck,
Margaret

Conclusion

No technology glitches were encountered during the in-home usability tests of the "Buddy," both with the individual volunteers and the two caregivers. We saw no real differences in this small sample in the data entered and transferred to the blog or in the frequency of usage of the different elements of the software. Complete analysis of the data captured during the home-use sessions continues in search of error patterns and individual preferences.

Several limitations of this initial study will be addressed in future work. A larger sample is needed in the home use of the proposed technology to identify potential areas for improvement, both in technology design and deployment. Future studies are needed that involve members of a support network for a lengthier period of time in distance monitoring of older adults using Buddy technology.

The research team continues to focus on the use of handheld technology to promote aging in place, with an emphasis on providing daily living support. Those handheld features that add little value or have a high level of complexity, as measured in number of mistakes and the ability to learn and remember, will be removed or redesigned. For example, during usability sessions held in a laboratory setting, it was discovered that a built-in calendar feature for scheduling appointments was too complex. Hence, it has been dropped as a feature until further design and usability testing can identify a viable solution. Usability studies, conducted in a laboratory environment, will continue to identify potential barriers that can be eliminated by novel interface designs.

Monitoring the activities of older adults who are aging in place, particularly when care of one family member by another is involved, represents one crucial mechanism of ensuring health and safety.[24] Some approaches to home monitoring are invasive, as described earlier, and often meet with resistance from the individuals involved.

By contrast, the Buddy system described in this paper allows the older adult to determine how much of their daily activities and their feelings are made available to others, since they control the entries in the PocketBuddy. Moreover, they also determine who may access the BuddyBlog, which presents these data to others.

One interest we have is the extent to which the older adult reporter will accurately document their daily affairs. Validating the accuracy of PocketBuddy data entered by adult caregivers is the objective of a further study. In the present study, we found the quality of information to be very helpful in tracking activities and monitoring psychological health and safety. Our one male caregiver, for example, entered painstaking accounts of his day, even though he had no family members who would be reading the entries. We were able to respond to a real threat to his safety and that of his spouse by being attentive to the data appearing in the blog over several days.

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Efficiency Gains with Computerized Provider Order Entry

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Abstract

Objective: The objective of this project was to measure efficiency gains in turnaround times with the implementation of a computerized provider order entry (CPOE) system. **Methods:** Pre- and post-CPOE turnaround times (TATs) were measured for orders placed for laboratory, radiology, and pharmacy. The pre-CPOE group was nonrandomized and included a convenience sample of 240 patients with a sample of 1,420 total orders (laboratory N = 340; radiology N = 490; and pharmacy N = 590). The post-CPOE group was randomized and included 241 patients with a sample of 2,390 total orders (laboratory N = 750; radiology N = 680; and pharmacy N = 960). **Results:** TATs were statistically significantly lower ($P < 0.0001$) in all three departments: laboratory TATs decreased 54.5 percent, from 142 to 65 minutes; radiology TATs decreased 61.5 percent, from 31.0 to 11.9 hours; pharmacy TATs decreased 83.4 percent, from 44.0 to 7.3 minutes. **Conclusion:** Implementation of CPOE resulted in dramatic improvements in TATs, which, in turn, can lead to more timely treatment of patients and enhanced communication of results to providers. It also supports the effort to improve quality of patient care and patient safety.

Introduction

Computerized provider order entry (CPOE) is an electronic process that allows a health care provider to enter orders electronically and to manage the results of those orders. CPOE has received increased attention, based on the Institute of Medicine (IOM) reports, *To Err Is Human: Building a Safer Health System*[1] and *Crossing the Quality Chasm: A New Health System for the 21st Century*,[2] and the recommendation of the Leapfrog Group (a coalition of public and private organizations providing health care benefits) that hospitals introduce systems for prescribing and that they be rewarded for it.[3] In 1994, Sittig and Stead[4] wrote a groundbreaking article on computerized order entry, and although much has since changed, we find that adoption of CPOE hinges largely on the financial investment and medication safety aspects of the technology. Our intent in this article is to describe further value in clinical efficiency of CPOE.

In order to improve both quality of care and patient safety, health care systems are implementing CPOE in ever increasing numbers. However, CPOE implementation is more than an information technology change; it involves a major change in health care delivery in both clinical and ancillary departments. It is not simply a technology implementation but a redesign of complex clinical processes, integrating technology at key points to enhance and optimize ordering

- Creating a culture of clinicians and managers working together as partners, not as adversaries.

The team addressed many issues, including development of common order lists and disease-based order sets, required data elements, appropriate order limitations, and other facets of system configuration and integration that were based on clinicians understanding information technology (IT) workflow and IT understanding clinical workflow. The goals the team identified included:

- Reducing the potential for human error.
- Reducing time to care delivery.
- Improving order accuracy.
- Decreasing time for order confirmation and turnaround.
- Improving clinical decision support at the point of care.
- Making crucial information more readily available.
- Improving communication among physicians, nurses, pharmacists, other clinicians, and patients.

A primary focus of the team was to integrate the computerized ordering process into the workflow of the providers and ancillary staff. In addition, the team was instrumental in setting direction for the overall rollout of CPOE, developing approaches to effective training and prioritizing requests for system enhancements. The team developed policies and procedures to support new operational workflow changes. These new approaches to implementation involved physicians, nurses, pharmacists, other clinicians, and IT staff.

The initial patient care unit for CPOE was the medical intensive care unit (MICU). Over the ensuing period, CPOE was rolled out progressively to the medical and surgical patient care units as well. As part of the project implementation evaluation, turnaround times for orders in medical-surgical patient care units were evaluated in each of three ancillary departments: radiology, laboratory, and pharmacy, and the pre- and post-CPOE turnaround times were measured for orders placed for these three departments.

Pre-CPOE measurements were conducted on a convenience sample of 240 patient records, which were reviewed by direct observation in real time (laboratory N = 340; radiology N = 490; and pharmacy N = 590). We observed a total sample of 1,420 orders from April through June 2005. In the pre-CPOE measurement, laboratory turnaround times were measured as the interval between the time the order was written and the time preliminary results became available to clinicians. Radiology turnaround times were measured as the interval between the time the order was written and the time the results became available to clinicians. Pharmacy turnaround times were measured as the interval between the time the order was written and the time it was verified by pharmacy/automated dispensing device release.

In the post-CPOE analysis, a randomized group of 241 patient records was reviewed (laboratory N = 750; radiology N = 680; and pharmacy N = 960). We observed a total sample of 2,390 orders between April and June in 2006. In the post-CPOE measurement, laboratory turnaround times were measured as the interval between the time the order was entered into CPOE and the time preliminary results became available to clinicians; radiology turnaround times were measured as the interval between the time the order was entered into CPOE and the time results

became available to clinicians; and pharmacy turnaround times were measured as the interval between the time the order was entered into CPOE and the time the order was verified by pharmacy/automated dispensing device release. All statistical analyses were performed using SPSS® software (Version 14.0). $P < 0.05$ (two-tailed) represented a statistically significant difference.

Results

Turnaround times for orders placed to all three ancillary departments decreased significantly when the pre- to post-CPOE time periods were compared. Absolute reductions in TAT occurred in all three departments, with decreases of 79 minutes for laboratory orders, 1,146 minutes (19.1 hours) for radiology, and 36.7 minutes for pharmacy. As shown in Table 1, TATs decreased by 55.6 percent ($P < 0.0001$) for laboratory, 61.6 percent ($P < 0.0001$) for radiology, and 83.4 percent ($P < 0.0001$) for pharmacy.

Table 1. Turnaround times before and after CPOE implementation

Department	Pre-CPOE		Post-CPOE		Percentage improvement	*P*- value
	N	Min	N	Min		
Laboratory	340	142	750	63	55.6	<0.0001
Radiology	490	1,860	680	714	61.6	<0.0001
Pharmacy	590	44	960	7.3	83.4	<0.0001

Discussion

The single most studied benefit of CPOE has been the reduction in medication errors. However, other benefits include process improvement, cost-conscious decisionmaking, clinical decision support, and efficiency. Time efficiency incorporates nearly all these identified factors and is a high priority in health care today. End-users more often recognize CPOE's efficiency aspects than its technology advances. Specifically, with enhanced time efficiency, clinicians can communicate more effectively, provide care more accurately, and focus more of their time on patients' needs.

We base this premise on the fact that a clearly legible, unambiguous electronic order does not require additional interpretation and results in fewer callbacks for clarification; callbacks interrupt clinical workflow, potentially increase errors, and decrease patient safety.

This project confirms that CPOE is an effective tool for increasing efficiency in health care. When the same patient care units were compared pre- and post-CPOE, decreases in turnaround time were remarkable. This study confirms the reduction in the time between order placement and the availability of medications for administration, the time for results of radiology procedures, and the time for reporting of laboratory results.

decisions and management. CPOE implementation also requires a new level of integration among all aspects of health care delivery. Order communication is a highly collaborative process, and interdependence in work is a key feature in creating successful computerized ordering systems.[5]

Hallmarks of a successful CPOE system implementation include a high level of leadership involvement, widespread commitment to the project, availability of resources, access to technology, and comprehensive training and communication.[6] If it is viewed simply as a tool for entering test and medication orders, the patient care benefits of CPOE are limited. However, when it is integrated into an organization-wide delivery process, its impact is dramatic.

The improvements in operational efficiency strongly support these efforts. Specifically, clinicians can communicate more effectively, provide care that is more accurate and more timely, and focus more of their time on patients' needs. Although much has been written about using CPOE to reduce medication errors,[7, 8, 9] there is limited published evidence related to clinical efficiency gains with CPOE.[10]

Our purpose was to further delineate those gains. The benefits of CPOE include safer, more consistent patient-centered care that is lasting and measurable. Denver Health has measured turnaround times for laboratory, radiology, and pharmacy as indicators of more rapid communication of results and medication availability as we have implemented CPOE.

Methods

Denver Health Medical Center (Denver Health) is an acute care hospital with over 500 beds that offers a range of inpatient medical, surgical, pediatric, obstetric, and behavioral health services. In 2007, Denver Health recorded over 22,300 inpatient admissions. Denver Health integrates acute hospital and emergency care with public and community health to deliver coordinated preventive, primary, and acute care services. This integration promotes continuity of care for each patient through the entire course of illness. Integration also assures that health care is delivered in the most cost-effective setting.

Beginning in 2003, Denver Health implemented a commercially available CPOE system. Unique features of the system included comprehensive integration with other systems, with bidirectional interfaces to radiology, laboratory, and pharmacy systems; extensive capabilities for customization; and Web-based access.

In order to reach the next level and transform clinically, Denver Health recognized that it needed an integrated systems approach to clinical and nonclinical patient care. Prior to CPOE implementation, a multidisciplinary team evaluated paper-based ordering processes and worked collaboratively to develop approaches incorporating new capabilities offered by computerization of the ordering process. The team recognized that success would involve:

- Enabling existing systems to become 100 percent operational and effectively optimized.
- Improving financial systems' performance with more accurate clinical data.
- Fully implementing clinical systems.

These results mirror to some extent the findings of Mekhjian, et al.,[11] whose methodology for measuring turnaround times differed from that used in this study, in that they measured initiation and completion of orders pre- and post-implementation of CPOE with an electronic medication administration record. Our study did not include an electronic medication administration record. However, they found similar magnitudes of changes, including a 64 percent decrease in medication TATs, a 43 percent decrease in radiology procedure completion times, and a 25 percent reduction in laboratory result reporting times. Similar to our study, their largest improvements occurred in medication TATs, which can potentially have a large effect on patient outcomes for many conditions, such as infectious disease, treatment of elevated blood pressure, pain management, and anticoagulation. These are all conditions where timing of medication administration is particularly crucial.

More recently, Mahoney, et al., reported on the results of implanting an integrated information technology system that included CPOE. They also demonstrated dramatic reductions in medication-related TATs, with an 88 percent reduction, from 90 minutes pre-implementation to 11 minutes post-implementation.[12] Their study differed from ours in that it included barcode-based, point-of-care medication administration across a multihospital health care system with a phased-in approach. By contrast, our study included a single hospital with CPOE, pharmacy and laboratory information systems, clinical decision-support systems, and electronic drug dispensing systems. Their primary endpoint was the reduction in medication errors, with secondary endpoints, such as reductions in medication order TAT and electronic drug dispensing device overrides. Our primary endpoint was the reduction in TATs for laboratory and radiology results and for medication availability.

Health care institutions continue to strive to improve care as it relates to patient safety and quality of care. Increasingly, institutions and organizations are also focusing on the efficiency of health care, realizing that this can affect patient safety and the overall quality of care. The Joint Commission highlighted the importance of efficiency when it defined the important dimensions of performance for quality of care as "patient perspective issues; safety of the care environment; and accessibility, appropriateness, continuity, effectiveness, efficacy, efficiency, and timeliness of care."[13]

Efficiency is considered an important part of three Joint Commission standards: (1) leadership, as it relates to efficient patient flow (standard LD.3.15); (2) management of information (standard IM); and (3) medication management (standard MM). Improvements in turnaround time represent efficiency improvements that can affect overall quality of care.

In addition to improved quality of care, previous studies involving emergency department physicians have found that laboratory TATs are an important component of physician satisfaction and, in their opinion, can influence patients' length of stay and potentially delay treatments.[14] Furthermore, CPOE addresses many deficiencies associated with paper-based ordering. Specifically, CPOE reduces or eliminates:

- The need to locate patients' charts.
- Overlooked orders by nurses or unit secretaries.
- The need for order clarification due to illegibility or poor fax quality.

- The need to manually reenter data, which in turn decreases transcription errors and allows immediate transmission of orders to ancillary services.
- Override rates from electronic drug dispensing systems, ensuring that more orders will be reviewed by a pharmacist.

Although this study demonstrated dramatic improvements in TATs, potential unintended consequences were not monitored. Other studies have described instances where automation of the ordering process has had negative effects, such as an increase in medication errors and actual delays in delivery of care, in contrast to enhanced delivery of care.[15, 16, 17]

However, these findings are countered by the Leapfrog response on CPOE errors,[18] which makes the following points: the primary study of medication error rate increase did not measure error rates prior to CPOE installation; the study compiled impressions and perceptions about problems with just one computer system—one of the oldest in use today; and while introduction of a new computer system can create some errors, it can also reduce overall error frequency.

Conclusion

The benefits of CPOE include safer, more consistent patient-centered care that is lasting and measurable. Efficiencies of the system support better patient safety and quality of care. Our experience demonstrates the importance of efficiency for delivering health care appropriately. At Denver Health, we have demonstrated that CPOE leads to enhanced efficiency by decreasing turnaround times in the ordering process for care related to medication management, as well as laboratory and radiology tests and procedures.

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Medication Safety

Clinical Pharmacists in Emergency Medicine

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Abstract

The purpose of this paper is to summarize the need for an emergency pharmacist (EPh) program, discuss the evidence showing that an EPh program is effective, and provide information and resources that can be used by hospitals considering the implementation of an EPh program. EPh programs have existed since the 1970s, but until recently, they have been rare. Their development in the emergency department (ED) is a result of the unique clinical environment that exists in the ED, which is considered high risk for adverse drug events from a systems perspective. The primary aims of the EPh program are to diminish the risks of adverse events and to reduce costs. The innovative EPh program works with the varied staff in the ED to improve medication safety and provide pharmacologic information to staff. This paper provides substantiation of the value of an EPh program and describes the details of the EPh role when optimized for patient safety.

Introduction

Involvement of clinical pharmacists in patient care in the inpatient hospital setting results in safer and more effective medication use.[1] These pharmacists are typically involved in assuring appropriate prescribing and administration of drugs, monitoring patient adherence to therapy, providing drug information consultation to providers, monitoring patient responses and laboratory values, and providing patient and provider education.

Clinical pharmacy services based in the emergency department (ED) are relatively rare.[2] This is likely due to the unique and complex nature of the ED. The paucity of ED-based clinical pharmacy services is perplexing, given that the ED is known to be a particularly high-risk environment with frequent medication errors.[3] The 1999 Institute of Medicine (IOM) report *To Err is Human* reported that the ED has the highest rate of preventable adverse events among clinical environments studied.[4, 5, 6] EDs care for approximately 110 million patients per year in the United States;[7] 5 percent of these patients experience adverse drug events;[8] 70 percent of these, or 3.8 million events, are thought to be preventable.[9] Clearly, adverse drug events that occur in the ED are a significant public health problem and need to be reduced, but this must be accomplished without making the ED less efficient.

Published reports have asserted that ED-based pharmacists have the potential to reduce iatrogenic harm to patients.[10, 11, 12, 13] Although a pharmacist-based safe-practice intervention

appears to have face value, no study has yet attempted to demonstrate that such an intervention actually reduces preventable adverse drug events in the ED.

The University of Rochester has undertaken a project to implement and optimize a formal Emergency Pharmacist (EPh) Program designed to study the effects of this safe-practice intervention. A large prospective study is underway to quantitatively look at the effect of the EPh program on the rate of adverse drug events and medication-related quality measures.

The purpose of this paper is to provide an overview to institutions considering the implementation of a program that uses clinical pharmacists in the ED. We provide a review of the current literature supporting the use of the EPh. A qualitative study to derive an EPh role optimized for patient safety is also described. In addition to the description of the optimized role, we present practical resources, such as a job description and job qualifications. An updated listing of resources can also be found at www.EmergencyPharmacist.org.

Evidence to Support the Value of a Clinical Pharmacist

Medication Errors in the ED

Data suggest that medication errors are a significant contributor to errors in the ED, as well as in the inpatient setting,[14] and that the prevalence of preventable adverse events in the ED is high.[9] One analysis of adverse drug events reported to a national database showed more than twice as many medication errors resulted in harm in the ED, compared with the inpatient setting.[15] A study analyzing the Centers for Disease Control and Prevention's National Hospital Ambulatory Medical Care Survey from 1992 to 2000 showed that emergency physicians frequently prescribed inappropriate medications for older adults, and that the rate of inappropriate prescribing did not change over the years analyzed.[16]

Another study found that 3.6 percent of patients were prescribed an inappropriate medication in the ED, and 5.6 percent of patients were prescribed one upon discharge.[8] Prescription of an inappropriate medication was associated with worse functioning on components of the health-related quality-of-life score. An Austrian study found that 5.4 percent of patients who received medications had the potential for an adverse reaction.[17] Patients also perceive a risk in the ED. A recent study found that 38 percent of patients presenting to a variety of EDs worried that a medical error might affect them.[18]

The High-Risk Environment of the ED

Many of the system challenges unique to the ED likely contribute to these medication safety issues. Unlike the medication procedures in most health care settings, medications in the ED are usually ordered, dispensed, and administered at the point of care. There is also a higher prevalence of verbal orders, particularly in urgent and high-stress situations.[19] In the ED, physicians usually are not familiar with the patient, and they often do not have access to the patient's complete medical record. As a result, they are not knowledgeable about the patient's medications, medical history, or allergies. Medications are often dispensed directly, without prospective pharmacy review of orders.

In contrast to inpatient wards, where medications are ordered on a routine basis, many medication orders in the ED are unpredictable and time-sensitive, which makes remote prospective review of all orders impractical. In emergency situations, there is also an increased use of higher risk intravenous infusion medications, such as inotropes and sedatives.[10] Physicians and nursing staff often treat multiple patients at once, with frequent interruptions.[20] The ED lacks the ability for direct followup, and thus, adverse interactions between medications prescribed in the ED may go unnoticed by the providers.[17]

Hospital crowding and the boarding of inpatients in the ED also contribute significantly to the high-risk environment in the ED. [21, 22, 23, 24] Nurses and physicians care for patients in the ED using medications with which they may be relatively unfamiliar, and they do so in an overcrowded, overly chaotic environment. As a result, the ED has become a small hospital, caring for emergencies, providing primary care to patients without regular PCPs,[25] and caring for ill patients who wait for scarce inpatient beds. In these chaotic conditions—where inpatients, outpatients, and critically ill patients coexist—few, if any, medication safeguards exist.

The Clinical Pharmacist as a System-Level Solution

Traditionally, error reduction in medicine has focused on the responsibility of the individual health professional and less on the system.[11] Safety experts agree that this is an outmoded and counterproductive method of improving patient safety over time.[26] A systems approach to the reduction of adverse events can create multiple layers of protection that greatly reduces the effect of hazards, before they reach the patient.[27, 28]

Leape and colleagues have described a two-fold approach to the objectives of system design for safety. [29] First, make it difficult for errors to occur, and second, "absorb" errors that do occur. In other words, these hazards should be detected and corrected before harm occurs.[29] The addition of a clinical pharmacist to the patient care team is a systems-level patient safety intervention that serves both of these functions.

The role of the hospital pharmacist has evolved into one that involves active prevention of adverse medication events, in part by screening physician orders for accuracy in dosing, drug interactions, contraindications, and allergies. Traditionally, this role has been carried out remotely from the clinical setting, usually in a centralized hospital pharmacy area.

However, many hospitals have established inpatient and ambulatory clinical pharmacist positions that enable pharmacists to develop personal relationships with nurses and physicians and to have access to more patient information and clinical data. This model increases the pharmacists' involvement in medication choice decisions tailored to specific patients. It has been shown that pharmacists, as members of an inpatient care team, reduce the number of adverse drug events,[30, 31, 32, 33] and that pharmacist involvement in care is financially advantageous for health care institutions.[34] Several authors assert that including a pharmacist in the clinical team is a critically important patient safety solution.[31, 35, 36] A recent analysis of patient safety practices by the Agency for Healthcare Research and Quality (AHRQ) devotes an entire chapter to describing the clinical pharmacist's role in preventing adverse events.[37]

When it comes to emergency care, however, the potential of a clinical pharmacist has gone largely unrealized. In a 2000 consensus committee report that included recommendations regarding the initial steps that should be taken to address error in the emergency care environment, there was no mention of pharmacist involvement.[38] Similarly, an article describing teamwork in the ED and its relationship to patient safety did not describe the pharmacist as a member of the team, although the authors did include resources, such as respiratory care, phlebotomy, and diet and nutrition services.[39] Although many hospitals have programs in place in which the pharmacist responds to the ED for cardiac arrests or trauma team activations,[13, 40, 41, 42, 43] almost none have reported programs that involve a clinical pharmacist assigned exclusively to the ED.[12, 44] Some have recognized this deficit, as published reports have asserted that ED-based pharmacists would have the potential to increase patient safety.[10, 11]

See Appendixes 1 and 2 for summaries of the educational requirements for an EPh and a typical EPh job description.

The Business Model for an Emergency Pharmacist Program

No formal scientific cost-benefit studies have been conducted to assess the value of an EPh program. However, many authors have reported estimates of savings related to recorded pharmacist interventions in EDs and other settings.[34, 45, 46, 47, 48, 49, 50] Although there is a need for a large scientific study to assess the cost savings associated with an EPh program, the literature certainly suggests that emergency pharmacist programs have the potential to be cost effective.

Approximately 110 million patients receive care in EDs each year in the United States, more than four times the number of patients who undergo surgery each year.[7] Given these numbers and the evidence that EDs have the highest rate of preventable adverse events of any other clinical environment, adverse drug events that occur in the ED are clearly a significant public health problem in the United States. Thus, the presence of a clinical pharmacist in the ED would seem to be a necessary but so far grossly underutilized intervention.

Optimization of the Emergency Pharmacists' Role in Medication Safety

Although there is mounting momentum to increase the number of EDs that utilize clinical pharmacists, no study has yet attempted to develop an optimized role for the emergency pharmacist. The role of the emergency pharmacist in the study institution has been previously described.[13] We conducted a cross-sectional, qualitative study to develop a formal definition of an optimized emergency pharmacist role in one ED, using qualitative methods, by identifying perceptions and experiences of key stakeholders.

Study Overview

Qualitative data were collected by two researchers using a combination of two qualitative interview strategies: the general interview guide approach and the standardized open-ended approach. Questions were designed to elicit stakeholders' perceptions of how the emergency pharmacist role could be optimized, defined as one that would be most likely to improve the

quality of care and reduce adverse medication events in the ED. Participants were recruited from key stakeholder groups, including attending emergency physicians, emergency medicine residents, emergency nurses, hospital pharmacists, hospital inpatient nurses and physicians, ED patients, and emergency pharmacists. Data were collected during the interviews in the form of field notes that were transcribed within 24 hours by the interviewing investigator.

Data were compiled, coded, and thematically analyzed by a review committee using the framework approach to qualitative analysis.[51] This approach is characterized by a more structured data collection, which allows a focus on a pre-set objective (in this case, to optimize the pharmacist's role in patient safety). The framework approach involves five major steps. The analysis committee:

1. Reviewed the raw data (transcripts) for initial familiarization.
2. Identified themes by which the data could be further examined.
3. Indexed (coded) the data.
4. Sorted the data by these themes (charting).
5. Mapped the range and nature of the emerging themes (interpretation) to extract recurrent concepts and associations.

Summary of Findings

A total of 43 interviews were conducted before redundancy was reached. Interviewees included 13 emergency physicians, 13 emergency nurses, 9 mid-level providers, 3 ED patients, 2 consultant physicians, 2 emergency pharmacists, and 1 inpatient pharmacist. Several areas of focus were identified, including:

- Visibility of the EPh.
- Involvement in direct patient care.
- Involvement in teaching.
- Surveillance of medication orders.
- Identification of the EPh as a resource for the ED staff.

Based on these themes, strategies were developed to optimize the EPh's role:

- **Maintain high visibility so ED staff members are aware of the EPh's presence.** Staff members felt that periodic rounding through all areas of the ED was important, and that increased visibility in the pediatric and non-acute areas of the ED would be helpful. The continued use of portable telephones and pagers for immediate accessibility was recommended. Participants suggested that signs be posted to signify the status of the EPh (on or off duty), and that the EPh become more involved with review of medication instructions related to patient discharge.
- **Focus attention on ED patients.** Staff perceived that emergency pharmacists' involvement with routine medication issues for inpatients boarding in the ED was interfering with their ability to focus on ED patients. Since boarding patients benefit from protective systems of inpatient pharmacy services, the involvement of the EPh was thought to be redundant. As a

result of this finding, responsibility for boarding patients was formally assigned to inpatient pharmacy personnel.

- **Serve as an educational resource.** Participants highlighted the importance of the EPh as an educational resource. The EPh was perceived as having a role in assisting staff with the administration of beta-blocker medication in acute myocardial infarction and other similar functions. Faculty and residents valued the EPh's distribution of current medication-related articles relevant to the practice of emergency medicine, as well as in providing followup papers to support advice given in the clinical setting.
- **Be present in the ED during peak volume hours, including evening shifts and weekends.** At the time of the study, EPh duty hours were primarily weekdays. Participants overwhelmingly expressed a desire for a shift in coverage to hours that coincided with peak patient volume.
- **Maintain surveillance of provider orders.** In addition to responding to direct queries from nurses and doctors, the EPh role in surveillance of medication orders was emphasized. However, participants did not express a need for 100 percent review of orders but rather a focus on higher risk medications.
- **Respond to all trauma and medical resuscitations in the ED.** Participants reinforced the value of having the EPh present at all resuscitations. Nurses valued their assistance in preparing medications for administration; physicians valued their clinical advice, as well as what they perceived as improved efficiency of the medication delivery system when the EPh was present.
- **Limit time out of unit.** Some participants perceived that the EPh was often called out of the ED for administrative responsibilities (such as committees).

These recommendations are based on staff perceptions at this single academic medical center. Ongoing research will serve to validate the patient safety effects of the optimized EPh role.

Staff Perceptions of the Emergency Pharmacist Program

A survey of staff at the University of Rochester Medical Center's ED was conducted to evaluate their perception of the EPh role. The details of this study are provided elsewhere,[52, 53] but a summary is provided here. A survey was developed based on the results of the qualitative study. It was sent to a randomly selected subset consisting of half of the 182 eligible staff members; 82 percent of the surveys were returned (42 nurses, 33 providers), 41 percent of respondents spend at least part of their clinical time in the pediatric area.

Respondents felt that the EPh improved the quality of care in the ED, and that an EPh was an integral part of the ED team. In addition, most had consulted the EPh at least a few times during their last five shifts. The results of this survey reveal that the EPh role is highly valued and often utilized by staff when located on site. The staff also perceived that the EPh improved patient safety and quality of care.

Respondents to the survey felt it was important that high-risk and rarely used medications be checked by a pharmacist whenever possible. In addition, respondents who cared for children felt that a mandatory review of certain medication orders for children under 1 year of age would

improve medication safety. The majority of respondents felt that the EPh was helpful with medical and trauma resuscitations, reviews of high-risk medications, and consultations and as a patient educator. Respondents also reported that they tended to consult with the EPh more often than they would if the pharmacist were remotely located. Furthermore, certain valued duties—such as patient education, checking orders, and attendance at resuscitations—are not possible from a remote location.

Our findings support the premise that once this program is established, staff will value it. This survey supports the principle of physically locating the EPh in the ED. We found that physicians and nurses in this academic ED overwhelmingly supported the presence of an EPh and regularly sought the EPh's advice. The physicians and nurses felt that the presence of an EPh improved patient safety and quality of care. These results reinforce the value of the many specific duties carried out by this EPh program, and the results also demonstrate that staff acceptance should not be a barrier to implementation of an EPh program.

These results have important implications for ED and hospital leadership teams that are considering the implementation of an EPh program. Although some may worry that resistance from physicians and nurses could be a barrier to implementation, this study clearly demonstrates that the EPh is seen as a highly valued resource and is sought out by ED providers and nurses in an on-site established program.

Conclusion

The use of clinical pharmacists in the emergency department setting is growing, and we anticipate an increasing demand for this role.[2, 54] We hope this paper will serve as a resource to institutions considering an emergency pharmacist program. Updated resources can also be found at www.EmergencyPharmacist.org.

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Appendix 1: Sample Education and Training Requirements for an Emergency Pharmacist position

- Required: Successful completion of PGY-1 (pharmacy practice residency or equivalent experience).
- Highly desired: Successful completion of PGY-2 in critical care or emergency medicine (General Pharmacotherapy PGY-2 acceptable).
- Highly desired: BCPS certified.
- Required: ACLS and PALS course completion
- Highly desired: ATLS Course Completion (audit).
- Well-versed in medication management and pharmacology in the following areas:
    - Airway management, RSI/Post-RSI sedation.
    - Ambulatory care.
    - Cardiology.
    - Critical care.
    - General medicine.
    - Infectious diseases.
    - Pediatrics.
    - Procedural sedation.
    - Psychiatry.
    - Toxicology/drugs of abuse/overdose.
- Some background in disaster management is preferred.
- An understanding of medication-related quality measures applied in the emergency medicine setting.

Note: this is not intended to be an exhaustive or a prescriptive list, but rather a starting point for institutions that wish to develop a listing of qualifications for a clinical pharmacist whose primary practice responsibility will be in the ED.

Appendix 2: Sample Emergency Pharmacist Job Description

The Emergency Pharmacist is responsible for providing comprehensive clinical pharmacy services for the ED and all associated areas (e.g., pediatrics, trauma, urgent care), including pharmacokinetic and therapeutic consultation. Specific responsibilities include, but are not limited to:

- Provide pharmacy review of high-risk medication orders prior to administration.
- Provide patient-specific medication use teaching for discharge medications when appropriate.
- Focus on cost avoidance and cost savings due to medication use in the ED.
- Facilitate proper information transfer with regard to medication use for patients converted to inpatient registry from ED.
- Work collaboratively with other clinicians and health care providers to implement and maintain innovative disease management programs and clinical pharmacy services.
- Participate in the development of medication management programs within the institution, including clinical guidelines, critical pathways, disease management, and drug use programs.
- Participate in providing didactic and experiential training in clinical pharmacy for PharmD students and clinical pharmacy residents.
- Actively participate in clinical research projects.
- Participate in the professional development and competency of clinical staff. Function as an educational resource for pharmacy staff.
- Assist in the development, implementation, and evaluation of critical care and emergency medicine pharmacy residency programs.
- Keep informed of all local, State, and Federal laws covering the storage, handling, and dispensing of drugs; and interpret each prescription order to determine that it meets all legal requirements.
- Keep informed of the actions, side effects, and proper use of all new drugs as they are made commercially available, as well as of all investigational drugs being studied at this institution.
- Maintain awareness of contemporary trends in the profession through the professional literature and regular attendance at professional meetings, institutes, and seminars.
- Participate collegially in the development of new programs, services, and practices in the education activities of the department and the management and administration of the department.
- Perform other related duties as required.

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

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Abstract

At a 644-bed, tertiary-care, “magnet” system, intravenous (IV) infusion medication errors were determined to present the greatest risk of harm. An IV infusion safety initiative focused on multidisciplinary collaboration, standardization of IV dosing, and medication safety technology. A modular IV infusion safety system was determined to provide the greatest “speed to impact” in reducing harm. In 9 months, the system averted 166 overdoses; IV Medication Harm Index analysis identified 33 as highest risk overdoses (heparin and propofol accounted for 73 percent of these highest risk averted overdoses). Although 78 percent of infusion devices were used with critical care patient types, 52 percent of the highest risk-averted overdoses occurred with noncritical care types. For patient controlled analgesia, respiratory monitoring modules helped avert numerous undesired outcomes. Other results included improved best practices, communication, nursing satisfaction, retention, and recruitment. From January to June 2006, infusion safety systems recorded 328 averted high-risk overdoses. Based on the Agency for Healthcare Research and Quality’s (AHRQ) value of $6,000 per accidental drug overdose, the system helped avert 6-month costs of $1,968,000. IV infusion safety systems provide rapid, effective, and cost-effective patient safety improvement.

Introduction

“First, do no harm” is the ethical imperative for every patient safety effort. In working to reduce the frequency of medication errors, first priority must be to prevent those errors with the greatest potential for harm. The leading cause of patient harm is medication errors, which account for almost 20 percent of medical injuries.[1] Twenty-eight percent of medication-related injuries (adverse drug events, ADEs) are considered preventable.[2] Administration is the stage of the medication use process most vulnerable to error,[2] and the intravenous (IV) route of drug administration often results in the most serious outcomes of medication errors.[3] IV infusion errors, which involve high-risk medications delivered directly into a patient's bloodstream, have been identified as having the greatest potential for patient harm.[4, 5, 6, 7, 8]

The use of patient controlled analgesia (PCA) for IV opioid infusion presents particular challenges, due to the variability of patient response. The Anesthesia Patient Safety Foundation (APSF) notes a significant, underappreciated risk of serious injury from PCA in the postoperative period, including a low but unpredictable incidence of life-threatening opioid-induced respiratory depression (RD) in young healthy patients.[9] Even correctly programmed IV infusion of therapeutic doses can result in opioid-related respiratory depression (RD). Respiratory status changes are a leading indicator of an adverse patient response to opioid infusion. Thus, monitoring patient response to PCA therapy is also critical.[10]

At St. Joseph's/Candler Health System (SJCHS), a 644-bed, tertiary-care, "magnet" system, a multidisciplinary medication safety team determined in 2001 that reducing the incidence of highest risk medication errors—i.e., IV medication administration errors at the point of care, particularly those involving continuous drug infusions—would have the greatest, most immediate impact on improving medication safety and quality of care. To achieve this goal, SJCHS undertook a long-term IV Infusion Safety Initiative. Key elements included a culture of safety; a multidisciplinary team comprising physicians, pharmacists, nurses, respiratory therapists, risk managers, and others; standardized IV drug nomenclature, concentrations, dosing units, and ranges; and implementation of IV medication safety technology.

In working to improve patient safety and quality of care, the goal is to change the system—i.e., to make it easier to do the right thing, prevent individuals from committing errors, and build high-reliability organizations. To achieve this goal, the use of technology is essential.[7] Ultimately, computerized prescriber order entry (CPOE), barcode medication administration (BCMA), and "smart pumps" (computerized IV infusion safety systems) are all essential. However, simultaneous implementation of all these technologies is rarely feasible.

To help prioritize implementation, the SJCHS IV infusion safety team established multiple criteria for the assessment of available technologies:[4]

- Comparative speed to impact (cost and return on investment, staff resources required, time required for implementation, and potential to reduce harm).
- Impact on quality of care.
- Impact on nursing satisfaction and productivity.
- Continuous quality improvement (CQI) data capabilities.
- A platform that would allow future integration with other technologies.

SJCHS's IV Infusion Safety Initiative led to hospital-wide implementation of a modular IV infusion safety system that incorporated various modules as they became available, i.e., point-of-care units (the programming "brains" with dose-error-reduction software [DERS]), large-volume syringe and PCA pump modules, and continuous respiratory monitoring modules.[4, 10]

In this article, we describe the need to improve IV infusion medication safety at the point of care, our culture of safety and team approach, and the IV infusion safety system's core capabilities to help avert errors, monitor patient respiratory response, and provide actionable data. In sharing our experience, results, and lessons learned, we hope this information will be helpful to other

health care professionals in prioritizing implementation of IV infusion safety systems as they work to improve safety and quality of care for all patients.

Need for Improved IV Medication Safety at the Point of Care

Medication administration. In the medication use process, the nurse at the bedside is most vulnerable to errors.[2] Compared with other steps in the process, the administration stage has the fewest safeguards and the fewest support mechanisms.[4, 11, 12, 13, 14] Leape, et al., showed that 38 percent of medication errors causing preventable ADEs occurred during administration, and only 2 percent of these errors were intercepted.[15] Errors with the potential to harm patients are considered potential ADEs. Of the nonintercepted potential ADEs and preventable ADEs, 51 percent occurred during the administration stage.[15] Because administration occurs at the end of the medication use process, with no naturally occurring redundancies, opportunities to intercept errors at this stage are lessened. Critical care studies in high-alert IV medication administration found error rates of 34 percent[14, 16] and 49 percent.[14, 17]

IV infusion medications. Only a few high-risk medications—such as warfarin, some forms of chemotherapy, and some sedatives—are administered orally. A far greater number can be delivered intravenously, e.g., heparin, insulin, morphine, fentanyl, propofol, and midazolam.[4] IV medications have been associated with 56 percent of medication errors[18] and 54 percent of potential ADEs.[19] Data from a major teaching hospital indicate that overall, 61 percent of the most serious and life-threatening potential ADEs are IV drug-related.[a]

General-purpose infusion devices can deliver IV medications at any rate within a 10,000-fold range (0.1 - 999 mL/hr) and can be programmed for any patient weighing from 600 g to more than 300 kg.[4] Without programming safeguards, it is relatively easy to inadvertently deliver a comparatively massive overdose. For example, a missing decimal point or a double key press can result in a 10- or 100-fold overdose (e.g., by programming 64, 604 or 66.4 instead of 6.4). A clinician can easily confuse dose, flow rate, and bolus or loading-dose amounts. A 24-hour dose can be programmed to be delivered over 1 hour.[4]

Undesirable variability in IV medication practices further increases the risk of harm. A review of infusion safety system software datasets from more than 100 individual hospitals revealed huge variability in drug names, concentrations, dosing units, dose limits, maximum infusion rates, weight limits, volume limits, and other variables.[20] For example, in programming an infusion of magnesium sulfate, a clinician had to choose from among 10 different dosing units: grams/hr, grams/kg/hr, grams/min, mg/hr, mg/kg/hr, mg/min, mcg/kg/hr, mcg/min, mEq/hr, or mEq/kg/hr.[20] Selecting a wrong dosing unit can be tragic. For a 73-kg patient, inadvertently using weight-based mcg/kg/min instead of mcg/min would deliver a 73-fold overdose.

Thousands of medications are currently available, and more are being introduced every year. Look-alike and work-alike drugs and drugs with sound-alike names all increase the possibility of error. The increasing complexity of the patient care environment, the high turnover rates among

[a] Personal communication, D.W. Bates, MD, MSc, Brigham & Women's Hospital, Boston, MA, October 2001.

nursing staff, and nurses working in multiple settings further increase the risk of harmful medication errors.

IV medication infusion errors are widespread. Aggregated data from IV safety systems in 18 hospitals documented that 1.1 potentially life-threatening IV medication programming errors and an additional 1.5 potentially significant IV medication programming errors were averted for every 1,000 patient days.[21] While not every potential ADE results in patient injury, compared with other medication errors, IV infusion programming errors have a greater likelihood of causing injury. Once a nurse presses "Start" on an infusion device, unless a programming error can be intercepted automatically, the misprogrammed infusion will be delivered to the patient. An ADE is especially likely to result with drugs, such as heparin, for which dosing errors have a low detectability.[22] For acutely ill patients, even a minor over- or underdose can result in serious adverse events.[4]

Patient Controlled Analgesia

Despite the effectiveness of PCA for opioid administration, responses to opioids vary greatly among individuals, and significant hazards are associated with PCA therapy.[10] Even correctly programmed, appropriate doses of opiates can suppress respiration and decrease heart rate and blood pressure.[10, 23, 24, 25] Episodes of bradypnea and desaturation can escalate to respiratory depression (RD) requiring rescue. The success rate for in-hospital cardiopulmonary resuscitation remains less than one in five patients.[26, 27, 28] If detected early, most cases of opioid-induced respiratory depression can be treated with naloxone. However, severe cases can be fatal.[29] The risk of patient harm due to medication errors with PCA pumps is 3.5-times the risk from any other type of medication administration error.[30]

A recent study of continuous respiratory monitoring found an incidence of RD based on desaturation consistent with previous estimates. However, the incidence of bradypnea was many orders of magnitude greater than the 1 to 2 percent widely reported in the literature.[26] Thus, respiratory monitoring is a critically important element of PCA pain management. Capnographic monitoring—measurements of ventilation using respiration and exhaled carbon dioxide ($EtCO_2$)—is particularly important because it can provide an earlier warning of respiratory depression than pulse oximetry (SpO_2) in some patient populations.

The Institute for Safe Medication Practices (ISMP) recommends that technology for PCA be developed that can alert clinicians to unsafe dose settings, programming errors, and RD.[31] The APSF urges health care professionals to consider the potential safety value of continuous oxygenation and ventilation monitoring in these patients and implementation of "smart" PCA pumps containing dose-error reduction software (DERS).[9]

The IV Infusion Safety Initiative at St. Joseph's/Candler Health System

SJCHS, a "magnet" system comprising two tertiary-care hospitals with 644 beds and 291,504 discharges annually, has long had a highly collaborative, nonpunitive culture with a strong focus on patient and medication safety. In 2000, an ISMP article detailing the hazards associated with PCA[32] prompted our multidisciplinary medication error team to focus intently on IV medication

errors. Recognizing that not all medication errors have the same potential to cause serious adverse events, the team decided that first priority should be given to averting errors that pose the greatest risk of harm.

In 2001, completion of an ISMP Medication Safety Self-Assessment[33] led the team to focus on administration and IV medications. The team established the following Infusion Safety Goals[4]:

- Increase detection/prevention of IV medication administration errors, resulting in improved patient care and decreased mortality/morbidity.
- Increase documentation of detected/prevented errors, specifically, types of errors; where/when errors were occurring; and identification of error-prone drugs.
- Implement an error-detection system with built-in feedback loops, so that continuous quality improvements (CQI) could be made over time.
- Decrease complexity of infusion technology.

IV Infusion Safety Technology

In the past, it has been difficult to use technology to help avert IV infusion pump programming errors. CPOE systems do not address this type of error,[4] and bedside barcode scanning alone is not sufficient.[34] Unless infusion and barcode technologies are fully integrated, accurate device programming cannot be confirmed. For a continuous IV infusion that spans multiple nursing shifts, several clinicians might make periodic dosage adjustments based on laboratory results, protocols, or verbal orders that might not be included in the barcode system, which increases the possibility of programming errors.[35]

Computerized IV infusion safety systems ("smart pumps") are specifically designed to avert IV infusion programming errors and provide actionable data on various aspects of the averted errors. For these reasons, in 2002, the SJCHS multidisciplinary team identified implementation of an IV infusion safety system as the best initial approach to safeguard patients against high-risk medication errors.[4]

After comparing and evaluating all "smart" infusion devices on the market at the time and reviewing published reports, we selected a modular, computerized, integrated IV infusion system with medication-error prevention and CQI data-collection software (Alaris System with Guardrails® Suite of Safety Software, Cardinal Health, Alaris Products, San Diego, CA). Nurses involved in reviewing the IV medication safety system actively expressed their support for its selection. The system's unique modular design provides a technology platform that can include large-volume syringe and PCA pumps, as well as pulse oximetry and noninvasive capnography modules for continuous respiratory monitoring of patients receiving PCA therapy.

Having a single interface for all modules simplifies staff training, reduces programming complexity, and increases ease of use. This combination of features suggested a dramatically improved infusion system that promised a potentially significant reduction in infusion-related medication errors.[4, 10]

Based on our institution's best practice guidelines, a review of the literature, and input from key physicians and nursing staff, we customized the DERS database to create drug libraries for different patient care areas. The database standardizes concentrations, dosing units, and dosing limits for IV infusion medications, which also improves safety and efficiency. The medication-use profiles, known as "drug libraries," standardize how the device is used in different types of patients. CQI data logs provide detailed information, including data on "alerts" (indicating that a dosing limit has been exceeded) and averted errors (an alert resulting in reprogramming or canceling the infusion). Data analysis helps identify opportunities for improving IV medication safety and best practices.[4]

Nurse education. Following selection of the system, clinical experts from various patient care areas were designated as trainers. In a multitiered process, staff received training through expert sessions, skills labs, hands-on exposure, and an internet computer-based training module provided by the vendor. As a result, nurses, pharmacists, and physicians realized the benefits of using the safety software to help prevent high-risk IV medication errors.[4]

Installation. In October 2002, the new infusion system was installed on all units in our three-hospital health care system. Installation of 584 point-of-care units and 760 large-volume pump modules was completed within an 8-hour period. Hospital-wide implementation required no changes in nursing workflow, had minimal impact on productivity, and required no additional full-time employees (FTEs).[4, 8] CQI logs documented immediate impact on prevention of IV programming errors (Table 1). Syringe pumps were added to the system in 2003.

Analysis of Prevented ADEs and Associated Harm

In July 2003, an innovative harm-assessment tool was developed by the IV Medication Harm Index Study Group, which included physicians, pharmacists, and nurses, who are recognized patient safety experts. The index comprised three subscales: (1) the inherent risk of the drug being infused, (2) the risk associated with patient acuity, and (3) the risk that an infusion-related ADE might go undetected. Totaled subscale scores ranged from 3.5 to 14; higher scores indicated greater harm/risk.[22] Use of this innovative tool allowed us to assess the extent of harm averted by the system.

Wireless Networking, Expanded Drug Libraries

In 2004, further safety improvements were achieved with expanded drug libraries and the implementation of wireless networking with system management capabilities. Wireless networking allows pharmacy to remotely monitor any patient receiving an infusion outside pre-established limits and to quickly install software upgrades, revise best-practice datasets, and gather CQI data for analysis.

PCA with Continuous Respiratory Monitoring

In 2004, PCA, capnography ($EtCO_2$) and pulse oximetry (SpO_2) modules (Alaris System with Guardrails® Suite of Safety Software, Cardinal Health, Alaris Products, San Diego, CA with Oridion Microstream® capnography technology and Nellcor® OxiMax® pulse oximetry technology) became available and were added to the IV infusion safety system to monitor

Table 1. Examples of averted programming errors[a]

Location	Drug	Variable	Initial	Reprogrammed
Medical-surgical	Hydromorphone	PCA dose	3 mg	Decreased to 1 mg
Medical-surgical	Hydromorphone	Maximum limit	25 mg	Decreased to 10 mg
Medical-surgical	Hydromorphone	Continuous dose	30 mg	Decreased to 1 mg
Medical-surgical	Morphine	Loading dose	10 mg	Decreased to 4 mg
Critical care	Fentanyl	Continuous dose	300 µg	Decreased to 150 µg
Medical-surgical	Hydromorphone	Maximum limit	200 mg	Decreased to 10 mg
Medical-surgical	Fentanyl	PCA dose	1 µg	Increased to 50 µg
Critical care	Morphine	Lockout (time)	30 min	Increased to 15 min
Critical care	Meperidine	Continuous dose	20 mg	Decreased to 10 mg

a Alerts are not posted until the "start" key is pressed and programming is completed. All limits are initially set up as "soft" (can be administered as override).

Source: Maddox RR, Williams CK, Oglesby H, et al. Am J Health-Syst Pharm 2006;; 63: 157-64 Reprinted with permission.

nonintubated patients receiving PCA therapy in critical care units and in general nursing units. The monitors provided PCA/$EtCO_2$ and PCA/SpO_2 trending data at the bedside to assist clinicians in assessing respiratory response to PCA therapy. The system was designed to supplement, but not substitute for, clinician monitoring. The combination of system components allowed monitoring of practice (i.e., infusion programming) and patients (i.e., individual respiratory responses to opioids).

As an initial beta site, SJCHS evaluated the new PCA and respiratory monitoring modules for 6 months. Based on this evaluation, continuous respiratory monitoring of each PCA patient was made the standard of care. PCA and respiratory monitoring modules were implemented hospital wide in June 2004. Pharmacy and nursing originally had planned to purchase a pulse oximetry module for each PCA module. However, beta-testing results underscored the difficulty of predicting patient response to opioids and showed capnography to be the "first indicator" of opioid-related respiratory depression. As a result, a capnography module was purchased for each PCA module, and pulse oximetry modules for use with selected patients.[11]

Respiratory Therapist's Expanded Role

Hospital PCA policy was revised to require respiratory therapy to round on every PCA patient at least once per 12-hour shift. When continuous capnography is being used with a patient, if an issue arises and a nurse cannot resolve the alarm situation, respiratory therapy functions as the "first responder" for patients at risk of respiratory depression. The respiratory therapist assesses the patient, reviews the patient's trended capnography data and the amount and type of medication the patient has received, and assists the nurse in finding the cause of the patient's change in status, determining the appropriate intervention, and working with the physician.

Respiratory therapy also developed a patient selection algorithm to help clinicians determine appropriate respiratory monitoring for patients.

Patient Selection

All SJCHS patients who receive PCA therapy have $EtCO_2$ monitoring to help protect against narcotic-induced respiratory depression. In addition, all patients are intermittently monitored for SpO_2. Patients with the following conditions are continuously monitored for SpO_2: patients at risk of pulmonary embolism, CO_2 retainers, initial $SpO_2 \leq 92$ percent, and congestive heart failure. In addition, SpO_2 may be initiated "as needed" anytime that nursing or respiratory therapy deems it necessary.[11]

Results

Implementation of a modular, IV infusion safety system for large-volume, syringe, and PCA pumps and continuous respiratory monitoring achieved the SJCHS Infusion Safety Initiative Goals established in 2000. Representative results include the following:[4, 8, 11, 23]

IV Infusion Safety

- The number of different types of infusion devices at SJCHS was reduced from five to one, increasing standardization and decreasing opportunities for error.
- Standardization of decision-support drug libraries, including drug names, concentrations dosing units, and dosing limits across the two hospitals, as well as decreased complexity and opportunities for error.
- Failure modes and effects analyses (FMEA) showed a 73 percent reduction, from 210 to 56, in risk priority score for IV heparin therapy.
- Direct observation showed greater than 98 percent nurse compliance with the use of safety software that provides warnings based on the decision-support library.
- From October 2002 to July 2003, CQI data documented 245 averted errors, including 166 averted overdoses.
- Application of the IV Medication Harm Index identified 33 of these 166 as highest risk averted overdoses—e.g., IV heparin at 13 times the intended dose.
- Heparin and propofol accounted for 73 percent of the highest risk averted overdoses.
- Even though 78 percent of large-volume modules were used with critical care patient types, 52 percent of highest risk averted overdoses occurred with non-critical care patient types.
- From January to June 2006, CQI data from 558 expanded IV safety systems documented 967 averted errors (Figure 1).
- Of these, 328 were averted overdoses greater than 1.5 times the maximum dose and likely to cause harm.
- IV Medication Harm Index of data from January to December 2006 identified 90 highest risk-averted overdoses.

Nursing Satisfaction

Medication Management Readiness Team analysis and informal interviews showed that the nursing staff has embraced the new system. We feel that implementation of this innovative system demonstrates the hospital's commitment to nurses and gives SJCHS an edge in nursing retention and recruitment by placing practice safety at the forefront.[4]

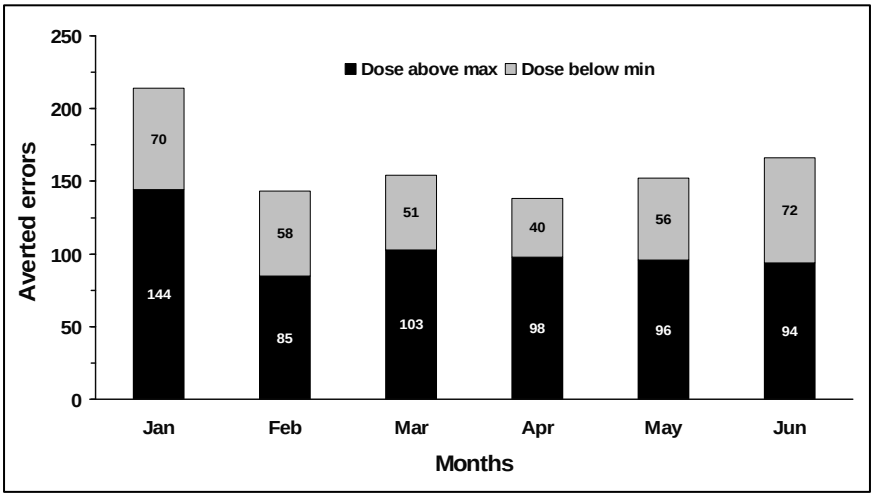

Figure 1. Number of programming errors prevented by smart pump alert: January – June 2006.

PCA Safety[11]

- CQI data indicate significant patient harm has been averted from inadvertent misprogramming of PCA devices by nurses. During the initial 4 months, with PCA syringes initiated for 225 patients, the system averted 52 PCA programming errors.
- During the first months of use, continuous respiratory monitoring helped clinicians identify numerous cases requiring intervention, even when programming was correct, and a patient received therapeutic dosing.
  - Multiple cases of undiagnosed obstructive sleep apnea (OSA) and pulmonary embolism have been identified before undue clinical outcomes occurred.
  - In the 33 months from July 2004 through March 2007, 16 patients with declining physiologic status were identified by continuous respiratory monitoring and avoided unwarranted outcomes and possible transfer to the intensive care unit (ICU). This value is the number of instances for which there are documented case reports. There were other instances in which RR alarms were triggered, interventions made, and unwarranted outcomes averted. However, no case reports were submitted.

Nursing Satisfaction

Subjective feedback from SJCHS nursing staff indicates that nurses feel more comfortable in aggressively managing patients' pain and are less reluctant to give additional medication now that they have information to help them ensure "right programming, right response." This is particularly important with sickle cell patients, who often require high doses of opioids. Knowing that patients will be more comfortable, have more energy, and do better increases nursing satisfaction. In addition, the common user interface for PCA and monitoring modules reduces training time and decreases the likelihood of error. Clinician assessments of patients receiving PCA therapy have been greatly enhanced by the availability of combined dosing and respiratory monitoring trend data, particularly for $EtCO_2$. In some cases, capnographic data provided the only indication of respiratory depression.[11]

Financial Benefits

From January to June 2006, 558 expanded infusion safety systems recorded 328 overdoses greater than 1.5 times the maximum dose and likely to cause harm. Using the conservative AHRQ value of $6,000 for costs of a medication-related adverse event/poisoning, which includes accidental drug overdose, these overdoses would have been associated with 6-month costs of $1,968,000, had they occurred. ADEs are also costly—in 2006 dollars, $8,750 per preventable ADE.[2, 3] This supports the decade-old contention that interventions that reduce the frequency of ADEs can be justified both economically and to improve the quality of care.[36]

Discussion

Practice improvements based on analysis of CQI data from the IV infusion safety software include the following:

- IV drug labels were reformulated to include total volume and amount of drug, allowing nursing staff to program the system to deliver the correct dose of medication more easily.[4]
- For neonatal and pediatric patients, the efficiency and safety of IV medication administration for infrequently used drugs were increased, since clinicians can quickly reference the drug database programmed in the pump's drug library at the bedside, knowing that information is adequately backed by the current literature.[4]
- Propofol and heparin were associated with the greatest number of safety software alerts, which allowed staff to better focus process improvement efforts.[22]
- The SJCHS heparin protocol was revised to eliminate at least three steps, multiple calculations, and multiple opportunities for error, thus improving safety and timeliness of heparin administration.[4]
- Unique bolus dosing parameters were developed for propofol, and an ICU sedation protocol was implemented that requires sedative dosing using targeted goals according to a predefined objective consistent with the Society of Critical Care Medicine Good Clinical Practice guidelines.[35]
    - Propofol dosing alerts were reduced by more than 50 percent.
    - Bolus doses of propofol were almost eliminated.
    - The total cost of propofol was reduced to $650,330 from $1,774,395.
- Creation of a respiratory monitoring algorithm increased ease of patient selection for $EtCO_2$ and/or SpO_2 monitoring.[11]

SJCHS's IV Infusion Safety Initiative has taught us the importance of giving focused attention to the following issues in order to effect a successful multifaceted collaborative effort:

Multidisciplinary team approach. A collaborative approach is key to improving patient and medication safety. Involving a multidisciplinary team to research technology alternatives was an effective way to "make our case" to our health care system leadership. The team conducted comprehensive analyses, from the information-gathering stage through final price negotiations. While time-consuming, this approach was well worth the effort and was effective in obtaining

leadership approval of “smart pump” technology. Involvement of nursing in research and implementation of the technology resulted in a high level of nursing acceptance and compliance.

Focus on highest risk errors. Identifying and averting errors that have the highest risk—i.e., IV administration errors—have an immediate impact on reducing patient harm. “Speed-to-impact” analysis can help to prioritize selection of medication safety technologies. Implementation of IV infusion safety systems has immediate, measurable impact on helping avert high-risk medication errors. Implementation also results in practice improvements, increased interdisciplinary communication, and improved nursing satisfaction, retention, and recruitment.

Continuous respiratory monitoring of PCA therapy. When PCA pumps are involved, the risk of harm is more than 3.5 times as great as it is with large-volume pumps.[30] However, PCA programming errors are not the only cause of oversedation. For this reason, the use of respiratory monitoring, especially capnometry, is important for patients receiving PCA therapy. Continuous SpO_2 and $EtCO_2$ are important clinical parameters and should be used in conjunction with each other. SpO_2 reflects oxygenation, while $EtCO_2$ reflects ventilation; one may be normal while the other demonstrates an abnormal respiratory status. Noncritical care nurses and physicians are generally unfamiliar with the information provided by these devices and might have problems applying the data to the care of the patient. Because of this unfamiliarity, nurses are sometimes reluctant to call physicians when the system alarms. Respiratory therapists may be needed to interpret the data.[11]

Ongoing analysis of CQI data. Analysis of CQI data is useful to identify opportunities for practice improvements and to target medication safety efforts. Importantly, the software in the IV safety system provides not only interdiction of untoward events but also information. Analyzing the CQI data from all devices allows the multidisciplinary team to identify further opportunities for best practice improvements. Wireless networking and multidisciplinary collaboration allow implementation of those improvements efficiently and effectively, providing continuous safety improvement for patients and clinicians.

Conclusion

SJCHS’s experience shows that a modular IV infusion safety system offers a highly effective safety net for detecting IV medication errors and monitoring patient respiratory responses. The harm and costs averted using this technology are substantial. There is little doubt that morbidity and mortality have been reduced because of the investment in this system.

Patients not in critical care units are usually more hemodynamically stable, receive fewer IV infusions, and are typically perceived to be at lower risk of infusion-related errors. Findings from the IV Medication Harm Index challenge this perception, particularly when anticoagulants, such as heparin are being infused. Data analysis showing that more than half of the most serious averted errors were associated with patients outside the ICU supports the importance of using IV safety systems for critical care and non-critical care patients.[22]

The results of using these technologies have convinced us that respiratory monitoring with PCA must be the standard of care within SJCHS. This system demonstrated immediate improvement

in the care of patients receiving PCA, as evidenced by multiple cases during the first months of use. Pulse oximetry and capnography with PCA prevented potential harm in these labile patients, decreasing the need to admit or transfer them to higher acuity departments, such as a step-down unit or ICU.

The achievements of the SJCHS Infusion Safety Initiative have further strengthened our culture of safety and confirmed the importance of multidisciplinary collaboration. Infusion safety technology now helps clinicians identify and, most importantly, avert the medication errors associated with the greatest risk of harm—IV administration errors at the point of care. Using wireless technology, staff can remotely monitor all infusions in both hospitals. Trend data from respiratory monitors can be used to help avert PCA programming errors and monitor patient responses to opioids.

Benefits of "smart" infusion technology include a safe work environment for nurses; standardization of IV medication concentrations, dosing units and dosing limits; improved safety by avoiding high-risk IV medication administration errors; improved patient satisfaction and safety perception; and improved financial performance through avoiding these costly errors. IV infusion safety system implementation provides a rapid, effective, and cost-effective means to improve patient safety and quality of care.

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

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Abstract

The Anesthesia Patient Safety Foundation has noted an underappreciated risk of serious injury from patient-controlled analgesia (PCA)—including life threatening respiratory depression (RD) in young, healthy patients—and has urged consideration of "smart" PCA pumps and continuous oxygenation and ventilation monitoring of patients receiving PCA therapy. St. Joseph's/Candler Health System was the first U.S. hospital system to implement such technology. Clinical experience shows that non-invasive capnographic monitoring provides the earliest warning of RD. Use of this technology documented an incidence of PCA-related RD-bradypnea many times higher than previously reported. We describe implementation of "smart" PCA pumps with continuous respiratory monitoring and results achieved in significant programming errors averted and patients protected even when the PCA infusion was correctly programmed. Our experience shows that continuous respiratory monitoring of PCA therapy, especially non-invasive capnography, assists clinicians in early identification of RD and other complications to prevent serious adverse events and the need for costly interventions.

Introduction

Effective pain management is essential to patient satisfaction, quality of care, and institutional compliance with Joint Commission standards.[1] Patient-controlled analgesia (PCA) is a widely used, effective method of opioid administration for postoperative pain management. However, PCA therapy is also associated with serious risks.[2, 3, 4, 5, 6, 7]

The Anesthesia Patient Safety Foundation notes that the significant, underappreciated risk of serious injury from PCA in the postoperative period includes a low, unpredictable incidence of life threatening, opioid-induced respiratory depression (RD) in young, healthy patients.[8] A recent study using continuous noninvasive monitoring of both oxygenation and ventilation found that the incidence of RD based on bradypnea was many orders of magnitude greater than the 1 to 2 percent widely reported in the literature.[9] MEDMARX[SM] and U.S. Pharmacopeia (USP) data show that when PCA pumps are involved, the chance for patient harm increases more than 3.5 times.[10]

The Joint Commission has noted that health care professionals' concern about opioid-related RD is one of the barriers to adequate pain management.[1] Improving the safety of PCA is thus a major factor in improving both medication safety and the quality of postoperative care.

Numerous factors can lead to opioid-related RD: prescribing errors, PCA pump programming errors, "PCA by proxy," improper patient selection, improper patient and clinician education,[3, 4] and the variability of patient response to opioid administration. Accurate dosing and administration of opioids are critical. However, even when correctly programmed, therapeutic doses of opioids can suppress respiration.[5, 6, 11] Comorbidities, diagnosed or undiagnosed, also affect how a patient responds to a particular dose of narcotic,[2, 3, 4] even one that is within approved administration limits. If a patient requires mechanical ventilation or some other supportive intervention secondary to RD, this can result in increased length of stay, risk of hospital-acquired infections, and associated costs.

If detected early, most cases of opioid-related RD can be treated with naloxone. However, severe cases can be fatal.[11] PCA opioid-induced episodes of bradypnea and desaturation can escalate to RD requiring rescue, and in-hospital cardiopulmonary resuscitation is successful in fewer than one in five patients.[9, 12, 13] Detection of a patient's declining respiratory status before progression to RD can help avert unwarranted outcomes and the possible need for critical care. Thus, safe, effective use of PCA requires monitoring of both practice (i.e., correct pump programming) and patients (i.e., individual respiratory response to opioids).[2]

Current protocols for respiratory monitoring of hospital ward patients receiving PCA therapy typically require documentation of the respiratory rate (RR) and less commonly, the oxygen saturation (SpO_2) value, initially at 30-minute intervals but thereafter at intervals as far as 2 to 4 hours apart.[9] RR is often determined by clinician assessment, even though manual respiration counts may be inaccurate when compared to capnometry.[14] SpO_2 is measured by intermittent or continuous pulse oximetry. Typically, only some high-risk patients are monitored by capnography, a technology that assesses ventilation by measuring RR and the concentration of exhaled carbon dioxide ($EtCO_2$).

The American Society of Anesthesiologists emphasizes that, because ventilation and oxygenation are separate physiologic processes, monitoring oxygenation by pulse oximetry is not a substitute for monitoring ventilatory function by capnography.[15] Oxygen saturation usually is maintained, even at a low respiratory rate, so that pulse oximetry might fail to detect respiratory deterioration, particularly if a patient is receiving supplemental oxygen.[7] The use of supplemental oxygen does not correct desaturation due to hypoventilation; it simply delays the progression of respiratory failure from bradypnea to apnea. Thus, even continuous monitoring of heart rate and SpO_2 by pulse oximetry is not a substitute for monitoring $EtCO_2$, respiratory rate, and apneic events by capnography. Capnographic monitoring can anticipate a patient's desaturation by warning of a decrease in RR and rise in $EtCO_2$.[8] In a procedural sedation study, pulse oximetry identified only 33 percent of those patients with respiratory distress, while capnography captured 100 percent.[16]

Until recently, continuous capnographic monitoring required that a patient be intubated, and its use was limited mostly to patients in critical care areas. Now noninvasive capnography systems with modified cannulae can be used for continuous monitoring of nonintubated patients in

general care nursing areas. By providing clinicians with information on the patient's ventilatory response to PCA therapy, continuous capnographic monitoring helps provide an early warning of potential RD.[2]

The Anesthesia Patient Safety Foundation urges health care professionals to consider the potential safety value of continuous oxygenation and ventilation monitoring in patients receiving PCA therapy and implementation of "smart" (computerized) PCA pumps containing dose-error reduction software.[8] The Institute for Safe Medication Practices (ISMP) recommends that technology for PCA be developed that can alert clinicians to unsafe dose settings, programming errors, and RD.[3] St. Joseph's/Candler Health System (SJCHS), a 644-bed, tertiary care, "magnet" system, is the first hospital system in the United States to implement such technology.[a] The use of "smart" PCA pumps with continuous pulse oximetric and noninvasive capnographic monitoring was made the standard of care at SJCHS in 2004.

In this article, we describe the implementation and use of these technologies, including an automatic PCA "pause" feature, development of a patient selection algorithm, the innovative involvement of respiratory therapists in a multidisciplinary team approach, results achieved in averting significant programming errors that would have likely caused serious negative outcomes, patients protected from adverse physiologic responses to PCA even when infusions were correctly programmed, and improved nursing satisfaction and confidence in their ability to aggressively manage patients' pain. In sharing our experience, results, and lessons learned, we hope this information will be helpful to other health care professionals in their appreciation for the value of implementing PCA monitoring safety systems as they work to improve pain management, medication safety, and quality of care for all patients.

Implementation Methodology

St. Joseph's/Candler Health System

St. Joseph's Hospital and Candler Hospital, the two main facilities of SJCHS, are two of the oldest continuously operating hospitals in the United States. Patient volume is 291,504 discharges annually. Staff includes 517 community-based, private practice physicians, 987 nurses, and 38 pharmacists. SJCHS is an American Society of Health-System Pharmacists-accredited residency site and trains four clinical pharmacy practice residents per year.

In 2002, following an extensive review and systematic evaluation of its nursing practice by the American Nurses Credentialing Center, SJCHS received the designation of "magnet hospital." Interaction among staff and administration is characterized by a high degree of collaboration. Our multidisciplinary Medication Error Team includes pharmacists, respiratory therapists, risk managers, physicians, and others. Experience has taught us that to improve patient safety, the goal must be to improve processes and focus on the issues, not on the individual.

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[a] The Alaris® System with the Guardrails® Suite of safety software, Cardinal Health, Inc., San Diego, CA, with Nellcor OxiMax™ pulse oximetry technology and Oridion's Microstream® capnography technology.

IV Safety Systems

In 2000, an ISMP article detailing the hazards associated with PCA[17] prompted our Medication Error Team to focus first on infusion-related errors. In 2001, completion of an ISMP Medication Safety Self-Assessment[18] led to an intense focus on the administration of intravenous (IV) medications. After evaluating various medication safety technologies, the team determined that implementation of a modular, computerized IV infusion safety system with dose error reduction software would provide the greatest "speed to impact" in terms of cost, resources, time, and reduction of harm.[19] In 2002, IV safety systems for large volume infusions were implemented hospitalwide.

Prior to installation of the new systems, safety software embedded in the point-of-care units (the system's "brains") was used to create hospital-specific drug libraries with standardized concentrations, maximum and minimum dosing limits, and other infusion parameters for various patient care areas. If nurse programming of the infusion device exceeds the pre-established limits, the system generates an alert that must be addressed before infusion can begin. Software logs record all device programming, alerts, and whether the infusion was reprogrammed or cancelled in response to the alert (i.e., "near misses"). Continuous quality improvement data documented that the IV safety systems helped avert significant IV medication errors with the potential for severe patient harm.[19] Wireless technology was deployed to support ongoing data collection for quality assessment and to facilitate software upgrades.

PCA Practice and Patient Monitoring

Recognizing opioids' potential for harm, the Medication Error Team sought additional technology that would not only help protect against PCA programming errors but also help protect the patient once infusion had begun. Respiratory therapy became an important member of the multidisciplinary team.

"Smart" PCA pump, pulse oximetry, and noninvasive capnography modules were added to the system in 2004. A single safety technology platform with a common user interface for all modules increased ease of use and reduced the time required for staff training. If either pre-established drug or respiratory limits are exceeded (pulse rate <50 beats/min or >120 beats/min; SpO_2 <90 percent; RR <10 breaths per minute; $EtCO_2$ >60 mmHg; apnea >30 seconds), the system generates alerts. If any of the pre-established parameters noted above are exceeded, a PCA "pause" protocol can automatically halt drug infusion.

The system is designed to supplement, not substitute for, clinician monitoring. Figure 1 illustrates the multipurpose cannula used to collect exhaled CO_2 and to administer O_2 to patients who may require supplemental oxygen. As shown in Figure 2, by providing up to 24 hours of PCA dosing history with corresponding time-based values from pulse oximetry and/or capnography, the system helps clinicians monitor patient response to self-administered opioids. Trend data allow clinicians to better assess a patient's physiologic response and help provide an early warning of potential RD.

An initial beta test period was begun in June 2004. After 6 months of testing, continuous respiratory monitoring of each PCA patient became the standard of care. Pharmacy and nursing originally planned to purchase a pulse oximetry module for each PCA module and a lesser number of capnography modules for use with high-risk patients. However, beta testing revealed the difficulty of predicting patient response to opioids and showed that capnography, not pulse oximetry, provided the first indication of opioid-related RD. As a result, the original decision was reversed; implementation included a capnography module for each PCA module and a smaller number of pulse oximetry modules for use with selected patients receiving PCA analgesics.

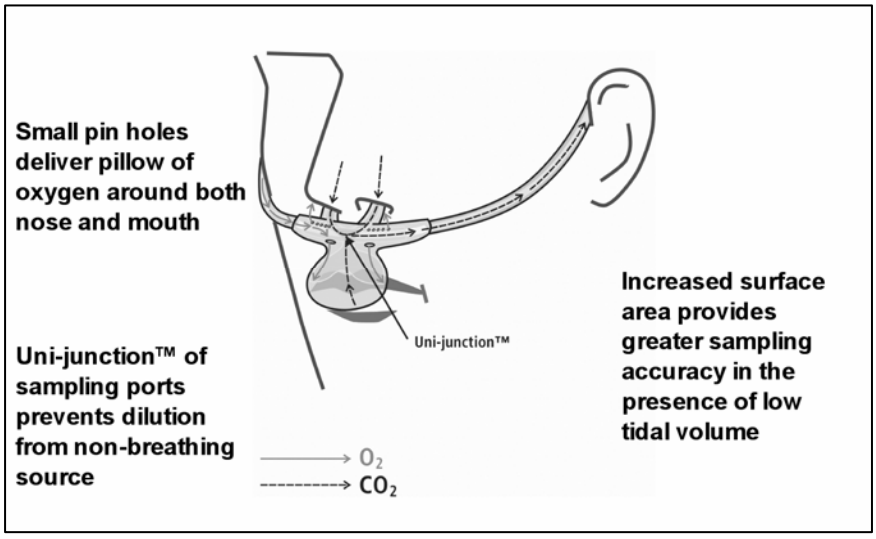

Figure 1. CO_2 sampling/O_2 delivery for nonintubated patients; modified cannula. Source: Oridion Capnography, Inc., Needham, MA. Used with permission.

Patient Selection

As shown in Figure 3, all SJCHS patients who receive PCA therapy have continuous capnographic monitoring and intermittent pulse oximetry monitoring. Continuous capnographic monitoring is used for all patients, while continuous pulse oximetry is used for selected individuals. Patients at high risk for deep vein thrombosis are also at risk for pulmonary embolism. In these cases, continuous pulse oximetry provides a more sensitive assessment of inherent pulmonary pathology, while capnography helps protect against opioid-related RD. Patients with chronic obstructive pulmonary disease who are CO_2 retainers have naturally high levels of $EtCO_2$ levels and also require continuous pulse oximetry monitoring. The SJCHS oxygenation protocol requires that oxygen saturation be maintained at greater than 92 percent; any patient whose SpO_2 is ≤ 92 percent upon admission is monitored with both pulse oximetry and capnography. If a patient shows signs or symptoms of congestive heart failure, SpO_2 monitoring is required and a nurse is to contact respiratory therapy for assistance. In addition, nursing or respiratory therapy may initiate continuous pulse oximetry monitoring as needed, anytime they deem it necessary.

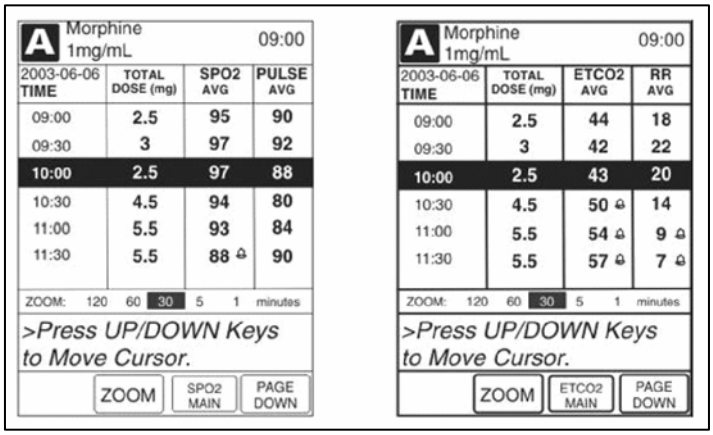

Figure 2. PCA, SpO^2 and $EtCO_2$ trending data: Representative examples. Source: Cardinal Health, Dublin OH. Used with permission.

Training

Nurses and respiratory therapists worked together to provide staff training on enhanced pain management, pulse oximetry, and capnography monitoring. Topics included use of technology and appropriate clinical interventions based on patients' physiologic responses to PCA. In particular, training on capnography included patient assessment, evaluation of $EtCO_2$ wave forms and trend data, recognition of patient-specific normal/abnormal values, appropriate interventions, and collaboration with physicians.

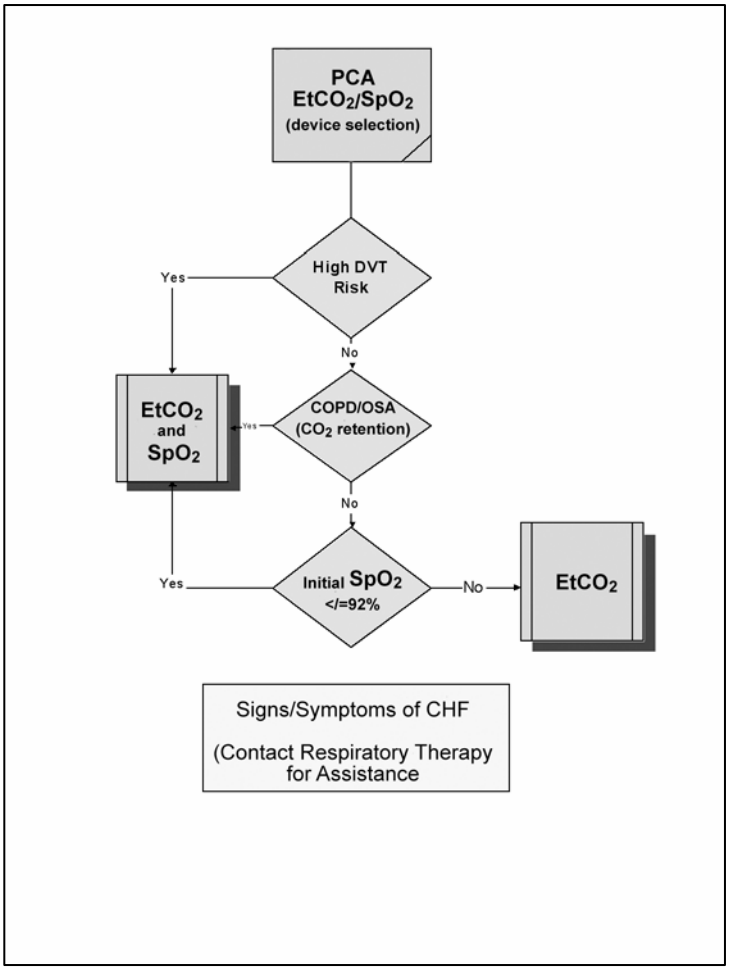

Figure 3. Patient selection algorithm for SpO_2 and $EtCO_2$ monitoring. (DVT = deep vein thrombosis; COPD = chronic obstructive pulmonary disease; OSA = obstructive sleep apnea; CHF = congestive heart failure)

Clinical Practice

During continuous respiratory monitoring, a nurse responds to infrequent $EtCO_2$ or low RR alarms by stimulating the patient to take some deep breaths. In response to frequent alarms, the nurse arouses and stimulates the patient, verifies that the capnography module is functioning correctly, and if so, contacts respiratory therapy. The respiratory therapist and nurse work together to determine the best course of action—e.g., ordering arterial blood gases to verify the patient's respiratory status or supporting the patient with supplemental oxygen or noninvasive ventilation (C-PAP or Bi-PAP). If they are unable to readily correct the situation and the patient further deteriorates towards respiratory failure, they consult the physician regarding additional treatment and possible transfer to an intensive care unit. In addition, revised hospital PCA policy requires respiratory therapy to round on every PCA patient at least once every 12 hours.

Results

PCA Infusion Programming: Averted Errors

During the initial 4 months, IV safety systems with PCA modules were used on one unit in each of the two SJCHS hospitals. During this time more than 750 PCA syringes were initiated on the systems for a total of 225 PCA patients. Data collection documented 52 instances when a nurse

received an alert that programming exceeded drug library limits and either reprogrammed or cancelled the infusion—i.e., 52 averted errors.[2] Representative examples are shown in Table 1.

Table 1. Examples of averted programming errors[a]

Location	Drug	Variable	Initial	Reprogrammed
Medical-surgical	Hydromorphone	PCA dose	3 mg	Decreased to 1 mg
Medical-surgical	Hydromorphone	Maximum limit	25 mg	Decreased to 10 mg
Medical-surgical	Hydromorphone	Continuous dose	30 mg	Decreased to 1 mg
Medical-surgical	Morphine	Loading dose	10 mg	Decreased to 4 mg
Critical care	Fentanyl	Continuous dose	300 µg	Decreased to 150 µg
Medical-surgical	Hydromorphone	Maximum limit	200 mg	Decreased to 10 mg
Medical-surgical	Fentanyl	PCA dose	1 µg	Increased to 50 µg
Critical care	Morphine	Lockout (time)	30 min	Increased to 15 min
Critical care	Meperidine	Continuous dose	20 mg	Decreased to 10 mg

[a] Alerts are not posted until the start key is pressed and programming is completed. All limits are initially set up as "soft" (can be administered as override).

Source: Maddox RR, Williams CK, Oglesby H, et al. Clinical experience with patient-controlled analgesia using continuous respiratory monitoring and a smart infusion system. Am J Health Syst Pharm 2006; 63:157-64. Used with permission.

Patient Respiratory Monitoring: Averted Outcomes

During the first months of use, continuous respiratory monitoring helped clinicians identify numerous cases requiring intervention by the respiratory therapist. These included cases in which PCA programming was correct, and opioid dosing was within established limits.

In the 33 months from July 2004 through March 2007, 16 patients with declining physiologic status were identified by continuous respiratory monitoring; unwarranted outcomes and possible transfer to the intensive care unit were avoided. This value is the number of instances for which there are documented case reports. There were other instances in which RR alarms were triggered, interventions made, and unwarranted outcomes averted. However, no case reports were submitted.

The following representative examples illustrate the effectiveness of continuous respiratory monitoring to assess patient response to PCA opioids and, in particular, the effectiveness of noninvasive, continuous capnography in detecting impending RD in nonintubated patients in noncritical care settings.[2]

Postanesthesia Respiratory Decline

An obese, 71-year-old male with multiple comorbidities, including obstructive sleep apnea, had bilateral total knee arthroplasties. A PCA pump was set up in the postanesthesia care unit and

programmed for patient "demand-only" dosing. A capnography module also was attached. The PCA demand button had not been pressed, and no PCA doses had been administered since pump setup.

Shortly after the patient was transferred to the medical/surgical unit, "$EtCO_2$ High," "Low Respiratory Rate," and periodic "No Breath" alarms were activated, which prompted a STAT call from the nurse to respiratory therapy. Upon entering the room, the respiratory therapist noted that the patient had RD and marked lethargy that required aggressive verbal stimulation for arousal. The patient's $EtCO_2$ levels were in the mid-60s mmHg (nl 35 - 45), and RR was 4 to 6 breaths per minute (nl 10 - 14). His SpO_2 level on 2.5 liters per minute (Lpm) of oxygen was 90 to 91 percent (nl >92 percent). The patient was assessed, stimulated, and positioned to optimize patency of his upper airway. A physician was called on consult and an arterial blood gas performed with the patient on oxygen at 2.5 Lpm. The results were pH 7.19 (nl 7.35 - 7.45); PCO_2 61.2 mmHg (nl 35-45); PaO_2 78 mmHg (nl 75 - 100); HCO_3 23.5 mEq/liter (nl 22 - 26); and SaO_2 91.3 percent (nl >92 percent). The patient was placed on noninvasive ventilation (Bi-PAP) via full face mask.

It was discovered that the patient had received additional narcotic analgesia in the postanesthesia recovery unit (not through PCA). The patient was given naloxone, immediately awakened, and his $EtCO_2$ level decreased from the 60s to the mid-40s. RR increased from 4 to 6 bpm to 8 to 10 bpm. The SaO_2 increased from the low 90s to the upper 90s. The patient was awake, alert, and responding appropriately. Followup blood gases were pH 7.26; PCO_2 48.5; PO_2 93; HCO_3 22.1; and SaO_2 95.8.

As a result of clinical interventions prompted by continuous respiratory monitoring data, a possible adverse outcome was avoided. This case suggests that the postoperative period can be one of the most critical times when respiratory monitoring is required, with or without PCA.

Obstructive Sleep Apnea Without Obesity

PCA therapy was initiated postoperatively for a normal-weight, 44-year-old female with no known risk factors for PCA therapy.[2] Initial dosing was continuous PCA infusion of 1 mg/hr morphine and 1 mg every 6 minutes PCA doses, with a 4-hour maximum limit of 35 mg. When the patient arrived in the nursing unit, her oxygen saturations were in the high 80s. After applying 2 liters of supplemental oxygen via nasal cannula, a nurse decreased the basal PCA infusion from 1 mg to 0.5 mg. The patient's O_2 saturation increased to the high 90s.

Several hours after beginning PCA the patient was put on continuous capnography. Initial $EtCO_2$ readings ranged from the high 50s to low 60s. Respiratory rate was 6 to 12 bpm, with periods of apnea when the patient fell asleep. While the patient was sleeping, the $EtCO_2$ module indicated frequent low respiratory rate alarms. A nurse determined that respiratory rate by manual count was 4 effective breaths/min. The nurse discontinued PCA therapy, began oral oxycodone hydrochloride 5 mg/acetaminophen 325 mg (Percocet®) therapy, and continued the monitoring. The patient's respiratory status improved, as indicated by oxygen saturations in the low to mid-90s, $EtCO_2$ in the mid-40s, and a respiratory rate of 12 to 14 breaths per minute. This case illustrates that a patient can be at risk for respiratory depression even with no known risk factors and when opioid administration is within established dosing limits. For this patient with no

known risk factors for PCA therapy, continuous respiratory monitoring helped clinicians identify opioid-associated respiratory depression and prevent a potential adverse drug event.

Bilateral Pneumonia

Following orthopedic surgery, PCA therapy was initiated for a 56-year-old, 75-kg, Caucasian, female patient with a history of lung cancer and a lower lobe partial lobectomy.[2] Patient monitoring included continuous pulse oximetry and capnography. Trend data from the monitoring modules documented that her SpO_2 levels decreased from the mid-90s to the low 80s. $EtCO_2$ decreased from 36 to 32 mmHg; respiratory rate increased from 20 to 24 bpm. After respiratory therapy staff increased the patient's supplemental oxygen from 2 to 10 liters, the patient's SpO_2 increased to the low 90s. Two hours later the SpO_2 module generated alarms for SpO_2 levels in the 70s, RR in the 30s, and an $EtCO_2$ of 31 mmHg. The patient was quickly transferred to intensive care. Pulmonary embolus was ruled out with appropriate radiographic and laboratory tests. Chest x-ray revealed bilateral pneumonia. In this case, continuous respiratory monitoring, particularly pulse oximetry, alerted clinicians to the acute development of serious bilateral pneumonia.

Study Results: Greater Incidence of RD

As reported elsewhere,[9] the pulse oximetry and continuous capnography monitoring modules were used in an observational study of 178 patients receiving PCA therapy at SJCHS. Findings showed an incidence of RD based on desaturation consistent with previous estimates. However, we found the incidence of RD based on bradypnea was many orders of magnitude greater than the 1 to 2 percent widely reported in the literature.[9] Defined by traditional "threshold criteria" (at least one 2 minute or longer low-RR event), the incidence of RD was 58 percent. Defined conservatively (at least one ≥3-minute low-RR event, RR <10 bpm), the incidence of RD was 41 percent.[9]

Nursing Satisfaction

Nursing staff indicate that the availability of dose error protection and continuous respiratory monitoring trend data allows nurses to feel more comfortable in administering PCA therapy and in giving additional medication so they can manage patients' pain aggressively. Knowing that patients will be more comfortable, nurses are more satisfied. Nurses are also alerted early to potentially life threatening events, such as RD during recovery, so they can intervene faster. A common user interface for PCA and monitoring modules increase ease of use and reduce possibilities for error.[2]

Discussion

More than 3 years' clinical experience with an IV safety system that combines PCA pump, pulse oximetry, and continuous, noninvasive capnography modules on a single platform has taught us the importance of the following issues regarding the management of postoperative pain.

Multidisciplinary Team Approach

A highly collaborative approach is essential to effective pain management and to the selection, implementation, and use of this technology. Physicians, nurses, pharmacists, and respiratory therapists must work together as a team to maximize its benefits. Respiratory therapists play a vital role in nursing education, patient assessment, and the development of a patient selection protocol and algorithm. During continuous respiratory monitoring, respiratory therapists may need to help interpret the data. Noncritical care nurses and physicians initially may be unfamiliar with the information provided by these devices and have problems applying the data to patient care. Unfamiliarity may make nurses reluctant to call a physician when the system alarms. In these situations respiratory therapists provide valuable assistance.

Monitoring

Practice monitoring. Misprogramming IV infusion pumps can result in serious, potentially life threatening adverse events.[20] Opioid analgesics are associated with a high risk of harm. Implementation of "smart" IV safety systems with dosing parameters for each narcotic is essential to help avert errors in PCA infusion programming.

Patient monitoring. Due to the variability of patient response to opioid analgesics, even when correctly programmed, therapeutic doses can result in an adverse drug event.[2] While some patient populations are at higher risk of an opioid-related event, clinical experience has shown that it is not possible to prospectively identify all patients who may be at increased risk.[8] This fact underscores the need for continuous respiratory monitoring that provides trend data to the nurse at the bedside on a patient's physiologic response to PCA and helps prevent oversedation and undesirable outcomes. Use of this technology may also allow clinicians to identify undiagnosed clinical conditions that predispose patients to respiratory complications from IV opioids.

Capnography

SpO_2, $EtCO_2$, and RR are all important clinical parameters that should be used in conjunction with each other. SpO_2 reflects oxygenation, while $EtCO_2$ and RR reflect ventilation; one may be normal while the others demonstrate an abnormal respiratory status. Capnography provides the earliest indication of opioid-induced RD. It is important to monitor changes from a baseline $EtCO_2$ level. As the $EtCO_2$ level starts to increase, early intervention and changes in medication can be made. Capnography monitoring should be used for all patients receiving PCA, not only for those at heightened risk of toxicity.

Need for Greater Care

Clinical experience and study findings suggest that greater care might be needed with PCA therapy. The incidence of secondary RD may be greater than previously thought.[9] Patients can progress to RD even when correctly programmed doses are within the dose range of the safety software data set.[2] In particular, the belief that most preventable episodes of RD are caused by programming errors[21] might not be correct.

Improved Pain Management and Efficiency

Pain management. Continuous pulse oximetry and capnography monitoring during PCA therapy allows improved opioid delivery. By monitoring both pulse oximetry and capnography, medication doses can be adjusted more safely to prevent over- and undermedication and to keep patients comfortable. Patients whose pain is unrelieved from initial PCA therapy are at high risk for oversedation and respiratory depression from increased doses. The use of continuous pulse oximetry and capnography reduces this risk.

Efficiency. In addition to providing early identification of impending RD in patients receiving PCA therapy, this technology also allows respiratory therapists to care for patients more efficiently, so that existing staff can oversee more patients. Earlier identification of respiratory distress allows respiratory therapists to intervene before a patient's condition becomes serious, which saves time and helps increase the likelihood of a positive outcome.

Reduced Likelihood of Critical Events

As a result of training and working with respiratory therapists, nurses can increase their ability to interpret trend data from capnography and pulse oximetry. The availability of these data enhance clinician assessments and their ability to intervene earlier, thereby reducing the likelihood of critical events.

Additional Applications

SJCHS clinicians have used the respiratory monitoring modules with non-PCA patients, such as those receiving epidural infusions, moderate sedation, or procedural sedation. Respiratory therapists have used the capnography modules to monitor patients in respiratory failure on hypoxic drive, for whom increasing oxygen administration by only 0.25 Lpm can have adverse effects. Compared with current monitoring by blood gas analysis, the use of capnography can allow clinicians to titrate supplemental oxygen administration much more efficiently. Capnography can also help early detection of severely asthmatic patients who are beginning to "fatigue out" and go into RD, so that aggressive treatment might prevent ventilation and intubation.

Conclusion

Data indicate that the use of "smart" PCA infusion devices with dose error-reduction systems helps avert significant patient harm from inadvertent misprogramming of PCA therapy by nurses. In addition, capnography and pulse oximetry are valuable tools that help clinicians with early identification of PCA-related RD and other complications to prevent serious adverse events and the need for costly interventions. The availability of combined dosing and respiratory trend data greatly enhances clinical assessments of patients receiving PCA therapy. Nurses are more satisfied using these technologies, patients' pain is better controlled, safety is improved, and costly adverse events are avoided.

Capnographic monitoring to measure ventilation (RR and $EtCO_2$) is particularly important because it can provide an earlier warning of respiratory depression compared to pulse oximetry (SpO_2) in some patient populations. Thus, the combination of IV safety system components allows monitoring of both practice (PCA programming) and patients (individual respiratory response to opioids). Implementation of "smart" PCA pumps combined with continuous respiratory monitoring is in keeping with professional practice recommendations and can help hospitals comply with Joint Commission standards for effective pain management, while improving medication safety and quality of care.

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

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Abstract

Little is known about the effectiveness or optimal design of medication therapy management (MTM) programs as mechanisms for improving patient safety, motivating this multicenter trial sponsored by the Agency for Healthcare Research and Quality. Six hundred subjects at high risk of adverse drug events (ADEs) will be enrolled across three study sites. The study is designed as a randomized controlled trial with three arms. The control group (Arm 1) will receive usual care and have no MTM visits. Intervention groups (Arms 2 and 3) will undergo two MTM visits with a pharmacist over 6 months. The main safety outcomes are the number of ADEs, hospital admissions, and emergency room visits at 90 and 180 days, which will be compared among all three study arms. Additional safety outcomes include measures of MTM process and delivery. This paper details the methods of this study evaluating the impact of community-based MTM on enhancing patient safety.

Introduction

Pharmacotherapy is central to the medical care of individuals over age 65, a population that consumes more than 30 percent of all prescriptions.[1] Of these patients, approximately 50 percent take five or more medications regularly, and 12 percent take at least 10 medications regularly.[2] The pervasiveness of therapeutic drug use in community-dwelling elderly has major implications for patient safety. A cohort study of Medicare enrollees in the ambulatory clinic setting demonstrated an adverse drug event (ADE) rate of 50.1 per 1,000 person-years, with 38 percent of the events categorized as severe, life threatening, or fatal.[3] Furthermore, each ADE in ambulatory patients older than 65 is estimated to cost an average of $1,300 in additional health care expenditures.[4] Key factors predisposing elderly patients to ADEs include age-related changes in physiology and drug metabolism; polypharmacy (use of five to seven medications regularly doubles the risk for an ADE; use of eight or more medications regularly triples this risk); number of comorbidities; and visits to multiple physicians.[5, 6, 7]

Addressing risk factors for ADEs in an outpatient population is challenging. Ambulatory care is largely decentralized in multiple independent practices, and as such, pharmacotherapy quality and safety initiatives implemented in hospitals or long-term care facilities often do not translate well to community health care settings. One approach to managing pharmacotherapy in the ambulatory elderly has focused on inappropriate prescribing based on the Beers list, which indicates medications thought to pose an undesirably high risk of adverse effects in geriatric populations.[8]

In isolation, identifying specific drugs to avoid is not sufficient for improving safety.[9] Failure to prescribe potentially useful medications in the elderly may be equally or even more harmful. For example, a recent study indicated that patients with diabetes who were older and had more comorbidities were less likely to receive intensification of pharmacologic therapy than were younger patients, despite similarly poor glycemic control.[10] Likewise, beta-blockers and lipid-lowering drugs are apparently underused in elderly patients with cardiovascular disease.[11, 12] Further areas of concern in pharmacotherapy for community-dwelling elderly include erroneous prescription writing, deficiencies in drug education given to patients, inadequacies of ADE detection systems, and suboptimal monitoring for medication toxicity.[13, 14]

Given these conditions, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003[15] (MMA) included a drug benefit and required that prescription drug plans and Medicare Advantage plans offering prescription drug coverage have a medication therapy management (MTM) program for those beneficiaries who meet certain risk criteria. The law describes MTM as "a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries ... that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions."[16] Pharmacies (both chains and those associated with health care systems), managed care organizations, State Medicaid programs, disease-specific clinics, and third-party insurers have all successfully employed various forms of MTM.[17, 18, 19, 20]

The core components of MTM entail patient education, improved adherence to medication, determining patterns of prescription drug use, and detection of ADEs. MTM programs are typically provided by pharmacists, although this is not mandated by the MMA. The value of this approach in the ambulatory setting has been demonstrated in several studies. One randomized controlled trial found that comprehensive chart review by a consultant pharmacist with subsequent modification of a patient's medication regimen led to 1.5 fewer medications.[21] Pharmacist-physician collaboration facilitated resolution of drug-related problems (DRPs) in a Medicaid population receiving four or more medications.[22] Utilization of an electronic prescription database and an alert system for high-risk medications, followed by pharmacist outreach, prompted physicians to adjust drug therapies to more appropriate agents.[23]

We do not have information on whether critical outcomes of patient safety, morbidity, and mortality can be influenced by MTM program participation.[24] Also, issues of MTM program design—such as visit frequency, mechanisms of patient-to-pharmacist and pharmacist-to-physician communication, and optimizing ADE prevention—require further elucidation. To begin to address these questions, it is essential to undertake a prospective multicenter study with well defined patient safety outcomes. This paper details the methods of an Agency for

Healthcare Research and Quality (AHRQ)-funded study responsive to that need. The study is being conducted as part of AHRQ's Effective Health Care program, which was established through Section 1013 of the MMA and authorized AHRQ to conduct research on the outcomes of health care items and services relevant to Medicare, Medicaid, and the State Children's Health Insurance Program.[15]

Methods

Study Overview and Specific Aims

The trial is designed as a randomized controlled study of an MTM program structured to prioritize patient safety that is being conducted at three sites. The main components of the patient safety-oriented MTM model used in this study are medication reconciliation (MR), assessment of DRPs, and resolution of identified DRPs. Two different methods of achieving these MTM components will be assessed and compared to a usual care group receiving no formal MTM in a population of elderly, community-dwelling Medicare beneficiaries at risk for DRPs. Main objectives for this study are to:

- Evaluate the effects of a DRP list generated by MTM clinicians on patient safety (measured by number of ADEs, hospitalizations, and emergency room [ER] visits).
- Determine if an MTM program with clinician access to patient-specific information improves measures of patient safety (such as fewer discrepancies in medication lists) and health care quality.
- Determine whether a structured MTM program focused on patient safety increases patient satisfaction.

Study Sites, Population, and Enrollment Criteria

Three health care systems with affiliated ambulatory clinics representing geographic and demographic diversity will participate in the trial. The University of Illinois at Chicago (UIC) is the study's coordinating center. The majority of patients seen at UIC clinics are African American (65 percent) and Hispanic (24 percent); 10 percent are Caucasian. Baylor Health Care System (BHCS) in Dallas, TX, is enrolling patients through its senior health center. A recent sample of senior health center demographics indicated a population that was 50 percent Caucasian, 35 percent African American, 14 percent Hispanic, and 1 percent Asian. Duke University Medical Center (DUMC) in Durham, NC, is enrolling patients through its primary care network, a practice population that is 54 percent Caucasian, 31 percent African American, 2 percent Hispanic, and 13 percent of other race. Each site cares for large numbers of patients over the age of 65 (BHCS ~2,500; DUMC~8,700; UIC~6,000). From this population, more than 600 patients at each site have met preliminary screening criteria for the trial and constitute the pool for active recruitment, expediting patient accrual and study completion over a 1-year period.

Study entry criteria were determined based on elements from a literature review (indicating patient risk factors for ADEs in the ambulatory population), discussions with MTM stakeholders (Centers for Medicare & Medicaid Services, private insurers, pharmacy groups), and AHRQ's priority on targeting this trial to vulnerable elderly patients most susceptible to ADEs who

potentially would yield the highest safety benefits from MTM. Inclusion and exclusion criteria are displayed in Table 1.

Study Protocol

The study protocol was developed by investigators at each of the three sites and at AHRQ. The final protocol was approved by the institutional review boards at participating health care systems. To screen candidates for eligibility out of these large ambulatory populations, a search of each site's clinic administrative data was performed to identify patients above the age of 65 who have three or more comorbidities, two or more clinic visits, and a documented telephone number. Patients satisfying this initial screen received a letter and then a phone call inviting their participation and confirming eligibility.

Table 1. Inclusion and exclusion criteria for multicenter Medication Therapy Management (MTM) trial

Inclusion criteria
• ≥65 years of age at enrollment
• Primary use of English for oral and written communication
• ≥3 comorbid conditions associated with increased health care utilization (e.g., CHF, DM, COPD, HTN)
• ≥2 visits to a physician (or advanced practice provider) at study site clinic over the past year
• ≥8 chronic prescription medications over the 6 months prior to study enrollment
• Have a telephone line available for at least 6 months
• Situation placing patient at risk for a drug related problem (DRP):
→Change in medication, new physician visit, ER visit, hospitalization, invasive procedure within last 30 days
→3 or more providers seen within 12 months
Exclusion criteria
• Terminal condition with life expectancy ≤6 months
• Previous enrollment in MTM program with medication reconciliation or assessment for DRPs within 12 months

Physician and nursing staff at each of the clinic sites can also refer patients to contact the study team directly regarding their eligibility. Patients expressing interest are instructed to come to the clinic for enrollment, randomization, and a baseline study visit. Since transportation can be a barrier for many elderly patients, attempts are made to schedule enrollment, baseline visit, and if applicable, the first MTM visit with the pharmacist at the same appointment. For patients who normally receive assistance with their medications (from a spouse, adult child, or other caregiver), this person is allowed to accompany the patient to study visits. The study flow process, including a description of visit event content and temporal relationships, is summarized in Figure 1.

Arm 1 is a control group made up of patients who receive medication counseling per their clinic's normal routine but no formal MTM from a study pharmacist. Arms 2 and 3 represent the MTM intervention groups. Arm 2 entails basic MTM, with the pharmacist performing MR and assessment for DRPs through the patient interview alone. Arm 3 involves enhanced MTM, with MR and assessment for DRPs through the patient interview and an additional two-page clinical synopsis. This synopsis is extracted from the patient's clinic chart by nonpharmacist study team personnel. It contains data on medical history, laboratory values, and medications and can be

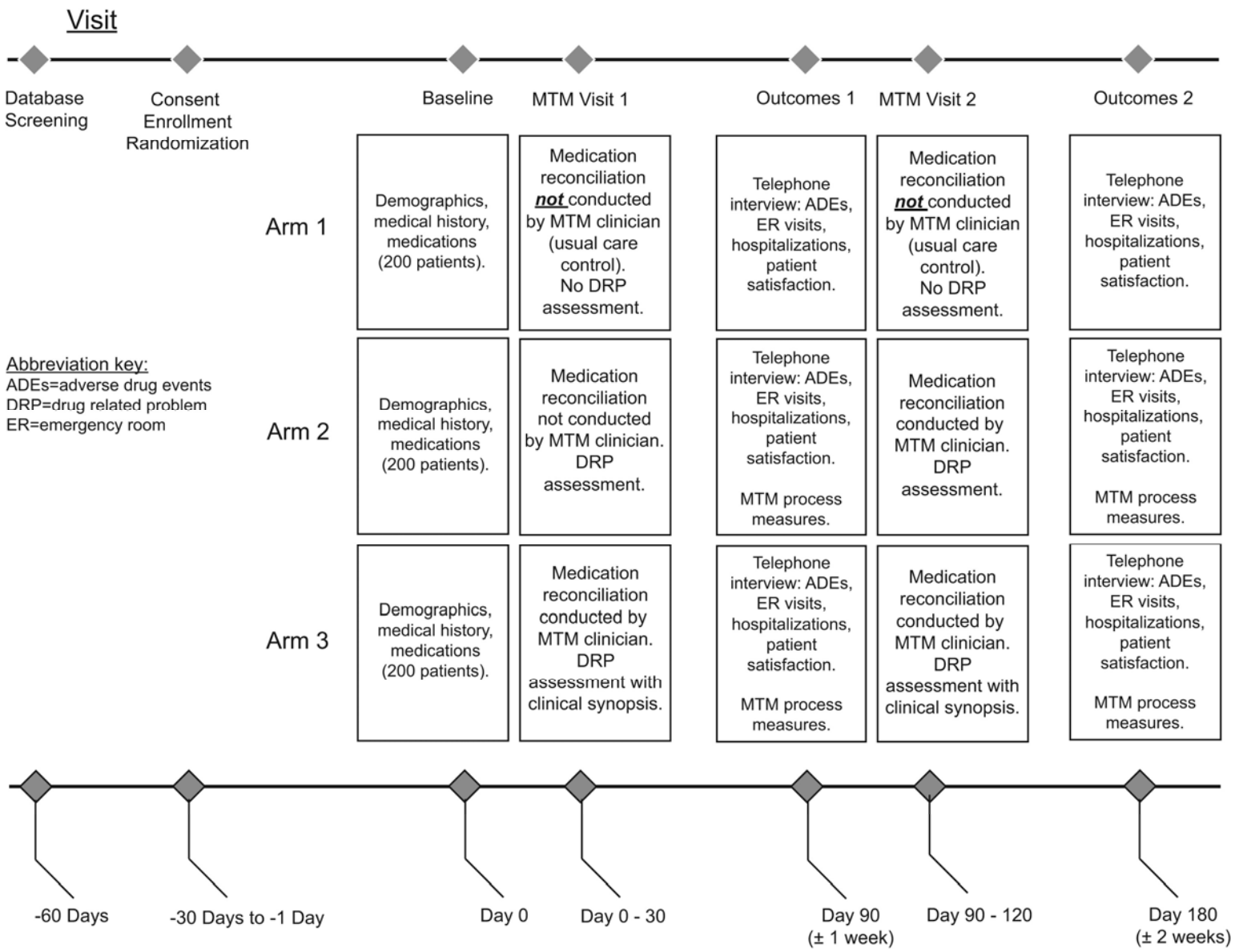

Figure 1. Medication Therapy Management (MTM) trial study flow.

completed in less than 15 minutes. Specifics of patient-pharmacist interaction and the tools used to facilitate information exchange during the MTM visits are detailed in Table 2.

Implementation of the MTM intervention was standardized through a 90-minute training session given to participating study pharmacists immediately prior to the start of enrollment. Trial design precludes blinding of either patients (they will be aware of whether or not they received the MTM intervention) or the MTM pharmacist. Study personnel conducting telephone interviews to assess outcomes at 90 and 180 days will be blinded as to patient treatment groups.

A total of 600 patients (200 per site) will be enrolled across the three sites over a 12-month study period in a 1:1:1 ratio (Arm 1: Arm 2: Arm 3) via a permuted block randomization scheme. Accrual is tracked via a computer-based enrollment log. Patients receive $10 for completion of each study phase (baseline visit, outcomes via telephone questionnaire 1, outcomes via telephone questionnaire 2), such that each participant is eligible to receive up to $30 total, regardless of study arm assignment. Reimbursement is not tied to receipt of the MTM pharmacist intervention in any way.

Outcomes, Sample Sizes, and Analysis Plan

Study outcomes, associated measurement tools, and anticipated statistical tests are displayed in Table 3. All patient data will be analyzed using an intent-to-treat plan according to original group assignment. The primary outcome of ADEs reflects the study focus on patient safety. Published reports on outpatient ADE frequency and a study using a validated ADE collection tool suggest an incidence of one to nine ADEs per patient.[3, 25] With a power of 0.80, 200 patients in each study arm (600 patients total), and statistical significance at the 0.05 level, an effect size of 10 to 25 percent relative risk reduction in ADEs from the MTM intervention compared to the usual care group should be measurable.

Even with the most conservative estimate (10 percent) in relative risk reduction of ADEs stemming from MTM, overall study accrual of 600 patients will allow detection of a statistically significant difference between groups. Furthermore, if indicated by dropout trends in a frail, elderly population, each site may enroll a few extra patients above the 200 required to achieve an adequate sample size completing the full study. Baseline rate of hospitalization or ER use within 30 days prior to study initiation will be captured during the enrollment visit. ADE occurrence and secondary safety outcomes of incident ER visitation or hospital admission over the trial period will be determined by patient self-reporting during structured telephone interviews performed (at approximately 90 and 180 days after enrollment) by study personnel independent of the MTM pharmacist (Figure 1). These safety outcomes will be compared among all three study arms.

Additional outcomes of processes of care related to different methods of MTM delivery (with or without the clinical synopsis) will be assessed between Arms 2 and 3 only (Table 3). For the medication list accuracy outcome, non-MTM pharmacist study personnel will create a “Best Possible Medication History” (BPMH) constructed from the patient’s self-reported medication list obtained at the baseline visit and complete review of available medical records, including prescription claims if applicable. Due to the intensive time resources required to create this BPMH, the medication list accuracy outcome will only be performed on a subset of MTM intervention patients in the study, 43 each in Basic (Arm 2) and Enhanced (Arm 3) MTM groups.

Table 2. Components of medication therapy management (MTM) visits with study pharmacist

Medication therapy management activity[a]	Tool(s)
Medication reconciliation	Patient interview script; medication record (generated by pharmacist)
Assessment for drug-related problems	Pharmaceutical care network Europe drug assessment form[b]
Communication of drug-related problems to practitioners	Physician communication fax form
Medication education/review	Medication record given to patient at end of visit

a For patients in the enhanced medication therapy management group, study pharmacist will also have access to a 2-page clinical synopsis to complete these activities.

b Modification of Pharmaceutical Care Network Europe drug-related problem classification form.[26]

Table 3. Medication Therapy Management (MTM) study outcomes, measurement tools, and analysis plan

Outcome	Measurement tool(s)	Analysis plan
Safety		
Adverse drug events	Adverse drug event self-reporting script Naranjo algorithm[a]	GLMM[d]
Hospital admissions	Patient self-reporting log	GLMM
Emergency room visits	Patient self-reporting log	GLMM
Medication therapy management process		
Number of drug-related problems	Pharmaceutical Care Network Europe drug assessment form	GLMM
Medication reconciliation accuracy	"Best Possible Medication History"[b]	Mann-Whitney U
Physician acceptance of pharmacist recommendations	Physician-pharmacist communication sheet	Chi-square
Pharmacist time	Pharmacist time log	Mann-Whitney U
Number of medication therapy management interventions	Physician communication sheet	Mann-Whitney U
Satisfaction		
Patient satisfaction with pharmacotherapy	Pharmaceutical care questionnaire satisfaction survey[c]	GLMM
Patient satisfaction with overall care	Satisfaction survey	Mann-Whitney U

a Naranjo et al., 1981[27]

b www.saferhealthcarenow.ca[28]

c Gourley et al., 1998[29]

d Generalized Linear Mixed Model

Based on the limited literature describing outpatient MR, it is estimated that there will be approximately 1.5 discrepancies between the BPMH and MTM pharmacist medication list in the basic MTM group and at least 1.0 discrepancy between the BPMH and MTM pharmacist list in the enhanced MTM group.[30] The subset sample size of 86 patients will allow for detection of a difference between the two groups with a power of 0.80 at a statistical significance level of 0.05. Lastly, in all three study arms, patient satisfaction regarding both their pharmaceutical regimen and overall medical care will be evaluated with short surveys that have been validated in the outpatient setting. These assessments will allow measurement of any incremental benefit in patient satisfaction from a safety-oriented MTM program compared to medication management provided solely by clinic staff in the usual care group.

Discussion

The influence of MTM programs on patient safety in the ambulatory elderly population remains unclear, and few models have been tested in controlled settings. Likewise, elements of the MTM process that are most effective at improving communication regarding patients' medication regimens and quality of care are indeterminate. In addition to answering important research questions, this study is designed specifically to:

- Target that portion of the elderly population at highest risk for ADEs.
- Create an MTM intervention involving pharmacists, physicians, and other health care professionals that can be standardized and replicated in broader settings.
- Construct an MTM intervention that promotes patient safety.
- Provide useful clinical quality outcomes information on MTM from a multicenter clinical trial in an accelerated, 12-month period.

Within the population over age 65, there are varying levels of disease burden, frailty, and medication use.[2, 31] It is unlikely that an MTM program applied universally to all elderly ambulatory patients would be useful or cost efficient. The entry criteria for this study (Table 1) were chosen explicitly to identify patients who were frequent health care utilizers and had an elevated risk for ADEs, hospital admission, or ER visitation. In turn, the effectiveness of an MTM should be especially apparent in this group. The frequency of ADEs using this population, with multisite sampling built into the study design, will be assessed and compared to other published reports on ADEs in ambulatory settings.[3] Whether additional factors are increasing the value of MTM to individual patients, such as low health literacy, is a subject for further research beyond this investigation.

The study team emphasized consistency and reproducibility of the MTM intervention delivered to patients, particularly since heterogeneity in current MTM practice has hindered evaluations of its efficacy. The MMA provides general principles regarding the development and administration of MTM programs, but it leaves numerous unanswered details. Geriatric and pharmacy advocacy groups offer few specifics on program implementation in their MTM consensus statement.[16] As a result, stakeholder groups involved during the early phases of trial design stressed the importance of creating an MTM intervention that would have defined parameters and could be applied broadly. Efforts were thus made to avoid practices that would require unrealistic use of time and resources from the perspectives of patients (i.e., twice monthly visits over a 6-month period are

unreasonable) and pharmacists (i.e., it would not be feasible for a community pharmacist to work without a set of visit objectives). The schedule of two MTM visits total over a 6-month period is consistent with existing MTM programs and not overly burdensome to patients or their health care providers.

Each study arm correlates with a "real-world" situation for both patients and providers. Arm 1, as the control group, represents the current state of affairs for most patients, where pharmacotherapy occurs without any formal MTM. In Arm 2, the MTM intervention occurs primarily on information obtained from patient interviews and, thus, mirrors the scenario encountered by most community-based pharmacists. Arm 3 reflects an optimized arrangement where the community-based pharmacist has access to relevant clinical information on the patient from the physician's office, which can be used to supplement the interview and guide the MTM intervention.

The general components of the study's MTM pharmacist-based intervention visits (Table 2) provide a framework for improved patient safety while still allowing each visit to be tailored according to patient needs. The clinical synopsis used in the enhanced MTM arm of the study is an example of an approach combining uniformity and practicality, while maintaining flexibility to serve individual patient needs.

In current practice, external MTM pharmacists often have little information about patients other than a record of prescriptions; access to full charts (outside of academic or Veterans Health Administration facilities) is rare. The premise of the clinical synopsis is that additional patient-specific data (e.g., list of comorbidities, formal record of allergies) will improve recognition of DRPs, facilitate patient-pharmacist communication, and promote informed decisionmaking on medication changes compared to MTM visits performed in the absence of such data. The clinical synopsis template was assembled so that members of a physician's office staff (medical assistants, nurses) could complete the form in less than 15 minutes and fax it to an outside MTM pharmacist. Some commercial pharmacies already have an analogous system in place.

Study outcomes (Table 3) are all linked to patient safety. For ADEs, hospital admissions, and ER visits, the relationship is clear. With the outcomes assessing MTM processes of care, the associations are less direct but trace back to patient safety concerns. For instance, incomplete or inaccurate MR during transitions of care is a major issue and source of adverse events.[32] Much of the previous work on MR has been conducted in inpatient settings; published data on MR in the ambulatory population (and methods to achieve outpatient MR) are sparse. This study has been designed to compare the accuracy of MR vs. a "gold standard" (the BPMH) in a subset of basic and enhanced MTM patients.[28] Although the metric is MR accuracy, improvements in this outcome should ultimately correlate with increased patient safety. Improvements in pharmacist-physician communication and total number of DRPs detected may have similar carry-over to patient safety.

The difficulty of performing large-scale clinical trials is well documented, as is the delay associated with translating effective research findings into daily patient care.[33] As MTM programs are being rolled out nationally, the demand for services has grown, and patient safety has become a heightened priority. Thus, the study investigators sensed the need to design and complete a study capable of answering focused questions within a 1-year period. The multicenter

collaboration between health care systems, pre-enrollment screening, and a protocol with a maximum of two study visits are strengths of the trial design and have fostered accrual towards the goal of 600 patients total. The geographic and demographic diversity of this MTM study population will support wider applicability of study results. Furthermore, to facilitate the uptake of elements in this MTM model found to be effective in improving patient safety, one of the end-products of the trial will be a toolkit, such that clinicians and researchers interested in instituting a similar MTM design in their own health care systems will be able to do so.

Several challenges arose while designing this study. The research team chose outcomes that would translate directly to patients and care providers (other evaluations of MTM have looked at surrogate measures, such as compliance and reductions in number of medications). It was felt that the number of deaths over the study period would be too small to demonstrate any mortality reduction with MTM, so a decision was made to pursue the more frequently occurring ADEs, ER visits, and hospitalizations as the key safety outcomes. Although the protocol was written to optimize capture of these outcomes, the potential for an insufficient number of events to demonstrate a statistically significant difference between the groups was recognized. With this in mind, elucidation of useful components of the MTM process (Table 3) was incorporated into the protocol so that the study would have residual value apart from patient safety.

Another issue centered on the short, 6-month study timeframe. Whereas longitudinal followup over several years would be ideal to demonstrate durable improvements in outcomes, it was not practical for this study in the context of AHRQ's pressing need for information on MTM interventions as drivers of patient safety. Furthermore, periods of health care transition (from hospital to home, major procedures, from one provider to another) have been identified as high prevalence times for ADEs, hospitalization, and ER visits.[34, 35, 36] Study entry criteria seek out those patients who have undergone a recent health care transition and, in turn, are most likely to experience those outcomes, reducing the importance of long-term followup. Finally, an all-encompassing evaluation of MTM in its entirety was beyond the scope of this trial. It is hoped that investigators will use this in-depth description of an MTM program modeled on patient safety as a reference point for exploring other issues in the field.

Conclusion

Medication use is closely related to patient safety in the ambulatory elderly population. The optimal design of MTM programs for improving patient safety remains unclear. The primary aim of this trial is to assess the effectiveness of a specific MTM model in improving patient safety through reductions in ADEs. Additional measures of the MTM process relating to patient safety and providing insight into the construction of MTM programs will also be evaluated. Methods and the rationale for conducting the trial with such a design have been detailed. If indicated based on results, this MTM program has been constructed as a patient safety intervention that can be reproduced and applied broadly in the outpatient setting, and it will motivate further research.

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

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Abstract

Objective: The objective of this study was to determine the feasibility of detecting medication errors by self-observation of office transactions related to medication management. **Methods:** Primary care physicians (N = 14) and office staff (N = 18) reported all their medication management transactions during the 4-hour study period. A study coordinator abstracted additional information from patients' charts. **Results:** Participants documented 440 medication management transactions for 246 encounters: 98 office visits, 70 patient refill requests, 34 pharmacy refill requests, 16 nonvisit patient phone questions, 13 encounters initiated by laboratory results, and 15 others. Errors were identified in 84 of the cases (34.1 percent). Error types included medication not listed on the chronic medication list (59); medication not listed anywhere in the chart (7); wrong dose prescribed (6); prescription incorrectly written (5); failure to implement medication across care settings (3); contraindicated medication prescribed (1); and other (3). None of these errors would have been detected by chart review alone. **Conclusion:** Self-reporting followed by chart review is feasible in primary care practices and discovers medication errors that might not have been detected by either method alone.

Introduction

Few studies have examined medication-related errors associated with medication management transactions occurring in primary care practices. Investigators have examined malpractice claims,[1] medical records,[2] and medication orders[3, 4] to determine the rates and nature of medication errors in ambulatory care. Gandhi, et al.,[2] and Blendon, et al.,[5] found that the most common primary care medication errors are related to monitoring the effects of medications and responding to reported symptoms. Among a sample of elderly patients, Gurwitz, et al.,[6] found that many adverse drug events were due to prescribing errors. Physician handwriting[3, 7, 8] and the general quality of prescription orders[4] are also sources of medication errors. When post-visit interviews with patients who received prescriptions are combined with chart review data, errors have been found to occur in as many as one of every four patients.[2]

No studies were found, however, that identify specific primary care office processes that are associated with medication errors. In busy primary care offices, the office staff is intimately involved in medication management transactions. For example, receptionists take messages about medication refills; nurses and medical assistants call or fax prescriptions to pharmacies based on practitioners' orders; and patients leave messages requesting refills on office voicemail. These communications are inherently complex, involve inter-professional communications, and

are susceptible to human error. Many medication management transactions are handled by phone, fax, and e-mail and involve written communications and hand-offs to several practice staff members. No investigator has explored the extent to which office processes contribute to medication errors.

The hypothesis of the present study was that physicians and staff may be able to identify and report in real time the errors they observe during routine medication management transactions, and that these observations might ultimately identify office processes requiring improvement. A pilot study was designed and implemented to investigate this notion.

Methods

The primary objective of the pilot study was to determine the feasibility of physicians and office staff to detect and report medication management transaction errors during the course of their routine work. A secondary objective was to determine the frequency of medication errors associated with specific factors. The following factors were examined:

- The role of the individual(s) handling the medication management transaction.
- The number of individuals involved in the medication management transaction.
- The method of communicating the medication management transaction (i.e., telephone, fax, e-mail).
- The type of medication (e.g., acute, new chronic, existing chronic).
- The type of medication management transaction.
- The number of medications involved.
- The prescribing method (electronic vs. paper).

The study defined error as "anything that happens in your own practice that should not have happened or did not happen that should have happened," a definition used in other primary care error-reporting studies.[9] Error categories were taken from the International Taxonomy of Errors in Primary Care – Version 2,[10] with additional detail for the "other" category. No attempt was made to classify outcomes or harm to patients.

The participants in the pilot study included the entire staff (14 physicians and 18 office staff) of three primary care family medicine offices located in Connecticut, who volunteered to participate. None of the sites in the study used an electronic medical record. However, one practitioner did supplement the paper chart with a handheld PDA to electronically support prescription management.

The primary care practice sites followed their own usual office practices for medication orders, refills, and responses to phone, fax, and e-mail questions from patients and pharmacies. Typically, after making a diagnosis, physicians, advance practice nurse practitioners (APRNs), and physician assistants (PAs) write medication orders on paper prescription pads, document the orders in the patient's paper chart, hand the prescription to the patient, and provide brief instructions about the medication. Faxed refill requests from a pharmacy are paper-clipped to the chart for response by the practitioner. Refill messages left by phone are transcribed onto an

adhesive-backed form approximately 2" by 5" in size. These are then paper-clipped to the chart for completion of drug dosage and amount to be refilled, which is completed by a physician, APRN, or PA. Nurses, medical assistants (MAs), and licensed practical nurses (LPNs) do not help write any prescriptions but will enter medications onto the medication list.

The study design involved two, 2-hour prospective self-observation time slots at the three family medicine offices. During the study period, physicians and staff documented on a Medication Transaction Study Form every transaction involving the management of a medication.[a] Physician and staff self-reported if they thought the medication management transaction involved an error. At a subsequent date, a nurse reviewer abstracted study variables from the office paper medical record for each patient involved in the medication management transactions. Because the study was a pilot, the team was not concerned about obtaining representative time slots to account for annual, monthly, daily, or hourly patterns. The categories on the data collection form included:

- Patient's name, date of birth, and study ID.
- Communication method (in person/phone/fax/e-mail, etc.).
- Names of medications and whether they were prescribed by a non-study physician.
- Reason for transaction (e.g., new diagnosis, renewals, medication change due to a lab result).
- Type of medication (new chronic, chronic, acute).
- Method of prescribing (electronic, other).
- Role of individual(s) involved in the medication management transaction (MD/PA/APRN, nursing staff, other clinical staff, medical record staff, or front desk).
- Description of any suspected error detected in the execution of the medication management transaction by any of the office staff.

To make completion easier than open-ended reporting, the data collection form included a set of responses to most questions. The second page of the data collection form, which was completed by the chart reviewer, included:

- Patient demographics (year of birth, ethnicity, insurance provider).
- Confirmation that each medication involved in the transaction was noted in the patient chart.
- Confirmation that each chronic medication involved in each transaction was noted on the chronic medication list.
- Number of chronic medications listed on the medication list.
- Confirmation of allergy listed in chart.
- Reviewer's comments as to possible error.

A third page of the data collection form was designed for the study coordinator and physician reviewers to record their comments about the transaction, make a final determination about any error, and provide a checklist for the type of error detected.

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[a] The data collection form can be obtained from the corresponding author upon request.

Prior to rollout of the study, all physicians and staff at the three sites participated in a training session. At the training session, the study coordinator reviewed the study protocol, including how to complete the transaction data collection form. Staff and physicians were instructed to attach the form to every medication-related phone message, fax, e-mail, or actual prescription that came into or left the office during the data collection period. For those patients scheduled to see the physician during the data collection period, a data collection form was attached to the medical chart prior to the patient being seen by a physician.

During the study, all staff and physicians at the three sites recorded all process interactions concerning medications during a 2-hour period on 2 different days (4 hours per site) on the data collection forms. The time slots were not preselected based on patient volume or other criteria suspected to be associated with errors. Time slots were at the convenience of each practice site.

During each study period, each medication management transaction was tracked from its inception to completion. Medication management transactions might begin with a call or fax from a patient or a pharmacy, a new prescription written for an acute problem, or a routine medication continuation initiated by a clinician during an office visit. The first individual to handle the medication management transaction attached a data collection form to the chart or medication request note and documented the patient's name, method of communication with the office, name of medication(s), reason for the medication management transaction, whether it was a new or existing medication, and whether the prescription was for an acute or chronic medical condition. For transactions that involved more than one medication, only one data collection form was used. As the transaction moved through the practice, each person who handled the transaction indicated his/her involvement with a check-off in a designated section of the data collection form and flagged potential errors. In addition, the study coordinator was onsite during the data collection period to respond to any questions. At the end of each 2-hour data collection period, the study coordinator collected all data collection forms.

At a later date, an independent nurse reviewer brought the data collection forms to each office site and abstracted patient charts associated with the medication management transactions being studied. The nurse reviewer collected basic demographic information for the patient, including year of birth, race/ethnicity, and insurance provider. The nurse reviewer noted whether the chart contained a notation regarding medication allergies and a medication list; whether the medication management transaction was noted on the medication list for a chronic medication or elsewhere in the chart for acute medications; and the total number of chronic medications listed for the patient. The nurse reviewer did not abstract any information about transactions leading up to or occurring after the transaction noted on the data collection form. After completion, the data collection forms were returned to the study coordinator.

The study coordinator reviewed each data collection form, categorized the transaction as involving error or no error, and categorized the error according to the International Taxonomy of Errors in Primary Care – Version 2,[10] with additional details for "other" categorization.

In the final step, one of the physician investigators reviewed all of the data collection forms, made a final classification about error, and noted the rationale. For the purposes of this study,

medication management transactions were classified into two categories: “no error” and “error.” The second physician investigator then reviewed the data collection forms, noted agreement or disagreement with the first physician’s opinion, and the rationale. If there was a disagreement, the data collection form was re-reviewed by both physicians. Only when both physicians agreed about the result was the final assignment of the error status considered complete. All information gathered on the data collection forms was then entered into a database for statistical analysis.

In dissecting the anatomy of an error for purposes of quality improvement, it was important to analyze medication management processes. The term “transaction” was used to define any unique process, where a different person participated in the medication management process. Examples include a receptionist answering or returning a patient’s phone call, nursing staff recording the medication in the chart, or a physician writing a prescription. Thus, there could be multiple transactions in a single “encounter.” We also recognized that medication management has a life cycle and could include an “episode” of multiple encounters, during which prescribing, dispensing, recording, administering, and monitoring take place. Each encounter could include multiple individual transactions. An error could occur during any of the transactions during any of the encounters making up the medication management episode.

Not all errors result in harm to a patient; some errors are discovered before harm takes place. Therefore, a mitigation transaction was defined as a transaction where such discovery takes place. As with error, a mitigation transaction could take place during any of the multiple encounters making up the medication management episode. During analysis of the results, it was important to distinguish between encounters during which there was an error transaction and encounters during which there was a mitigation transaction. Although the mitigation transaction/encounter was an opportunity to identify an error, the transaction processes surrounding the mitigation (e.g., person handling, type of transaction) were not considered appropriate processes to be associated with causes of the actual error for quality improvement. Thus, when analysis was performed on a variable that reflected office processes surrounding a mitigation transaction (who handled the transaction, number of times the transaction was handled, and communication method), that (mitigation) transaction was excluded from the analysis. If the variable being analyzed reflected the underlying patient or medication being managed (e.g., type of medication, number of medications, insurance provider), the mitigation transactions/encounters were included in the analysis.

Because of the pilot nature and small size of this study, the data analysis was primarily descriptive in nature. Summary statistics appropriate to the distributional characteristics of the variables of interest were computed. Bivariate relationships between number and percent of errors were explored for the role of the individual handling the medication management transaction, number of individual(s) involved in the medication management transaction, communication method, type of medication, type of medication management transaction, number of medications prescribed, and prescribing method.

Results

After eliminating one record for insufficient data, the 12 hours of observation yielded 440 medication management transactions involving 246 patient encounters and 337 medications. The

demographics of the 246 patient encounters were as follows: mean age, 52 years (range, newborn to 99 years); 93 percent Caucasian (Connecticut's population is 89.3 percent Caucasian); 4 percent African American (Connecticut's population is 8.7 percent African American); and 3 percent other races (Connecticut's population is 2.0 percent other races). Although the highest error rates were documented for middle-aged patients (aged 26-65 years), no significant trends were noted for any of the demographic variables.

Several study variables did not lend themselves to analysis. Too many unique medications were involved in the transactions to associate errors with detailed medication names. There were only four transactions where the medication was "prescribed by another physician." There were only eight transactions where the list of allergies was not present in the chart. Of these eight, two had medication documentation errors. Because of the methodologies used, no transactions reflecting the adverse events/patient harm were identified.

The types and frequency of errors identified are summarized in Table 1. Errors were identified for 84 of the medication management encounters (34.1 percent); 67 errors (80 percent) were chart documentation errors. The physicians and staff identified 18 errors during the study periods, an error rate of 7.3 percent per medication management encounter. The chart review identified 66 additional errors, mostly documentation errors; 16 of the errors (19.1 percent) were discovered during mitigation encounters.

Role of individual handling the medication management transaction. Before excluding mitigation transactions, the transactions were handled a total of 440 times by front desk staff, nursing staff, APRNs, PAs, other medical staff, and other nonmedical staff. Physicians, PAs, and APRNs handled the prescription(s) most frequently (N = 210), followed by nursing staff (N = 97), medical record staff (N = 60), clinical staff (N = 51), and finally the front desk (N = 22). After excluding mitigation transactions, the error rate was higher for front desk staff, but there was no statistically significant difference (Table 2).

Number of people involved in the medication management encounter. Before excluding mitigation encounters, the number of staff handling the transactions were: one person (N = 113); two people (N = 50); three people (N = 69); four people (N = 10); five people (N = 3); and six people (N = 1). After excluding mitigation encounters, the error rate increased significantly (P <0.01) as the number of personnel involved in the transaction increased (Table 3). Error rates increased from 25 percent to 100 percent as the number of people handling the medication management transaction increased from one to four or more people. The 16 mitigation encounters that were excluded were handled 41 times, reflecting the burden of mitigating the error but not processes associated with the error itself.

Method of communicating the medication management transaction. All but one error associated with mitigation encounters were associated with phone or fax communications. In these cases, it was the phone or fax that was responsible for mitigating the error but not how the error occurred. After excluding mitigation encounters, the error rates were fairly consistent across communication methods, except for online encounters (only two cases), which had a 100 percent error rate (two documentation errors) (Table 3). The method of communicating the medication management transaction showed no statistically significant differences.

Table 1. Frequency of error by type of medication management and type of error

Type of medication management/type of error	Error transactions (N)	Total errors (%)
Stage-1 errors[a]		
Not listed on chronic medication sheet	59	70.2
Not listed in chart	7	8.3
No listing of medication for date of service phone call	1	1.2
Wrong patient chart given to medical staff for review	1	1.2
Subtotal stage-1 errors	68	80.9
Stage-2 errors[b]		
Wrong dose prescribed	6	7.1
Prescription incorrectly written	5	6.0
Failure to implement long-term medication across settings	2	2.4
Contraindicated medication prescribed	1	1.2
Failure to implement changed medication across settings	1	1.2
Info patient received led to patient decision not to take medication	1	1.2
Subtotal stage-2 errors	16	19.1
Total errors	**84**	**100.0**

a Identified during prescribing encounters or chart review.

b Identified during mitigation encounters.

Table 2. Frequency of error by role of person handling transaction

Role of person handling transaction[a]	Transactions with errors	Total transactions	% Error	*P*-value[b]
Physician/PA/APRN	65	201	32.3	
Nursing	27	86	31.4	
Other clinical staff	17	49	34.7	
Medical records	16	52	30.8	
Front desk	8	15	53.3	
Total	**133**	**403**	**33.0**	**0.54**

a Excluding mitigation encounters.

b Chi-square.

Table 3. Frequency of error by number of times transaction was handled and by communication method

	Errors	Encounters	% Error	*P*-value
Number of persons handling transaction[a]				<0.01
One person	28	112	25.0	
Two people	19	66	28.8	
Three people	17	48	35.4	
Four or more people	4	4	100.0	
Communication method[a]				0.28
In-person appointment	29	101	28.7	
In-person walk-in	2	6	33.3	
Phone call	24	79	30.4	
Fax	11	42	26.2	
Online	2	2	100.0	
Total	**68**	**230**	**29.6**	

a Excluding mitigation encounters.

Type of medication. Error rates varied widely by the type of medication (Table 4). For new chronic medications, errors occurred in 74.2 percent of encounters; for renewal of existing chronic medications, 37.0 percent of encounters; and for acute care medications, 13.8 percent. The difference in errors by type of medication was highly significant (P <0.00001).

Reason for encounter. Error rates also varied by reason for the encounter (Table 4). Reasons for the encounter included 98 for initial patient diagnosis/treatment, 70 for patient-initiated medication renewal requests, 34 for pharmacy renewal requests, 16 for nonvisit patient questions, 13 for discussion of laboratory results, and 7 for insurance benefit-type medication management transactions.

Although the numbers are small, three reasons for the medication management transaction are worth noting because of their high error rates. Insurance coverage issues were associated with a 71.4 percent error rate; patient medication renewal requests had a 44.3 percent error rate; and transactions related to the results of lab tests initiating medication requests had a 38.5 percent error rate.

Number of medications involved. Of the medication management encounters, 73 percent (180/246) involved a single medication (Table 4). However, the error rate was significantly higher (P = 0.02) when two or more medications were handled in an encounter, compared to one medication: 45.5 percent vs. 30.0 percent, respectively. Although the numbers were small, there was a trend for documentation errors to increase as the number of medications increased. This could have been a byproduct of managing the overall number of medications the patient was taking (not just the transactions recorded during the study). On average, patients were taking 3.81 chronic medications; range, 0 to 17 chronic medications.

Table 4. Frequency of error by type of medication, reason for encounter, number of medications involved, and insurance provider

	Errors	Encounters	% error	*P*-value
Type of medication				<0.00001
New chronic medication	23	31	74.2	
Renewal of chronic medication	50	135	37.0	
Acute care medication	11	80	13.8	
Reason for encounter				0.05
Initial patient diagnosis/treatment	26	98	26.5	
Patient-initiated renewal request	31	70	44.3	
Pharmacy-initiated renewal request	9	34	26.5	
Patient followup questions (no visit)	4	16	25.0	
Results of lab-initiated Rx	5	13	38.5	
Insurance coverage issue	5	7	71.4	
Other	4	8	50.0	
Number of medications involved				0.02
One medication	54	180	30.0	
Two or more medications	30	66	45.5	
Insurance provider covering encounter				0.71
Private	54	158	34.2	
Public and private	20	54	37.0	
Public	8	30	26.7	
Self-pay	2	4	50.0	
Total	**84**	**246**	**34.1**	

Prescribing method. Although none of the practitioners in the study used an electronic health record, one did supplement the paper charts with a handheld, stand-alone electronic prescribing software package. A total of 14 e-prescription transactions were documented; three (21 percent), resulted in error, compared to 34.9 percent error for all other methods. All three errors were described as “not listed on chronic med sheet.”

Discussion

The issue of medication errors or adverse events leading to increased patient morbidity and mortality in the primary care setting has been little explored and is daunting to analyze. Patients receive multiple medications from multiple sources with the potential for interactions and overlapping therapies. Patient confusion concerning the appropriate use of medications and individual idiosyncrasies reflecting biases for or against the use of certain medications all complicate the issue of adequate care. In addition, the complexity of patient communication within the modern medical office further confuses the problem.

Intercommunication processes were the focus of the study. When face-to-face encounters, pharmacy-to-physician and physician-to-pharmacy phone calls, patient phone calls, faxed messages, online communication, and after-hours contacts are included, the ability to determine exactly which medication a patient is and/or should be taking is a complex and daunting proposition.

The two, 2-hour time slots in our study yielded only a narrow snapshot of a medication management episode and then only from the primary care office site viewpoint. The time slot did not span all medication management processes (i.e., prescribing, dispensing, recording, administering, and monitoring) associated with complete medication management episodes that might evolve over hours, days, or weeks. The time slot from the primary care viewpoint does not include medication management processes from either the patient's or the pharmacist's viewpoint, other than where they intersect with the primary care office site. Not all medication errors result in patient harm. Neither method used in the study—self-observation of medication management transactions and review of patient charts documenting identified transactions—was used retrospectively to look at events leading up to an identified transaction, nor was it used to look past the identified transaction to subsequent mitigation encounters or adverse events arising from identified errors.

Our results show that it is feasible to detect medication errors by self-observation of medication transactions in the office. The study methodology worked very well in identifying transaction errors from the perspective of primary care practices. The study methodology did not address transaction errors from the perspective of either the patient (compliance) or the pharmacy (processes). The methodology also did not address patient harm or other undesirable consequences of transaction errors.

Documentation errors could not have been detected simply by reviewing charts or self-reporting of transactions alone. Most errors were identified only by a gap analysis, comparing chart-abstracted information to self-reported summaries. Both methods were needed to discover the high volume of errors.

When the study detected mitigation transactions, the measures reflected processes occurring when the error was discovered rather than the circumstances at the time that the error occurred. Although the methodology investigated single encounters, it should be revised to track all encounters in the complete medication management episode. When a mitigation event is identified, a retrospective review should track back to the encounter where the error occurred and identify office processes associated with the error. All events should be tracked forward in time to sufficiently identify additional encounters where possible adverse events or recovery transactions are recorded.

The limited time snapshot should be expanded to identify yearly, monthly, weekly, daily, or hourly differences. For example, an after-hours snapshot might reveal an even larger volume of documentation errors, since the practitioner might be covering without benefit of a chart and without a mechanism to record interactions in the chart, possibly leading to increased documentation errors.

In the limited context of this study (three individual group practice sites, a finite period of study time within the context of busy practices), the absolute number of both documentation and nondocumentation errors was nonetheless remarkable. Of the 246 encounters, 11 (4.5 percent) were associated with an incorrect prescription written or a wrong dose prescribed. The medications included cardiovascular, antibiotic, and narcotic analgesic medications. Most of the errors involved failure to document medications on the chronic medication list. With inadequate documentation, the likelihood of further mistakes and confusion down the road is greatly increased. Incomplete medical record documentation can pose a serious hazard to the patient.

The analysis of rates of error detected in the study was complicated by the reporting on encounters that included both prescribing and mitigation transactions in the same results. If detected, an error might require additional effort (mitigation transactions) to resolve the error. If undetected, an error might require additional effort to resolve an adverse event. Any efforts expended to resolve mitigation or adverse events become measures of the cost and productivity impact caused by error transactions. One needs to be careful not to associate such additional workflow as a cause of the error.

When the transaction took place during a prescribing encounter, a physician, PA, or APRN was always involved, and the number of people handling the transaction was fewer. When the communication method involved incoming phone calls, faxes, or online interactions, more people were involved.

Errors that were discovered and mitigated by pharmacists or patients typically involved incoming phone calls, faxes, and e-mails that raised the concern and involved staff in multiple roles to receive the question, pull patient charts, and coordinate the response. By their nature, incoming communications involve nonmedical staff to receive the communication, a clinical staff person to triage the communication, and medical record staff to pull the patient's chart for use in the decision. Thus, mitigation events should be excluded from any analysis that attempts to associate the frequency of handling the transaction or the role of the individuals involved in the transaction with a cause of error.

Because phone calls (N = 24), faxes (N = 11), and online communications (N = 2) were associated with 61.9 percent of all errors, quality improvement studies should focus on these modalities to identify cases of error that need to be studied. It is fairly straightforward to identify which incoming communications are mitigation transactions and to use mitigation transactions as a way to identify errors. Although electronic health records (EHRs) might reduce the number of documentation errors, special work flow considerations might be needed to document phone calls, faxes, and other online communications not automatically incorported into an EHR.

Other particular areas needing quality improvement and further study include office processes involving laboratory results that initiate a change in medication; office workflow when multiple people are handling a single transaction; processes involved in new chronic medications; and processes taking place when a chart might not be available, such as incoming patient phone calls and online communications with the patients or pharmacists.

In addition to the microcosmic view of medication-related transaction errors this study provides, we can get a sense of the global impact of errors. For the practitioners and timeframes involved in this study, the error rate averaged 1.5 errors per hour. However, the findings of the study are difficult to generalize because of the limited time of data collection, limited numbers of absolute errors, and the small number of practices involved.

The sheer volume of potential problems related to the prescribing of medications in the primary care setting speaks to the need for a more comprehensive study to validate this study's findings and to propose and test possible office-based solutions to reduce medication errors. One obvious process change/intervention that merits close study is the use of e-prescribing that provides documentation directly into the record. The opportunity to achieve automated documentation and benefit from system prompts that alert the prescribing clinician to potential drug-drug interactions and prescription errors is powerful medicine indeed.

Conclusion

Direct self-observation followed by review of charts and a gap analysis of differences among the findings is feasible in primary care practices and uncovers medication management transaction errors that normally would not be detected by self-reporting or chart reviews alone.

Other methods to track the high probability of error processes might help pinpoint error episodes without engaging practitioners in time-consuming self-observation. Because phone calls, faxes, and online communications were associated with 54.4 percent (37/68) of all the stage-1 errors we detected (Table 3) and most stage-2 mitigation events, quality improvement studies should focus on these communication modalities to identify cases of error for study. Other office processes that demonstrate opportunities for focused improvement include prescribing new chronic medications, medication changes initiated because of laboratory results, and patient requests for medication renewal. Methods to expand the time slot—such as a retrospective review of transactions prior to the point of error discovery and a prospective review of downstream sequellae—might also provide a broader picture of the error episodes.

This pilot study demonstrates that the typical daily medication management transactions that occur in primary care practices using paper records and paper prescriptions provide many opportunities for errors. Many of these errors might not have occurred with electronic prescribing embedded in an electronic medical record. For example, such systems typically automatically update the medication list when a prescription is ordered or modified. Additional larger studies in more venues and studies of transaction errors that occur with ambulatory electronic prescribing mechanisms are needed.

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

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Abstract

Automated dispensing machines (ADM) are a computerized companion technology that reduces labor and contributes to patient safety. When stocked, ADMs store medications and control electronic dispensing. In emergent situations, facilities can approve nursing retrieval of medications prior to pharmacy review via override from the ADM. However, retrieving medications by the override mechanism and administering prior to pharmacy review increases the risk for medication errors. The primary objective of this study was to evaluate the appropriateness of medications removed from the ADM using the override function at a facility owned by Hospital Corporation of America (HCA). The secondary objective was to determine the barcode scan rates of medications removed by the override function. Information was collected to determine which medications were removed from the ADM and the shift, indication, and medication barcode/patient armband scanning rates. Based on medication errors identified, significant changes have been made to the override process, including the number of medications available for override and the requirement of an indication prior to medication removal. Formulary changes were made and opportunities for education identified during the evaluation. This study highlighted an opportunity to embed the culture of patient safety to promote safe medication practices.

Introduction

In February 2000, shortly after the Institute of Medicine's seminal publication of *To Err is Human*,[1] Hospital Corporation of America (HCA) began developing electronic medication administration recording (eMAR) and barcoding technology with the goal of improving medication administration safety and fostering a culture of patient safety. eMAR and barcoding represent the use of technology to prevent and detect errors by using data to identify and measure improvements. The implementation of an information technology solution (eMAR) paired with item-specific identification (barcoding) enables the user to administer medications with general confirmation of the Five Rights of Medication Administration: Right Patient, Right Medication, Right Dose, Right Route, Right Time. In addition to these "five patient rights," the system allows for review of lab values and for allergy/interaction verification. For the successful

implementation of the system, the pharmacy was required to barcode all medications at the unit of use or to provide a patient-specific prescription barcode, which is applied to piggybacks, intravenous solutions, and multidose medications. All patients admitted to the facility receive a barcoded armband that is unique to their identity and to that particular hospitalization.

The eMAR and barcoding system uses mobile carts with laptops, tethered barcode scanners, or desktop computers with wireless scanners to read barcode labels on medications and patient armbands. Pharmacy order entry creates the patient's medication profile, which provides a cross-reference when the medication is scanned. If a medication is required urgently, the system is integrated with the Automated Dispensing Machine (ADM) to display available "override" medications on the patient's profile. This enables a caregiver to scan the medication and verify the patient's armband before administering a stat medication that has not been reviewed by the pharmacists.

Automated Dispensing Machines

ADMs, which interface with the pharmacy computer system, are employed in more than half of the hospitals in the United States.[2] Orders are entered into the pharmacy system and linked to the ADM, where a nurse can pull up a patient's profile and access the medication for orders that have been verified by the pharmacy. While this technology allows retrieval of scheduled medications, it also provides rapid accessibility for emergency medications via the override function. These automated medication storage and retrieval lockers help improve the accuracy and efficiency of medication dispensing, inventory maintenance, and charging functions. The dispensing machines allow for systematic monitoring of access to controlled substances, auditing capability in case of discrepancy, and medication storage per regulatory guidelines, while making medications accessible in a timely manner.[3] The impact of ADMs on medication error reduction has not been widely researched.[4]

ADMs may help with accuracy and efficiency, but they do not prevent medication errors. According to the U.S. MEDMARX data report, during 2003, 361 facilities submitted 8,862 records (4.1 percent) citing the dispensing device as the cause of error.[5] The highest percentage of errors was attributable to manual replenishment functions, returning drugs to the wrong location in the machines, human overrides, and circumvention of the machines' safety features.

Override Function

The override function allows a nurse to remove a medication from the machine before a pharmacist reviews the order. The purpose of the override function is to allow access to medications in urgent/emergent situations. The override function is frequently utilized in clinical settings with non-24 hour pharmacies, emergency departments, and most procedural locations. Inappropriate uses of the override function are often based on practice patterns and perceptions that the pharmacy cannot process orders as quickly as needed. It might also occur if staff has a verbal order and acts upon it, or if a physician demands that a medication be given stat.

Administering medications prior to a pharmacist review increases the risk of medication errors.[3-5] The Joint Commission Standard Medication Management 4.10 (MM.4.10) states that a pharmacist must review all medication orders before dispensing a medication, removing it from floor stock, or removing it from an automated storage and distribution device.[6] Exceptions

include situations in which a licensed independent practitioner controls the ordering, preparation, and administration of the medication and urgent situations, when a delay would harm the patient. The challenge with ADMs is to prevent medication overrides in nonurgent settings and to avoid administering medications from orders that have not been reviewed by a pharmacist.

Numerous medication errors secondary to ADM override have been identified in the literature. During one study, researchers examining 470 overridden medications found that 55 of the medications removed from the ADMs (11.7 percent) had not been retrieved in support of a physician's order; 47 of the 55 overridden medications (10 percent of total overrides) resulted from improperly documented orders, such as medications being ordered verbally. The remaining eight overrides (1.7 percent of total overrides) were a result of medication errors or "close calls," described as medications removed incorrectly but never given to the patient. The authors explained that these problems occurred when the pharmacy was closed and when all medications were available only through the override function. They suggested that the override function only be used when the hospital's pharmacy was closed, in emergencies, and pre-procedure, and that intravenous pain medications should always be obtainable via override.[7]

Another study of ADM-related errors found errors in pharmacy, in nursing, and in the ADMs themselves. Ten ADMs, holding 2,858 drawers, were studied. The researchers found expired medications in 10 drawers (0.3 percent); incorrect bulk medications were found in another 10 (0.3 percent) drawers. Both of these errors were due to mistakes made by pharmacy, which loads the bulk medications into the ADM. The authors combined errors created by the ADM together with those by nursing, reasoning that, for example, medications correctly placed in the ADM by nursing could have fallen between the drawers. Sixty-seven drawers (2.3 percent) were found to hold incorrect single-dose medications; 31 intended medications were not even stored inside an ADM.[8]

Objectives

This study was conducted at the Parthenon Pavilion, a psychiatric facility at HCA's Centennial Medical Center, which utilizes electronic medication barcoding technology. Hospital process calls for physician orders to be reviewed by pharmacy, and then for nursing to procure barcoded medications from the ADM once they are on a patient's profile. The barcodes from the medication and patient armband are scanned prior to administration of the medication. In urgent/emergent situations, medications can be retrieved prior to pharmacy review, using the override function. Historically, medications were added to the override list because of staff request only.

The Parthenon Pavilion has four automated dispensing machines; each floor has one machine that is used by two units. The medications available for override were not consistent throughout the building. This created a problem because staff frequently floated between the floors. A decision was made to reduce the override medication list to 23 medications and to standardize the override list among the four ADMs (Table 1).

The primary objective of this study was to evaluate the appropriateness of medications removed from the ADM using the override function. The secondary objective was to determine the

barcode scan rates of medications and patient verification when medications were removed using the override function.

Table 1. Medications available for override at Parthenon Pavilion

- Ammonia
- Aspirin
- Benztropine, PO/IM
- Chlorpromazine, IM
- Dextrose
- Diazepam
- Diphenhydramine, PO/IM
- Flumazenil
- Glucagon
- Glucose tablets
- Haloperidol, PO/IM
- Insulin (regular)
- Lidocaine
- Lorazepam, PO/IM
- Naloxone
- Nitroglycerin, PO/ointment
- Phenobarbital
- Ziprasidone, IM

Methods

The study encompassed all medications removed from the Parthenon Pavilion's four ADMs using the override function during the period from May 2006 through July 2006. In total, 59 transactions were analyzed retrospectively. The following information was collected from patient medical records: patient sex, diagnosis, and age; medication route; time the medication was reviewed by pharmacy; whether there was a medication error or subsequent adverse drug reaction (ADR); indication for medication administered; and whether the nurse scanned the medication barcode and the patient armband prior to administration.

A medication error was defined using the National Coordinating Council for Medication Error Reporting and Prevention definition as any preventable event that could cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[9] ADRs were tracked using the hospital ADR reporting system. Appropriateness of the medication override function was determined by a match between indication and symptomatology and by whether the physician order corresponded to the medication administered. Barcode medication and patient armband scan rates were evaluated for compliance with patient safety technology.

Results

Fifty-nine instances of medication removal via the override function were documented. The patients in this convenience sample had a mean age of 51.65 (±15.37) years. Fifty-nine percent of patients were female; the most common diagnoses were bipolar disorder (N = 17), major depressive disorder (N = 14), schizophrenia (N = 11), and schizoaffective disorder (N = 7).

The most frequently removed medication (N = 19) was lorazepam intramuscular (IM) formulation, followed by haloperidol intramuscular (N = 8), lorazepam oral tablet (N = 7), and nitroglycerin sublingual tablets (N = 6). Other medications removed via the override function included ziprasidone, benztropine, chlorpromazine, aspirin, diphenydramine, lidocaine viscous solution, glucagon, and phenobarbital.

Indications for the medications removed via the override function included: treatment of acute agitation (N = 28), chest pain (N = 8), unknown (N = 6), psychosis (N = 5), extrapyramidal side effects (N = 4), anxiety (N = 3), pruritis, alcohol or benzodiazepine withdrawal, hypoglycemia, seizure, and unscheduled procedure (N = 1 each). Of the 59 instances of override, 17 (28.8 percent) occurred during a first shift (7:00 am to 3:30 pm); 31 (52.5 percent) occurred during a second shift (3:00 pm to 11:30 pm); and 11 (18.6 percent) occurred during a third shift (11:00 pm to 7:00 am). Forty-five overrides (76.3 percent) occurred on weekdays. The hospital pharmacy was staffed 24 hours per day, 7 days per week.

Of the 59 override transactions, 50 were appropriate according to the match between symptoms and the medications' listed indications. Medication errors occurred with nine of the transactions: three administrations had no documented physician order; one involved the wrong route; in two instances, the wrong medication was given; and two patients received the wrong dose. In addition, one patient received lorazepam despite the generation of an allergy warning to this medication. Lorazepam and haloperidol were the most common psychiatric medications administered by override, most commonly in response to agitation or psychotic behavior. The barcoding scanning rates for the 59 transactions were 62.7 percent for the medications and 57.6 percent for the patient armbands.

The largest number of overrides occurred during the second shift, which was also when the majority of patients were admitted. Medications removed via override were used appropriately in 85 percent of instances. Nine override occurrences resulted in administering medications inappropriately. The lorazepam administration error did not result in an adverse event for the patient, since the allergy was disputed in the patient record. Based on the low scan rates identified in this study, the barcoding system was not used to its full patient safety potential during emergent situations. The average scan rate for both medications and patient armbands was 97.0 percent, compared to the 62.7 percent for medications and 57.6 percent for armbands during emergent overrides.

In six instances, the appropriateness of medication use could not be assessed because there was no documentation explaining why the medications were given. Antipsychotics were commonly removed via override and were also commonly associated with a wrong medication, wrong route, or wrong dose error. Agitation followed by chest pain were the most common symptoms associated with medications being removed via the override function. Scan rate compliance was lower for medications removed via override.

Based on medication errors identified, significant changes were made to the override process, including decreasing the number of medications available for override and adding the requirement of an indication prior to removal of medication (Table 2). Formulary changes were also made. Olanzapine IM was removed from the formulary to decrease the risk of the wrong medication being given for acute agitation.

Educational opportunities were identified during the evaluation, specifically the need for differentiation between chest pain and panic attacks. This study highlighted an opportunity to embed the culture of patient safety. By educating staff and helping them recognize the benefits of using scanning technology to prevent errors, we hope to decrease the number of system bypasses and increase the scan rates.

Discussion

This study demonstrated a wide variety of reasons for using the override function for retrieving medications from ADM. The high rates of complications in this situation suggest a need for greater control of utilization, while preserving rapid access for genuine emergency situations.

This study confirmed that, even with barriers in place, there was still a potential for inappropriate use of medications removed via the override function. Limiting override access could decrease medication errors and improve patient safety throughout the hospital.

Centennial Medical Center initiated review of all medications that were removed via the override function to evaluate for appropriateness of use. HCA's medication safety team is now sharing this learning throughout its more than 300 facilities, providing guidance to reduce the number of medications available for override and education to the staff regarding the appropriate use of the override function. The medication safety team is also reinforcing the importance of utilizing the electronic medication barcoding technology, especially in the "override" situation.

Table 2. Approved AcuDose-Rx® indications for override

- Acidosis, metabolic
- Acute MI
- Acute RDS
- Agitation, severe
- Allergic reaction
- Anxiety, severe
- Arrhythmia
- Benzodiazepine withdrawal
- Bleeding
- Chest pain
- Electrolyte imbalance
- Extrapyramidal symptoms
- Heparin (central line)
- Hypertensive emergency
- Hypoglycemia
- Labor admission
- Local anesthesia
- Narcotic reversal
- Nausea (new onset)
- Procedure (MD present)
- Sedation (emergency)
- Volume expansion

Organizations using ADM should establish usage and access requirements and regularly reconcile medications that have been removed via the override function. Periodically, safety checks should be conducted to ensure that the devices are being used and maintained as intended. These would include periodic "checks" to validate medication placement accuracy—checking presence, absence, and appropriate dose—within the specified compartments of the device.

Pharmacy departments should work with nursing departments to develop effective policies and procedures that address potential sources of error in order to prevent ADM errors. Establishing a limited selection of medications that can be removed via the override function and diligently reviewing the medication being accessed via the override function could help reduce medication errors. Requiring that pharmacy review and verify the appropriateness of all orders for medications prior to their administration, except when such a review might cause a medically unacceptable delay, should help decrease the number of medications that are removed via the override function. For a successful implementation of eMAR and barcoding, it is imperative to understand and follow the built-in safety triggers.

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Imbedding Research in Practice to Improve Medication Safety

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Abstract

Objective: The objective of this project was to improve medication safety at Kaiser Permanente Colorado (KPCO). **Methods:** Six projects that included over 400,000 members were conducted at medical offices and pharmacies. They focused on drug-drug interactions, warfarin-drug interactions, dosing in patients with impaired kidney function, prescribing among elderly patients, prescribing during pregnancy, and laboratory monitoring of therapy. Physicians and pharmacists collaborated to determine study medications, develop intervention guidelines, and implement interventions. Pharmacists were alerted to potential errors through a computerized tool that prevented prescription dispensing until after intervention. Multiple techniques were used in change management. **Results:** All interventions reduced errors (range, 13 to 45 percent), with more than 4,000 errors avoided during the research phases. Five interventions were maintained/modified into routine care at KPCO; some were implemented elsewhere. **Conclusion:** This program supports goals common to many health systems. It was developed through communication, staff support, and stakeholder involvement and successfully decreased medication errors through interventions implemented at medication dispensing.

Introduction

Patient safety initiatives are intended to reduce the occurrence of harm and the risk of harm from medical errors. One area for reducing errors is medication use, an Institute of Medicine (IOM) priority area for transforming health care.[1, 2] For several years, a collaborative team at Kaiser Permanente Colorado (KPCO) has worked to decrease medication errors and improve patient outcomes. Beginning in 2000, investigators from the KPCO Clinical Research Unit (now KPCO Institute for Health Research) conducted a series of epidemiologic needs assessment studies of medication errors in ambulatory care. These studies revealed several types of medication errors and prompted development of the KPCO Improving Medication Safety Program.

Using knowledge gained from the epidemiologic studies, we designed, implemented, and evaluated a series of projects for patients who: (1) are prescribed critically interacting drugs (Critical Drug Interactions); (2) receive anticoagulation treatment and are prescribed drugs that interact with warfarin (Warfarin-Drug Interactions); (3) receive high-risk drugs requiring laboratory monitoring (High-Risk Drug Lab Monitoring); (4) have chronic kidney disease and are prescribed drugs requiring dosage adjustment based on renal function (Renal Dosing); (5) are

pregnant and are prescribed drugs that are contraindicated during pregnancy (Prescribing during Pregnancy); or (6) are elderly and are prescribed drugs considered inappropriate in that age group (Prescribing in the Elderly).

The KPCO Improving Medication Safety Program was initiated at the end of 2000 and continues to the present. Our program has a unique focus on the ambulatory care patient setting with interventions that occur at the point of medication dispensing. Initial purposes of the Improving Medication Safety Program included:

- Develop and implement a Pharmacy Alert System (PAS) that uses linked data from pharmacy and clinical information systems to identify and alert pharmacists to potential medication prescribing errors.
- Develop and implement medication safety projects (that use the linked data) at KPCO medical offices and pharmacies.
- Evaluate the impact of each medication safety project on the occurrence of that type of medication error by comparing outcomes between the intervention group and a usual care group. In all projects, the outcome we were specifically trying to achieve was a reduction in medication errors.
- Translate the findings of each successful project into routine clinical practice at KPCO.
- Share the findings from the KPCO Improving Medication Safety Program across other Kaiser Permanente regions and disseminate the findings to other organizations.

The purpose of this article is to share what we did and what we learned from this series of projects (i.e., the Program). We briefly describe the methods and results of each of the six separate medication safety projects. The primary goal of this paper is to reflect on and share our experiences while conducting these studies. We describe how we aligned with organizational priorities and obtained sponsors and collaborators, managed change, and focused the projects to be transferable and sustainable. We also discuss what still needs to be done.

Methods

Population, Setting, and Intervention

KPCO Improving Medication Safety Program (the Program) projects were conducted in all 18 KPCO medical offices and all 21 KPCO pharmacies. They included more than 400,000 KPCO members in the Denver-Boulder area and involved all KPCO physicians, pharmacists, and nurses. KPCO health plan members were included in the initiatives if they had the targeted characteristic(s) that increased the risk of medication error or patient harm (e.g., all patients aged 65 years or older were included in the Prescribing in the Elderly initiative).

All projects promoted the KPCO principle of physician support in two ways: they were designed not to add work to the office visit, and they included redundant safeguards. Pharmacists working in standard clinical settings under usual circumstances delivered the interventions. Five projects were rigorously evaluated for at least 1 year to determine whether individual interventions were

successful. If evaluation showed that an intervention reduced medication errors, the project was continued, modified, or expanded. An interim evaluation was conducted after 4 months for the sixth project (Prescribing during Pregnancy), and the project was terminated early (see below for additional information).

The overall intervention design was similar for all projects. The projects used the KPCO-developed PAS to intercept potential medication errors after a prescription had been ordered but before it was dispensed. The PAS combined data from the electronic medical record (EMR) and clinical databases with screening functions of the pharmacy information system in order to alert pharmacists to potential errors in targeted medication prescribing for targeted patient groups. For example, for interventions for patients who had chronic kidney disease, were elderly, or were pregnant, the PAS contained a proprietary disease/medical condition module (proprietary to Medi-Span; licensed through McKesson, San Francisco, CA; at the time of some of the projects, NDC Health) within which medical conditions could be linked to specific patients. For these projects, we designed a file format to send medical record numbers for patients meeting the intervention criteria by way of an interface (usually a daily batch interface). The files were processed by linking each patient in the file by medical record number to the condition (e.g., age 65 or older, decreased creatinine clearance, pregnancy).

Each prescription was screened for potential errors using guideline-driven decision rules developed using nationally published recommendations and a consensus of KPCO clinicians, researchers, and administrators. Detection of potential errors triggered alerts. The pharmacist could not dispense a prescription carrying an alert without actively intervening. The pharmacist first confirmed an alert's validity and then consulted decision-support guidelines that assisted the pharmacist in resolving potential errors in collaboration with the prescriber (see Appendixes A and B for decision-support guideline excerpts).

Pharmacists used scripted conversations to explain to patients the reasons for the alerts and the rationale for medication changes in a manner that supported the physician-patient relationship. Factors documented to affect care processes and patient outcomes positively were incorporated into the PAS intervention (i.e., use of practice guidelines, opinion leaders, and audit and feedback). Project-specific information is briefly detailed below. The primary outcome measure for each project was the incidence of medication errors, defined as the dispensing or monitoring of the targeted medications that deviated from the agreed upon published clinical guidelines or product labeling recommendations (Table 1).

Critical drug interactions.[3] Pharmacists were alerted to the drug-drug interactions deemed most clinically significant in a manner that prevented these medications from being dispensed without active intervention. This active alert process was in contrast to traditional drug interaction screening that uses an easily bypassed passive alert process. In the Critical Drug Interactions project, the pharmacist recommended a therapeutically similar drug to the prescribing clinician as an alternative to the interacting medications (e.g., ranitidine instead of cimetidine in a patient also prescribed phenytoin).

Warfarin-drug interactions. Pharmacists were alerted to critical warfarin-drug interactions for the nearly 8,000 KPCO members prescribed warfarin. Typically, there is not a good alternative

Table 1. Kaiser Permanente Colorado improving medication safety program

Project	Outcome measure (direction of desired outcome)	Main Results
Critical-drug interactions[3]	Codispensing of interacting drugs (decrease)	• N = 555 instances of codispensing of 8 pairs of interacting drugs. • Patients with codispensings of interacting drugs: o Pre-intervention rate: 21.3 per 10,000 prescriptions. o Post-intervention rate: 14.7 per 10,000 prescriptions (*P* = 0.0125).
High-risk drug lab monitoring[4, 5]	Laboratory evaluation according to guidelines (increase)	<u>At therapy initiation:</u> • N = 9,565 patients received prescriptions to initiate therapy with any of the 15 intervention drugs. • Patient-drug combinations with laboratory evaluation at initiation of therapy: o Usual care group: 70.2%. o Intervention group: 79.1% (*P* <0.001). <u>During ongoing therapy:</u> • N = 9,139 patients received prescriptions for ongoing therapy with any of the 14 intervention drugs. • Patient-drug combinations with laboratory evaluation during ongoing therapy: o Usual care group, 58%. o Intervention group, 64% (*P* <0.001).
Prescribing during pregnancy[6]	Dispensing of contraindicated drugs (decrease)	• N = 11,000 women, randomized to intervention or usual care. • Patients dispensed contraindicated drugs: o Usual care group, 5.5%. o Intervention group, 2.9% (*P* <0.001).
Prescribing in the elderly[7]	Prescribing of drugs to be avoided (decrease)	• N = 59,680 health plan members, aged ≥65 years, randomized to intervention or usual care. • Patients newly dispensed prescriptions for drugs to be avoided in the elderly: o Usual care group, 2.2%. o Intervention group, 1.8% (*P* = 0.002).

Table 1. Kaiser Permanente Colorado improving medication safety program (continued)

Project	Outcome measure (direction of desired outcome)	Main Results
Warfarin-drug interactions[a]	INR monitoring (increase)	• N = 8,283 warfarin-drug interactions. • Patients with followup INR monitoring: o Pre-warfarin drug-interaction alert, 45%. o Post-warfarin drug-interaction alert, 58.2%.
Renal dosing[a]	Drug dosing not adjusted for kidney function (increase in appropriate dosing)	• N = 5,053 prescriptions for drugs requiring dosing adjustment in patients with chronic kidney disease received by patients with renal impairment. • Proportion of prescriptions with correct dosing for drugs for patients with chronic kidney disease that require dosing adjustment in renal impairment: o Usual care group, 60%. o Intervention group 77%.

a Preliminary, not final, results included in poster presentation: Chester EA, et al. Improving medication safety. Kaiser Permanente National Quality Conference. Monterey, CA. June 2005.

therapy, and the recommended intervention was to closely monitor the patient's anticoagulation status and adjust the warfarin dosage if needed.

High-risk drug lab monitoring.[4, 5] Pharmacists were alerted to missing recommended laboratory tests for the more than 10,000 KPCO members per year receiving prescriptions from among a group of high-risk drugs. An example of this intervention was assessing thyroid function in patients prescribed amiodarone.

Renal dosing. Pharmacists were alerted to errors in drug choice or dosing for the 19,000 KPCO patients with chronic kidney disease, a condition in which medication dosages frequently need adjustment based on the patient's level of kidney function. The intervention consisted of recommending an alternative drug or an adjusted dosage of the originally prescribed drug.

Prescribing during pregnancy.[6] Pharmacists were alerted that a patient who was pregnant was prescribed a medication classified in the United States Food and Drug Administration (FDA) pregnancy risk category D (i.e., evidence of fetal risk; therapeutic benefits of the drug can outweigh the risk) or category X (i.e., evidence suggests that the risk to the fetus outweighs the therapeutic benefit). The intervention consisted of recommending an alternate drug that was safer to use during pregnancy or contacting the obstetrics department for assistance in medication selection.

Prescribing in the elderly.[7] When a prescription was received for a medication for a patient aged 65 years or older, pharmacists were alerted if the medication was potentially inappropriate for use in the elderly. The intervention consisted of recommending an alternate drug that was safer to use in the elderly. For example, when a prescription was received for amitriptyline for depression, the pharmacist recommended nortriptyline according to guideline.

The Critical Drug Interactions and Warfarin-Drug Interactions projects employed a before-and-after design, with the intervention provided to all KPCO members. The effectiveness of these two projects was assessed by comparing rates of medication errors before and after the interventions. The High-Risk Drug Lab Monitoring, Renal Dosing, Prescribing during Pregnancy, and Prescribing in the Elderly projects were prospective and randomized in design, with all KPCO members randomized to either intervention or usual care groups. These four projects were analyzed by comparing rates of medication errors between the intervention and usual care groups. The proportion of medication errors was determined by dividing the number of patients who did not receive the recommended dosing adjustment, drug change, or monitoring specific to the project (numerator) by the total number of eligible patients (denominator).

Sponsors, Collaborators and Broad-Based Participation

As Henriksen and colleagues have pointed out, clear vision from organizational leadership is not enough to bring about commitment to change.[8] Consistency across decisions and actions from leadership results in commitment and trust throughout the organization. We sought and obtained sponsors, collaborators, and participation throughout KPCO. We recruited leaders from the Pharmacy Department, the Clinical Research Unit, the Patient Safety team, and the chiefs of physician departments. The leadership and staff of the Pharmacy Department were instrumental in developing both the commitment to the Program and the trust necessary to imbed the Program within the KPCO culture.

The individual projects were collaboratively developed and implemented by the Pharmacy Department and the Clinical Research Unit. The multidisciplinary project teams included strong representation from professional and administrative stakeholders within KPCO and Kaiser Permanente nationally, including health plan and medical group personnel. KPCO departments that contributed included Pharmacy, Information Technology, Clinical Research, Training and Development, Communications, Internal Medicine, Family Medicine, Pediatrics, Emergency Medicine, Obstetrics and Gynecology, Reproductive Endocrinology, Continuing Care, Long-Term Care, Gastroenterology, Neurology, and other medical specialties. Clinician physicians were actively involved in project development.

Kaiser Permanente has a strong commitment to organized labor[9]; pharmacists in KPCO pharmacies are members of the United Food and Commercial Workers Local 7 Labor Unit. From inception to implementation to completion of all projects, labor and management worked together as partners to communicate and solve problems, recognizing that the pharmacists at the point of project implementation possessed the expertise to ensure project success. Overall, 85 percent of the project team was from a labor unit. For example, clinical pharmacists from the Local 7 Labor Unit led the planning, delivery, and modification of the High-Risk Drug Lab Monitoring project.

Outside of KPCO, grant support was received from the Agency for Healthcare Research and Quality (AHRQ) and the Garfield Memorial Foundation. Without this sponsorship, the Program would not have been possible.

Concordance with Organizational Priorities

The Program interconnected with KPCO departmental, medical center, and patient safety program priorities. Patient safety priorities directly related to the Program included:

- Identifying and analyzing near-misses and errors.
- Identifying and analyzing potential risks of harm.
- Examining systems issues that contribute to near-misses or errors.
- Examining alternative patient safety strategies.
- Selecting and implementing strategies.
- Monitoring interventions to document the effectiveness of the program in reducing harm.

The Program also related to national Kaiser Permanente priorities. For example, the Kaiser Permanente Care Management Institute (www.kpcmi.org) monitors high-risk medication use in the elderly across the Kaiser Permanente Medical Care program nationally. The KPCO Program implemented an intervention designed to directly affect dispensing of several medications, the use of which was monitored through the Care Management Institute.

Change Management

With any patient safety project, change management issues should be encouraged to surface and then be effectively addressed. Most issues that surfaced during the Program were related to human factors and the time trade-off necessary to conduct the interventions within busy outpatient pharmacy settings—i.e., the universal production-protection space of the organization.[10] Essentially all change management issues that were encountered related to the perceived value of the Program compared to other initiatives.

These issues were addressed using several tools and techniques. The first group of tools and techniques involved preparing/disseminating background facts, encouraging stakeholder buy-in, and minimizing practical barriers to implementation. Existing data were analyzed to demonstrate medication error problems and to document problem scope. We sought and encouraged interdepartmental collaboration in developing and narrowing the foci of interventions. We paid attention to and addressed the demands of testing interventions in everyday work settings, and we listened and applied input from stakeholders. Our intent was to focus on practical challenges *a priori* to minimize problems, reduce resistance, and promote success. We pilot-tested the alerts to confirm software stability and flexibility. We also focused on smoothly integrating interventions into daily work routines, using systems already present in the work setting.

The second group of tools and techniques used in change management focused on providing education, information, and feedback to assist in building confidence among those providing or receiving interventions. Training programs were developed, as were awareness campaigns and reference documents, to help pharmacists and physicians understand, anticipate, and embrace the Program's dividends. We provided scripts to pharmacists to enhance their confidence with the

information provided during interactions with physicians and patients. We provided intermittent reports to pharmacy leadership to show levels of project performance/success and to identify problems. These reports were to be shared with pharmacists. The scripting used by pharmacists also served to inform patients who received the interventions that we were taking extra steps towards patient safety. For example, the following script was used when telling a patient aged 65 or older that the pharmacist was contacting his or her physician about a medication: “At Kaiser Permanente, we are trying to improve health care above and beyond the standard practice, so we are taking extra steps to ensure the best prescribing possible. I just want to double-check with your physician before I fill the prescription.”

The third technique was to foster the development of a cadre of opinion leaders on-site in the pharmacies. This opinion leader group of pharmacists was called the “Intervention Champions.” Although there were few external incentives (e.g., a couple of lunches) for the Intervention Champions, they continue to promote the Program and answer questions on a real-time basis in the pharmacies. These opinion leaders are motivated by internal incentives (e.g., a sense of contributing to improving the safety of medication use).

The final set of tools and techniques employed involved seeking feedback and modifying the Program to improve effectiveness. For example, the research team actively sought input and feedback from Intervention Champions about modifications to enhance Program processes. The Intervention Champions in turn gathered informal feedback from participating pharmacists on how the Program was working and what could be improved. The research team also met with Pharmacy Department leadership to discuss Program successes and limitations and to determine continuation of individual projects.

A dramatic example of addressing an emerging issue was provided by the Prescribing during Pregnancy project.[6] Although this project was successful at decreasing the proportion of pregnant women with contraindicated drug dispensings, the project was stopped after 4 months. Two major situations contributed to ending the intervention. First, due to limitations inherent to the pharmacy information system pregnancy software module, pharmacists received alerts for some drugs that were not contraindicated in pregnancy (e.g., inhaled albuterol). Second, information about the end of a pregnancy, especially a miscarriage, was not always promptly available in the clinical database that provided information to the pharmacy information system. This resulted in the pharmacist being alerted incorrectly that a woman was pregnant. Both situations were technically false-positive alerts. The first situation (receiving alerts for nontargeted drugs) resulted in a high false-positive alert rate, whereas the second situation (not receiving up-to-date clinical information) had the potential to—and in a few cases did—result in extremely awkward interactions between pharmacists and patients.

Systems limitations that resulted in false-positive alerts and unacceptable human interaction issues led us to stop the project. The problem of including nontargeted drugs should not occur in systems with more sophisticated software. However, we are uncertain as to whether the false alert problem of not receiving reliable pregnancy status information could be overcome on a systems level.

Results

The projects described here have been completed. Medication errors were reduced in all projects. The main results for each project are summarized in Table 1.[3-5, 7] During the research phases of the projects, more than 4,000 medication errors were avoided. For example, in the High-Risk Drug Lab Monitoring project, for patients with ongoing drug therapy, 1,981 recommended laboratory tests were ordered by pharmacists.[4] Five projects have been maintained as conducted during the research phase (with subsequent expansion to all patients, not just the intervention group), modified, or expanded.

Additional results from this Program included gratitude expressed by patients, enhanced professional satisfaction expressed by pharmacists, and appreciation expressed by physicians. Physicians commented that they appreciated the collaboration and assistance in monitoring laboratory test results for high-risk drugs and the reminders about reducing dosages of targeted drugs in patients with reduced kidney function. Pharmacists stated that they appreciated the opportunity to use their clinical knowledge and that they enjoyed the patient contact these interventions facilitated. Patients spontaneously stated interest and pleasure that we were paying attention to their individual needs (e.g., adjusting drug dosage based on kidney function, providing reminders to obtain recommended laboratory tests). Although an occasional complaint was received (e.g., a physician felt professional autonomy was challenged), the volume of positive feedback outweighed the negative.

Discussion

Measuring medication errors avoided is a surrogate marker for reduced adverse outcomes. It is not possible to directly evaluate numbers of hospitalizations or deaths prevented or patient suffering avoided. However, it is evident from the reduced number of medication errors observed with the Program that these interventions reduced hospitalizations, deaths, and patient suffering because the proper and safe use of medications was enhanced, and preventable medication errors were avoided. For example, numerous publications document patient hospitalizations due to bleeding complications related to the interaction between warfarin and trimethoprim-sulfamethoxazole, an interaction targeted in the Warfarin-Drug Interactions intervention. By avoiding such complications, these interventions enhanced patient safety and avoided patient harm.

Although the Program was not designed as a patient education or physician reminder program, these were benefits. The information provided by pharmacists about potential drug-drug interactions, the need for laboratory monitoring with selected medications, dosing adjustments for selected drugs in patients with kidney disease, etc., resulted in expressions of thanks from several patients. Physicians seemed particularly grateful for reminders that individual patients had reduced kidney function (and that the prescribed drug should have a reduced dosage) and that specific drug-drug combinations had potentially harmful interactions.

Transferability and Sustainability

Not only is the KPCO Program innovative, it also is generalizable and transferable. The projects within the Program are relevant to other health systems, as medication errors are common in outpatient medical office settings. Many health systems have access to the clinical data used in our Program (e.g., age, laboratory results) and have information systems that enable them to make these data available to pharmacists at the point of dispensing. Even in settings where pharmacists do not have routine access to patients' medical records, they often can access the data needed to inform these medication safety interventions. The interventions are practical and can be cost effective because they are delivered by pharmacists working in usual care settings. No increased staffing would be necessary to conduct these projects. Additionally, the structures and processes of these interventions are integrated into the usual work flow of pharmacy staff and of physicians and nurses in medical offices, thus enabling seamless, practical, efficient delivery of the intervention.

Some individuals maintain that medication safety programs should start with an EMR- or computerized prescriber order entry (CPOE)-based intervention that responds directly to prescriber input, rather than providing alerts at medication dispensing. There are important reasons why point-of-dispensing alerts remain vital in the EMR/CPOE environment. First, EMR/CPOE-based prescribing safety alerts are overridden by physicians in 49 to 96 percent of cases.[11] Second, software-based alerts cannot match the professional judgment of a pharmacist in determining the validity of an automated alert. Third, alerts in our Program do not interrupt physician workflow unless first validated by a pharmacist. Alerting the pharmacist frees the physician to focus on other patient needs while providing high reliability to specific medication dispensing processes. Fourth, a program like ours supports physicians in keeping patients safe without placing the sole responsibility for medication safety within the confines of an office visit. This Program of medication safety interventions supports physician practice by removing tasks from the face-to-face office visit and creating redundant safeguards for error-prone tasks that are sometimes overlooked during patients' medical office visits. In the KPCO Program, these error-prone tasks are incorporated into a high-reliability model elsewhere in the delivery system—i.e., at the point of dispensing medication. Thus, we believe that even health care organizations that want to start an EMR- or CPOE-based medication safety program can benefit by incorporating the pharmacy-level alerts we developed into their systems.

The results of this Program are sustainable. Five of six projects have continued through the period of this writing and have sustained reductions in medication errors beyond 1 year. Further evidence of the sustainability of these projects is found in the fact that the projects are not static. For example, newly recognized critical drug interactions were added in 2004, 2005, 2006, and 2007. In 2004 the Laboratory Monitoring intervention was modified to add some drugs (e.g., antidepressant combinations, spironolactone) and to drop others (e.g., metformin, nefazodone).

Although all the medication safety interventions within the Program are relevant to other health care systems, other organizations may not be able to introduce all six medication safety interventions concurrently. Also, the relative importance of the interventions can be debated and would vary depending on the organization's priorities. One approach to prioritizing intervention implementation is the following rank order: (1) Warfarin-Drug Interactions, (2) Critical Drug Interactions, (3) Renal Dosing, (4) Prescribing in the Elderly, (5) High-Risk Drug Lab

Monitoring, and (6) Prescribing during Pregnancy. This suggested prioritization is based on several considerations. For example, health care organizations typically have existing information systems that support implementation of the critical drug and warfarin-drug interaction interventions. Also, prescribers and pharmacists are familiar with reports of associations between drug interactions or lack of renal dosage adjustments and adverse clinical events.

The results of the Lab Monitoring intervention were not as impressive as those observed with the drug interactions and renal dosing interventions.[3-5] Prescribing in the Elderly also has many nuances (e.g., some indications for use are appropriate for certain medications) that make decision rules complex. Finally, the Prescribing During Pregnancy intervention was fraught with numerous barriers.[6]

Dissemination

The results of these projects are either already published in medical or pharmacy journals,[4-7] are being revised for submission to journals,[3] or manuscripts are in preparation. Additionally, the projects' results have been disseminated widely through invited presentations at national conferences (Gaps in Medication Safety Conference in Washington, DC, 2005; Annual Patient Safety and Health Information Technology Conference in Washington, DC, 2005; Kaiser Permanente National Quality Conference in Monterey, CA, 2005; HMO Research Network Conferences in Denver, CO, Dearborn, MI, and Santa Fe, NM, in 2003, 2004, and 2005, respectively; American College of Clinical Pharmacy Spring Practice and Research Forum in Monterey CA, 2006). Furthermore, the Program and its results have been featured by local and national media.[12, 13, 14]

With regard to others implementing the KPCO Improving Medication Safety Program, the KP Northwest region has adopted and put into practice portions of the High-Risk Drug Lab Monitoring, Renal Dosing, and Critical Drug Interactions projects. Furthermore, two other U.S. health care systems have sought consultation from KPCO on adapting and implementing their own versions of the High-Risk Drug Lab Monitoring project.

Looking Toward the Future

The implications of these projects include improved patient safety and clinical outcomes and reduced costs due to fewer medication-related adverse events. The projects have facilitated enhanced dialogue, improved collaboration, and fostered education among pharmacists, physicians, laboratory personnel, call center staff, and patients. Interventions from several of these projects are now routine clinical practice at KPCO.

We have recently introduced selected medication error alerts into the KPCO EMR system. These alerts have the potential to further improve medication safety in our health care system. We intend to evaluate the impact of the combined pharmacy-based and EMR-based alerts.

We believe further work is yet to be done to assist KP and other health care systems in implementing similar error-reduction practices. We are committed to working with other health care systems to assist in integrating these patient safety interventions into their delivery systems.

Conclusion

The KPCO Improving Medication Safety Program projects support patient safety goals common to many health systems. The KPCO Program was successful at decreasing medication errors through a series of interventions employing alerts implemented at the point of medication dispensing. This successful Program was team-based and developed and implemented through collaboration, communication, staff support, and key stakeholder involvement. We believe that a pharmacy-based alert program is complementary to EMR alerts.

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Appendix A

CIPROFLOXACIN

INTERACTION:

Dosage adjustment recommended for CIPROFLOXACIN when CrCl <51 mL/min

CrCl (mL/min)	Recommended Dose
<51	250-500 mg every 12 hours
<30	250-400 mg every 18-24 hours

CIPROFLOXACIN EXTENDED RELEASE TABLETS

Indication	CrCl (mL/min)	Recommended Dose
Complicated Urinary Tract Infection Acute Uncomplicated Pyelonephritis	<30	500 mg every 24 hours

INTERVENTION:

1. **Confirm:** Patient has CrCl <51 mL/min.
2. **Determine:** Whether CIPROFLOXACIN is dosed appropriately based upon patient's CrCI (*see above table*). If dosed at or below recommended dose, dispense Rx as written. If dosed too high, proceed with intervention.
3. **Contact:** Provider
4. **Inform provider:** CIPROFLOXACIN requires dosage adjustment in renal insufficiency.
5. **Recommend:** ➔ Appropriate dose based upon patient's CrCl (*see above table*).
6. **If provider disagrees:** Inform provider that CIPROFLOXACIN accumulates in renal insufficiency, and patient should be monitored for toxicity (e.g., acute renal failure, seizures). *Okay to dispense.*
7. **Documentation:** PIMS CENSUS NOTE.

Appendix B

Drug-Elderly Intervention Guidelines KAISER PERMANENTE®

Amitriptyline

Summary of Prescribing Concern
In many instances, amitriptyline is not recommended for use in older adults due to its strong anticholinergic and sedative properties.

Indications Which DO NOT Require Intervention:

- ☐ Irritable bowel syndrome
- ☐ Incontinence, urinary urgency or bladder spasm
- ☐ There may be other indications, not listed, for which the provider may wish to continue the medication for this patient

INTERVENTION:
For the indications listed in the table below, switch amitriptyline to an equivalent dose of nortriptyline. (Maximum dose for nortriptyline in the elderly is 75 mg daily and 150 mg daily for amitriptyline.)

Indication	Amitriptyline	Nortriptyline
Insomnia, pain (e.g., neuropathic, fibromyalgia, headache, migraine, etc.), depression, anxiety, or any combination of these indications	10 - 25 mg	10 - 25 mg
	30 - 50 mg	25 mg
	60 -100 mg	50 mg
	110 - 150 mg	75 mg

Intervention Script

1. **Review to determine if prior PIMS Elder census note exists for this drug and this dosage**. If a prior census note exists, determine if the prescriber of the current prescription has already been contacted. If the provider has already been contacted regarding this prescription and a final determination was made, you do not need to contact the prescriber again. Simply document this in the census note as "Provider previously contacted." If the current provider has not previously been contacted for this drug, please proceed with the next step. If a prior PIMS Elder census note does not exist for this drug, please proceed with the next step.
2. **Check in PIMS to determine if this is the first time amitriptyline is being dispensed at this dose for the patient in the past year.** No intervention is necessary if the patient has been previously dispensed amitriptyline at this dose. If no prior dispensing at this dose, proceed to step 3.
3. **Obtain indication information from the prescription.** If the indication is not available from the prescription, ask the patient or caregiver for indication information. If no indication information is available from either of the previous sources, consult HealthConnect or provider.
4. **If the indication requires intervention explain to the patient:** "At KP, we are trying to improve health care above and beyond the standard practice, so we are taking extra steps to ensure the best prescribing possible. I just want to double-check with your physician before I fill the prescription."
5. **Contact provider.** For indications listed in table above, recommend switching patients from amitriptyline

to an equivalent dose of nortriptyline. Refer *to* the above table to determine the right dose of nortriptyline. *Note: If therapeutic equivalent drug substitution for amitriptyline is authorized by the RDCs in the future, it will be incorporated in this guideline.*

6. **If provider disagrees: Dispense the medication as written.**
7. **Documentation: PIMS CENSUS NOTE.**

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

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Abstract

Introduction: Little is known about the prevalence of herbal and dietary supplement (HDS) use among ambulatory patients who use prescription medications or about the risk of adverse drug events (ADEs) related to drug-HDS interactions. **Methods**: We conducted a secondary analysis of a study of patients who received prescription medications at four primary care practices. We used chart reviews and patient interviews to identify potential drug-HDS interactions, and we used MICROMEDEX to classify interactions. **Results**: A total of 101 of 657 patients (15.4 percent) reported using HDS, including echinacea (21.8 percent), ginkgo biloba (13.9 percent), glucosamine (13.9 percent), omega-3 fatty acids (12.9 percent), garlic (7.9 percent), St. John's wort (6.9 percent), and ginseng (6.9 percent). Although we found no increased rate of ADEs among HDS users compared to nonusers, 14 percent of users had potentially dangerous interactions with their prescription drugs. **Conclusion**: HDS use is common in adult ambulatory care. The risk of interactions between these agents and prescription medications is worrisome.

Introduction

In 1994, Congress defined a dietary supplement as a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include vitamins, minerals, herbs or other botanicals, amino acids, and substances, such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and they may be found in forms such as tablets, capsules, softgels, gelcaps, liquids, and powders.[1]

The use of herbal and dietary supplements (HDS) has grown rapidly in the United States. In 2001, consumers spent $17.8 billion on dietary supplements, including $4.2 billion of this amount for herbs.[2] A comparison of the results of the National Health Interview Survey in 2002 with a 1997 survey of complementary and alternative medicine use[3, 4] found a 50 percent increase in Americans' use of herbal supplements, from 12.1 percent of adults in 1997 to 18.6 percent—or 38 million individuals—in 2002.[3]

Most dietary supplements are unlicensed, and manufacturers are not required to demonstrate efficacy, safety, or quality.[5] Although herbs are often promoted as natural and therefore

harmless, they are not free of adverse effects. An observational study showed that herbal supplements are associated with adverse events of all levels of severity and affect all age groups.[6] As the use of herbal medicine increases, so have reports of adverse drug events (ADEs) related to HDS. To date, research regarding drug-herb interactions is limited mostly to case reports and a few systematic reviews.[7, 8, 9, 10, 11, 12]

Despite concerns about possible harmful interactions between prescription drugs and HDS, little is known about the concurrent use of these products by ambulatory patients. Only one published study has investigated the potential prevalence of ADEs associated with HDS in ambulatory care settings. This study showed that 43 percent of patients seeking care at two Veterans Health Administration hospitals were taking at least one dietary supplement (including herbs, vitamins, and minerals) with prescription medications, and 45 percent had the potential for a significant drug-dietary supplement interaction.[13]

Because 60 to 70 percent of complementary and alternative medicine users do not discuss their use with a physician,[4] patients may have few opportunities to learn about potential interactions of herbal and non-HDS with their prescription medications. To increase understanding of HDS risk and to inform clinical practice, we conducted a secondary analysis of a study of ADEs among primary care patients.[14] The goals of the present study were to calculate the prevalence of HDS use among primary care patients taking prescription medications and examine the risk of drug-HDS interactions in this population.

Methods

Definition

We defined an ADE as an injury resulting from medical intervention related to a drug.[15] We interpreted this definition to include injuries resulting from an herbal or non-HDS and from a drug-HDS interaction.

Study Sites

We studied four Boston adult primary care practices affiliated with a teaching hospital. Two practices were located at the hospital, and two were community-based. One of each type of practice used a basic computerized system for prescribing drugs, but there was no automatic drug allergy or interaction alert feature. The other practices used handwritten paper prescriptions.

The study protocol has been described in detail and reported elsewhere.[14] Briefly, study subjects included 661 adult patients who received prescription medications from internists at the study sites. All patients who received a prescription from participating physicians at an appointment were enrolled once during a 4-week enrollment period at each site. Patients were excluded if they were too ill to participate, hard of hearing, or unable to speak English or Russian. Data were collected from September 1999 through March 2000. The Beth Israel Deaconess Medical Center institutional review board approved the study in advance.

Data Collection

One day after the patient's appointment, investigators sent patients a letter that described the study and requested their participation in a telephone survey. Ten to 14 days after the appointment, patients who agreed to participate were asked about medication-related symptoms and to read aloud their prescription bottle labels. Patients were also interviewed 3 months after the appointment regarding their symptoms. Patients were asked at 10 days and again at 3 months if they "regularly took any nonprescription drugs, such as herbal and other dietary supplements."

Three months after the appointment, a nurse examined subjects' medical records to identify any ADEs, drug allergies, comorbidities, demographic characteristics, number of medications, and duration of continuous care at the practice site.

Two physicians then reviewed the chart and survey data to ascertain the presence of ADEs. Physician reviewers attributed none of the ADEs of the original study to an HDS. However, the investigators did not evaluate the presence of potential ADEs related to drug-HDS interactions.

For the present study, we identified potential drug-HDS interactions by reviewing each patient's medication list. Interactions were classified according to the DRUG-REAX® system database from MICROMEDEX, which was available to clinicians at the four practice sites.[16] Potential drug-HDS interactions were classified by MICROMEDEX as "minor," "moderate," or "major" as follows:

Major: The interaction may be life-threatening and/or require medical intervention to minimize or prevent serious adverse effects.

Moderate: The interaction may result in an exacerbation of the patient's condition and/or require an alteration in therapy.

Minor: The interaction would have limited clinical effects. Manifestations may include an increase in the frequency or severity of side effects but generally would not require a major alteration in therapy.

If we identified a potential drug-HDS interaction, we used two additional databases to confirm the reported interaction from MICROMEDEX.[17, 18] In all cases, the three databases gave consistent results.

Statistical Analyses

We used Student's t-test and the chi-square statistic for continuous and categorical variables, respectively. Reported *P* values are based on two-tailed tests of significance. Logistic regression was used to examine factors associated with patients' use of any HDS. The model was adjusted for patient and practice attributes (i.e., age, sex, primary language other than English, ethnicity, years of education, type of practice, type of prescribing, number of medications, and duration of clinic care) found to be associated with ADEs in the original study.[14] A dichotomous variable for HDS use was included in the final model. SAS® (SAS Institute) version 8e was used for statistical analyses.[19]

Results

Herbal/Dietary Supplement Use

Of 1,202 potentially eligible patients in the original study, 661 (55 percent) completed the initial telephone survey and were enrolled. Of enrolled patients, 600 (91 percent) completed the telephone survey at 3 months. Chart reviews were completed for 653 patients (99 percent). We analyzed 657 of 661 potentially eligible patients for the present study because four patients did not answer the question regarding the use of herbal and other dietary supplements.

Of the 657 patients, 101 (15.4 percent) reported using at least one HDS (Table 1). Overall, patients used 39 different supplements. The most commonly used herbs were echinacea (22 percent), ginkgo biloba (14 percent), St. John's wort (7 percent), ginseng (7 percent), evening primrose oil (5 percent), and saw palmetto (4 percent). The most commonly used nonherbal dietary supplements were glucosamine (14 percent), omega-3 fatty acids (13 percent), garlic (8 percent), chondroitin (5 percent), coenzyme Q10 (5 percent), flax seed (4 percent), and cranberry (4 percent).

Subject Participation and Characteristics

Table 2 shows the characteristics of HDS users and non-users. Compared to nonusers, more users were white (88 vs. 79 percent, $P = 0.04$), college educated (90 vs. 80 percent, $P = 0.02$), English speaking (98 vs. 91 percent, $P = 0.02$), and had fewer than 3 years of continuous care at the practice site (44 vs. 34 percent, $P = 0.09$).

In the multivariable analysis, HDS use was associated with college education [OR 2.25, 95 percent CI (1.09, 4.65)] and English speakers [OR 4.32, 95 percent CI (1.01, 18.49)] and was inversely associated with 3 years or more of continuous care [OR 0.80, 95 percent CI (0.66, 0.97)] (Table 3).

Adverse Drug Events Among Herbal and Dietary Supplement Users

Twenty-nine (29 percent) of the 101 HDS users experienced an ADE, compared to 131 (24 percent) of the 556 nonusers ($P = 0.27$), a nonsignificant difference in univariate and multivariate analyses.

Although we identified no ADEs attributable to drug-HDS interactions, we identified 14 patients with 25 potential drug-supplement interactions among the 101 HDS users (Table 4). Potentially serious ("major") drug-herb interactions included St. John's wort with selective serotonin reuptake inhibitors (SSRIs) or with oral contraceptives, and ginkgo biloba with antiplatelet agents, nonsteroidal anti-inflammatory drugs (NSAIDs), or trazodone. Two of the 14 patients had multiple potential drug-supplement interactions.

Table 1. Most commonly used HDS and non-HDS

Supplement	Common uses	Supplement class	No. of HDS users	% HDS users[a] (N = 101)	% Patients (users + nonusers)[a] (N = 657)
Any supplement			101	100	15.4
Echinacea	Prevent common cold	Herbal	22	21.8	3.3
Gingko biloba	Enhance memory and concentration	Herbal	14	13.9	2.1
Glucosamine	Treat osteoarthritis	Nonherbal	14	13.9	2.1
Omega-3 fatty acids	Prevent cardiovascular disease	Nonherbal	13	12.9	2.0
Garlic	Prevent cardiovascular disease, improve hyperlipidemia	Nonherbal	8	7.9	1.2
St. John's wort	Antidepressant	Herbal	7	6.9	1.1
Ginseng	Stimulant	Herbal	7	6.9	1.1
Evening primrose oil	Treat premenstrual syndrome	Herbal	5	5.0	0.8
Chondroitin	Treat osteoarthritis	Nonherbal	5	5.0	0.8
Coenzyme Q10	Various uses, including treatment of hypertension	Nonherbal	5	5.0	0.8
Saw palmetto	Treat benign prostatic hypertrophy	Herbal	4	4.0	0.6
Flax seeds	Prevent heart disease and cancer	Nonherbal	4	4.0	0.6
Cranberry	Prevent heart disease and cancer, treat urine infection	Nonherbal	4	4.0	0.6
Other[b]			24	23.8	3.7

a Totals exceed 100% because 33 patients used multiple supplements.

b Other supplements included: arnica, bilberry, bromeline, chromium picolinate, comphrey, dehydroepiandrosterone, dong quai, ginger, goldenseal, grape seed, hawthorne, herbal tea, isoflavone, kava kava, L-carnitine, lecithin, lutein, lysine, melatonin, mistletoe, niacin, pyruvate, slippery elm, vitex, wild yam.

Table 2. Characteristics of study sample, by HDS and non-HDS use

Characteristic	Total (N = 657)	Users (N = 101)	Nonusers (N = 556)	*P*-value[a]
Mean age (±SD) (yrs)	52 (16.9)	52.5 (15.9)	52.6 (17.1)	0.94
Sex[b]				
Male (%)	34	33	34	0.82
Female (%)	66	67	66	
Race				
White (%)	80	88	79	0.04
Non-white (%)	20	12	21	
Primary language				
English (%)	92	98	91	0.02
Non-English (%)	8	2	9	
Education level				
<12 years (%)	18	10	20	0.02
≥12 years (%)	82	90	80	
Mean (±SD) medications	3.6 (2.9)	3.6 (2.7)	3.6 (2.9)	0.89
Years of continuous care				
<3	36	44	34	0.09
≥3	64	56	66	

A Student's t-test for continuous and chi-square for categorical variables.

b Based on N = 656

Table 3. Patient characteristics associated with HDS and non-HDS use

Characteristic	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Age (years)	0.99 (0.99, 1.01)	1.01 (0.99, 1.03)
Sex		
Female	0.94 (0.60, 1.48)	0.87 (0.55, 1.40)
Male	1.0	1.0
Race		
White	1.98 (1.05, 3.74)	1.54 (0.80, 2.98)
Non-white	1.0	1.0
Primary Language		
English	4.78 (1.15, 20.00)	4.32 (1.01, 18.49)
Non-English	1.0	1.0
Education level		
>12 yrs	2.24 (1.13, 4.45)	2.25 (1.09, 4.65)
≤12 yrs	1.0	1.0
No. of medications	1.01 (0.93, 1.08)	1.02 (0.95, 1.11)
Years of continuous care		
≥3	0.82 (0.69, 0.98)	0.80 (0.66, 0.97)
<3	1.0	1.0

OR = odds ratio; CI = confidence interval

Discussion

We examined the use of HDS among adult ambulatory patients using prescription drugs in a secondary analysis of a study of ADEs. We found that one in six patients used at least one dietary supplement along with their prescription medications. Echinacea, gingko biloba, glucosamine, omega-3 fatty acids, and garlic were the most commonly used supplements. Compared to nonusers, users had higher levels of education, were English speakers, and had fewer years of continuous primary care. A similar percent of HDS users had an ADE compared to nonusers (29 percent vs. 24 percent), a difference that was not statistically significant. However, we found potential drug-HDS interactions among 14 of 101 patients, and many of these interactions were potentially serious or life threatening.

Table 4. Potential drug-HDS and non-HDS interactions

Herb	Interacting drug	No. of interactions	Interaction severity[a]	Quality of documentation regarding interaction[a]	Description of interaction
St. John's wort	SSRIs	1	*MAJOR*	*Fair*	Increased risk of serotonin syndrome
	Oral contraceptives	2	*MAJOR*	*Good*	Decreased contraceptive effectiveness
	Benzo-diazepines	1	*Minor*	*Fair*	Reduced benzodiazepine effectiveness
	Statins	1	*Moderate*	*Fair*	Reduced atorvastatin & simvastatin effectiveness
Ginkgo biloba	SSRIs	7	*Moderate*	*Fair*	Increased risk of serotonin syndrome
	Antiplatelet agents[b]	5	*MAJOR*	*Fair*	Increased risk of bleeding
	NSAIDs	2	*MAJOR*	*Fair*	Increased risk of bleeding
	Nifedipine	1	*moderate*	*Fair*	Increased risk of nifedipine side effects
	Trazodone	1	*MAJOR*	*Poor*	Excessive sedation and potential coma
	Anti-convulsants	1	*Moderate*	*Fair*	Decreased anticonvulsant effectiveness
	Buspirone	1	*Moderate*	*Fair*	Changes in mental status
Garlic	Antiplatelet agents[b]	1	*Moderate*	*Fair*	Increased risk of bleeding
Ginseng	Nifedipine	1	*Moderate*	*Fair*	Increased risk of nifedipine side effects

a Based on MICROMEDEX classification.

b Aspirin was the only antiplatelet agent used by supplement users.

Although the news media have publicized cases of ADEs related to HDS,[20] few prior studies have examined the prevalence of drug-HDS interactions.[13, 21, 22] The rate of potential drug-HDS interactions in our study (25 percent) was greater than previous reports of drug-HDS interactions.[13, 21, 22] The rate was similar to the high rate of drug-drug interactions in studies of outpatients, where researchers have reported potential ADE rates of 9.2 percent to 70.3 percent of any severity, and 1.2 percent to 23.3 percent for more serious events.[23, 24, 25, 26, 27, 28, 29, 30] Our study also contributes to the literature in demonstrating that many drug-HDS interactions are potentially serious or life threatening.

How can we account for the number of potentially serious drug-HDS interactions in this study? It is possible that the commercial databases for classifying these interactions overestimate the severity of interactions, in part, because they rely on case reports to identify such events—a reporting bias. Because HDS are unregulated, rigorous premarket testing is not required, and as a result, the clinical importance of HDS-related ADEs and interactions are not well characterized. Another possibility is that HDS-drug interactions represent a serious and under-recognized hazard in clinical care. If patients and clinicians were better informed about the prevalence and potential severity of these interactions, perhaps they would be more cautious about the concurrent use of prescription or over-the-counter (OTC) medications and HDS.

Our findings regarding the prevalence of HDS use are consistent with previous studies and market data. National estimates of herb use range from 9 to 19 percent.[4, 31, 32, 33, 34, 35, 36, 37, 38] National rates of concurrent use of dietary supplements and prescription medications are 16 to 18.4 percent.[4, 36] Based on market data, the largest-selling herbs during 1999-2000 were ginkgo biloba, St. John's wort, ginseng, garlic, echinacea, and saw palmetto (Information Resources, Inc. Jan 1, 1999). In the same year, ginseng, ginkgo biloba, glucosamine, St. John's wort, and echinacea were reported to be the most commonly used HDS.[36] However, our results are inconsistent with several ambulatory care studies that found rates of use of up to 57 percent.[13, 21, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48] Differences may be due to practice type,[22] patient population,[13,] geographic variation,[48] differing definitions of dietary supplements,[13, 21] or secular trends. For example, two studies included vitamins and minerals in their definition of dietary supplements, thus accounting for a greater prevalence of reported dietary supplement use.[13, 21]

Like previously published national studies,[31, 32, 36, 49] we also found that HDS use was common in middle age, among women, among those with more than a high school education,[31, 32, 49] and with concurrent use of prescription or OTC medications.[36] Our results also corroborate work showing that complementary and alternative medicine users are more likely to have a place to go for usual care, to have a customary medical care provider, and to have seen a medical professional in the past 12 months.[37] All the patients in our study had a usual primary care provider, although higher HDS use was associated with less than 3 years of continuous care.

Our study offers several implications for clinical practice. First, clinicians may benefit from more effective education about HDS. Despite the widespread use of supplements, some physicians lack knowledge about HDS.[50, 51, 52] Only about half of physicians in one study were able to identify potential interactions between herbs and conventional medications. Educating clinicians about herbs and dietary supplements could help reduce the chance of dangerous interactions.

Second, given the potential for interactions with conventional drugs, health professionals should ask patients about their use of HDS and non-HDS. Our findings support the Joint Commission requirement that HDS and non-HDS use be included in patients' medication lists.

Third, electronic order entry systems should include drug-HDS alerts for potentially dangerous interactions. Given the large number of different drug-HDS combinations, physicians would benefit from the support of electronic knowledge databases that include information about the most serious drug-HDS interactions.[53, 54, 55]

Our study has several limitations. First, because we studied only four primary care practices, our results may not be generalizable. Our sample included many white, English-speaking, college-educated patients in an urban setting. Supplement use by other ethnic groups and in other cultures might differ. Second, we relied on patients' self-reports of HDS use, and they may have underreported. Third, we may not have ascertained completely the contribution of HDS use to ADEs because this information may not have been recorded in the chart or elicited accurately in the patient interviews. Fourth, our study was powered to examine ADE rates in primary care practices with and without computerized order entry systems. Although we found a slightly higher rate of ADEs among HDS users than nonusers, the study had only 16 percent power to examine this association. A study with a larger sample size would allow researchers to evaluate the impact of HDS use on ADEs.

Our results suggest that the use of herbs and dietary supplements is common in adult primary care. Although we observed no increased rate of ADEs among patients using supplements compared to nonusers, we identified many potentially serious interactions between these agents and conventional medications. Improvements in eliciting information about the use of HDS and non-HDS and providing electronic decision support for interactions between supplements and medications may be important for preventing ADEs in ambulatory care.

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Using Home Visits to Understand Medication Errors in Children

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Abstract

Current research methods are not well designed to detect medication errors that occur at home. We developed home visit methods to investigate home medication errors in children with chronic conditions. These methods include observation of parent administration of medication to the child by a trained nurse observer who takes detailed ethnographic notes; review of all prescription and over-the-counter medications for dispensing errors, pill counts, and medication reconciliation; and parent interviews to identify barriers to effective home use of medications, prior home medication errors that parents are aware of, and suggestions for systemic improvements. Details about each possible error detected are recorded using a structured data collection form (allergies, medication list, dispensing errors, administration errors). We conducted several pilot home visits and found that this approach has the potential to help understand home medication errors in order to develop interventions to improve the safety of medication self-management.

Introduction

Despite over 3,000 publications about medication safety over the last 5 years, there continue to be "enormous gaps in the knowledge required to implement a safe medication-use system," according to the July 2006 Institute of Medicine (IOM) report, *Preventing Medication Errors*.[1] This report called for research on the rate of errors in ambulatory care, particularly home care and pediatric care, and support for medication self-management. Among children, the rate of potentially dangerous medication errors is three times that of adults and outpatient wrong dose ordering errors are common, due to the complexity of weight-based dosing.[2, 3, 4, 5, 6] Although the majority of pediatric medications are taken in the home, data on pediatric medication errors in the home setting are limited, and risks for children with chronic conditions, who use many medicines, may be great.[7, 8] Research methods are needed to describe errors in the home use of pediatric medications.

Medical record review is not well suited for detecting medication administration errors.[9] The most efficient and accurate method to detect medication administration errors in the hospital setting is through direct observation of nurses by a trained researcher.[10, 11, 12] It is reasonable to expect that direct observation would also be a good method of detecting medication errors in the home setting, and so we sought to develop comparable methods. To that end, we reviewed the literature, developed home visit methods, and conducted a pilot study. Each of these steps is described in separate sections in this article.

Literature Review

We searched PubMed, Cochrane Collaborative, Up-to-Date, and Clinical Evidence for all articles relevant to home medication errors. We identified a total of 13 articles related to parent administration of medications to children; only one included visits to the home (Table 1). We also identified 10 articles related to adult patient medication errors (Table 2).

Table 1. Literature related to home medication errors in children

Study	Methods	Setting	Findings
Alander, et al 2000[19]	Retrospective chart review	Two hospitals	322 patients with acetaminophen overdose included 10 with dosing errors with therapeutic intent over 10 years.
Arnhold, et al 1970[29]	104 home visits	Parents recruited from group practice	Only 1/3 of teaspoons measured within 4.5 - 5.5 ml; 4/104 parents misunderstood dosing instructions; 15 were noncompliant.
Cohen 2006[18]	Case series	Email solicitation of medical examiners	3 deaths reported from National Association of Medical Examiners from over-the-counter (OTC) cold medicine; all children under 6 months of age.
Frush, et al 2004[28]	Randomized controlled trial	Parents waiting in pediatric emergency department	Color-coded method to measure acetaminophen reduced average deviation from correct dose from 26% deviation to 2% deviation
Gunn, et al 2001[17]	Case series	1 hospital	3 admissions for OTC cold medicine overdoses with therapeutic intent, including one death; all in children under age 3 years.
Heubi, et al 1998[14]	Case series	Cases from 1 hospital, FDA reports, literature	47 cases of hepatotoxicity after multiple overdoses of acetaminophen found, with 20 surviving, including 4 liver transplant patients.
Henretig, et al, 1989[13]	Case series	One hospital	2 children with hepatotoxicity due to repeated acetaminophen overdoses, both survived without transplantation.
Li, et al 2000[20]	Cross-sectional parent survey	Urban academic pediatric emergency department	51% of parents reported an inaccurate dose of antipyretic given prior to ED visit; children under age 1 year were more likely to receive inaccurate doses.

Table 1. Literature related to home medication errors in children (continued)

Study	Methods	Setting	Findings
Litovitz 1992[15]	Case series over 8 days	Calls to poison control centers associated with use of dispensing cups	34 reported cases over 3 days in children and adults.
Marinetti, et al, 2005[16]	Case series	Montgomery County Coroner's office	10 deaths associated with toxic levels of OTC cold medicine in children under age 12 months; 8 due to accidental overdose.
McMahon, et al, 1997[26]	Stratified randomized convenience sample	General pediatric clinic	Parents of children on liquid antibiotics underwent education, went to pharmacy, returned with med, and demonstrated dose. Verbal instructions only: 37% correct; 32 - 147% of dose). Verbal instructions: syringe with line marked: 83% correct (20 - 152% of dose). Verbal instructions: marked syringe, dose demonstrated: 100% correct
Taylor, et al 2006[27]	Prospective observational study	Outpatient pediatric oncology clinic	Parents of 69 children with cancer demonstrated how they would administer home medications (71% brought from home; 29% given sample medications in clinic); 12 medication errors detected; 5 prescribing errors.

Table 2. Literature related to home medication errors in adults

Study	Methods	Setting	Findings
Bedell, et al 2000[36]	Patient report, bottle review	Outpatient private practice	76% of patients had discrepancies between the medication list from the medical record and patient report or bottles from home medicines. 51% medications not recorded; 29% not taking medications on list; 20% wrong dose.
Britten, et al 2000[35]	Qualitative interviews	20 general practices in England	14 types of misunderstandings between physicians and patients involved in prescribing decisions are described.

Table 2. Literature related to home medication errors in adults (continued)

Study	Methods	Setting	Findings
Ernst, et al 2001[46]	Prescription renewals compared to med lists	Family medicine outpatient clinic	26% of requests were different from the medical record medication list; 59% were medications not on the list.
Field, et al 2007[31]	Chart review, computer-generated signals, and incident report review	Medicare enrollees in a group practice	Review of patient-related errors from Gurwitz study.[30] 32% administration errors, 42% changed medication regimen, 22% did not follow clinical advice about medication use (e.g., avoid alcohol on this medicine).
Gandhi, et al 2003[32]	Chart review, telephone interview	4 adult primary care practices	25% of patients had an adverse drug event. 19 of these events could have been ameliorated by physicians but were not because the patient failed to report symptoms
Gurwitz, et al 2003[30]	Chart review, computer-generated signals, and incident report review	Medicare enrollees in a group practice	13.8 preventable adverse drug events per 1,000 person-years found. 20% of these related to patient use of medications in the home.
Kuzel, et al 2004[34]	38 interviews	Random digit telephone dial	221 “problematic incidents” including problems with access, doctor-patient relationship, and racism. 23% resulted in physical harm to patients.
Manley, et al 2003[40]	Monthly drug interviews	Hemodialysis center	30% of patients had discrepancies between interview reports and their medication list. 50% placed patients at risk for adverse events and 30% for dosing errors.
Richelman, et al, 2007[37]	Patient survey	Outpatient oncology clinic	27% of patients had a drug interaction, 8% of patients were taking duplicate medications, most often corticosteroids, proton-pump inhibitors, or benzodiazepines.
Weingart, et al, 2005[38]	Patient interview, chart review	4 adult primary care practices	Only 69% of medication-related symptoms were discussed with patient’s doctor. This resulted in injury in 2 of 90 patients and in excessive pain that could have been ameliorated had they been discussed with doctors in 19 of 90 patients.
Wilson, et al 2006[39]	Cross-sectional survey	Community dwelling Medicare beneficiaries, national sample	27% of those who skipped doses did not discuss with doctor. 39% of those with cost-related nonadherance did not discuss with a doctor.

Pediatric Studies

Many studies have used parent report to detect administration errors. Several of these have described pediatric patients injured by parents who accidentally gave the children an overdose of medications.[13, 14, 15, 16, 17, 18, 19] In a case series of calls to poison control centers, Litovitz described 34 dispensing cup errors due to one of three causes: (1) confusing teaspoon and tablespoon, (2) assumption that the dispensing cup was the unit of measure, or (3) assumption that the full dispensing cup was the actual dose.[15] Heubi, et al., described cases of pediatric hepatotoxicity after multiple overdoses of acetaminophen, speculating that parents may have run out of pediatric acetaminophen and used the adult preparation for convenience, misread the label, or administered more medication because the child's fever was high.[14] Marinetti, et al., described 10 deaths from over-the-counter cold medicine toxicity in infants, of which 8 were accidental overdoses.[16]

Several surveys asked parents to recall their child's dose of medications.[20, 21, 22] In a cross-sectional survey of 200 parents of young children in an emergency department (ED), Li, et al., found that 51 percent of parents reported giving acetaminophen doses that were incorrect.[20] Yin, et al., surveyed caregivers of young children waiting in an ED and found that parents with a lower reading comprehension were more likely to use a nonstandard measuring instrument (e.g., a teaspoon rather than a measuring cup or syringe).[21] However, in another study, where less than 67 percent of parents were able to accurately repeat back medication use instructions, parental literacy level was not associated with use of preventive pediatric services or ability to follow medical instructions.[22]

We found three studies that discussed pediatric medication errors involving parents.[23, 24, 25] Of these, two surveyed parents about hypothetical errors.[23, 24] One interviewed parents about "mistakes, errors, and carelessness"; only two errors were described.[25] None of the studies systematically interviewed parents about medical errors, and none addressed errors in ambulatory care.

Three studies involved observation of parent administration of medication in the clinic or ED.[26, 27, 28] McMahon, et al., performed a study in which parents of young children with ear infections who had been prescribed liquid antibiotics were randomized to three forms of instruction about medications.[26] Parents then went to the pharmacy, filled the prescription, and returned to the clinic to demonstrate the dose using syringes and teaspoons provided by research staff. Only 37 percent of parents who received verbal instructions measured the correct dose. Of those with verbal instructions and a syringe with a line marked, 83 percent measured the correct dose. Of those with verbal instructions, a syringe with a line marked, and the dose demonstrated, 100 percent measured the correct dose.

In a study by Taylor, et al., parents of 69 children diagnosed with cancer demonstrated in clinic how they would dose their child's home medications.[27] Parents were given measurement tools, and those without their own medication were provided medications to use. Administration errors occurred with 7 percent of medications.

Frush, et al., developed a color-coded system to avoid home liquid acetaminophen administration errors.[28] Parents used a syringe with colored lines to measure doses and a chart to select the correct lines. Parents in an ED waiting room who used the color-coded system had an average

dose deviation of 1.7 percent compared to 25.8 percent for parents who used conventional measuring methods.

In each of these studies, measurement instruments were provided by research staff, so problems with measurement instruments could not be assessed. In 1970, Arnhold, et al., visited the homes of 104 pediatric patients recruited from private practices.[29] During the visits, researchers measured the teaspoons used to dispense medications and measured the quantity of the medication remaining to assess missed doses. Several parents stopped the medication before completing the prescribed course of treatment. Fifteen parents skipped medication doses. Of the teaspoons used to dispense the medications, one-third measured between 4.5 ml and 5.5 ml, 40 were less than 4.4 ml, and eight were above 5.5 ml. To our knowledge, this is the only study using home visits to study patient or parent medication administration errors.

Studies of Adults

Two medical record review studies in adult patients detected and described home medication errors.[30, 31, 32] Gurwitz studied outpatient adverse drug events among older individuals using medical record review, computer generated signal review, and incident report review, and found a rate of 13.8 adverse drug events caused by error per 1,000 person-years.[30] Of those adverse drug events caused by error, 20 percent were related to patient use of medications in the home. Field, et al., further described these patient medication errors which fell into six categories:[31]

1. Medication filling and refilling errors.
2. Medication administration errors.
3. Failure to perform some parts of the medication regimen.
4. Failure to follow clinical advice.
5. Failure to report information to providers.
6. Failure to adhere to followup.[31]

Gandhi, et al., used medical record review and patient report to describe adverse drug events and errors in outpatient adults. She described 19 adverse drug events that could have been ameliorated by proper medical care but were not because patients failed to inform their doctors of symptoms.[32]

Some investigators have used telephone interviews combined with chart review in adult patients to improve the detection of adverse drug events and errors.[32, 33] However, telephone interviews will only identify errors of which parents or patients are aware, making this method susceptible to reporting bias and to missing accidental measurement errors parents may not have noticed.

In adult patients, several studies have used in-depth interviews about medication errors and communication problems.[34, 35, 36, 37, 38, 39, 40, 41] Three studies about communication failure indicated that many patients who skip doses, stop medications, or experience side effects from medications do not inform their doctors.[36, 39] Britten described several misunderstandings about medication prescribing, such as a patient changing a dose without informing the doctor and two doctors each telling the patient to use a different dose.[35] Riechelman asked outpatients with cancer to describe what medications they took at home, and found that 8 percent were taking duplicate medications, and 27 percent had at least one potential drug interaction.[37] A fourth study

evaluated discrepancies between home medication regimens in physician medication lists in transplant patients and found patient errors and ordering errors to be common.[42]

In our review of the literature, rates of parental administration errors ranged from 0 to 63 percent of administrations. More than half of pediatric papers were case series. Only one study involved home visits, where all medications, including over-the-counter medications, could be reviewed, measurement instruments could be inspected, and administration could be observed.[29] Taken together, the findings from this literature review reveal that current methods used to detect errors, such as chart review, are not well designed for pediatric home administration errors. While the literature is limited, parent medication administration errors appear to be frequent, and parents may be unaware of the errors they are making. Research from adult patients indicates that communication problems between patients and physicians regarding medication use commonly occur and may affect patient safety.

Methods

Our approach to using home visits (Figure 1) to examine medication errors in children has four components: (1) observation of medication administration, (2) medication review, (3) in-depth parent interviews about errors in home medication use, and (4) event classification. Prior to the home visit, the research assistant obtains the patient's age and diagnoses from the chart. The patient's weight, height, and all medication allergies are also recorded. Dose and frequency of administration for all medications prescribed for home use are obtained from the chart and from copies of prescriptions written during the clinic visit (if available). All prescriptions are checked for physician errors. All medication doses are recalculated to check for dosing errors. Doses that deviate more than 10 percent from the correct dose are considered dosing errors.

Observation of Medication Administration

Home visits are to be performed by a study nurse or pharmacist trained in nonintrusive and nonjudgmental research methods. Methods used for direct observation are modeled after those used in hospitals to identify administration errors[10, 11, 12, 43] and refined based on pilot testing. These established methods employ ethnographic techniques, rooted in social anthropology.[44, 45] This technique emphasizes context in understanding errors and can "allow comparison between what people say and what they actually do."[45] The study nurse is instructed to observe the administration of each dose and not to review the patient's medication list until after performing direct observation of medication administration.[44]

Visits should be scheduled at the time when most medications are being administered to the child and when the person who normally administers medications to the child is available. Children and adolescents who self-administer medications should be asked to participate in the home visit.

The person who normally administers the medications is asked to administer medications exactly as he or she normally would, as if the study nurse were not present.

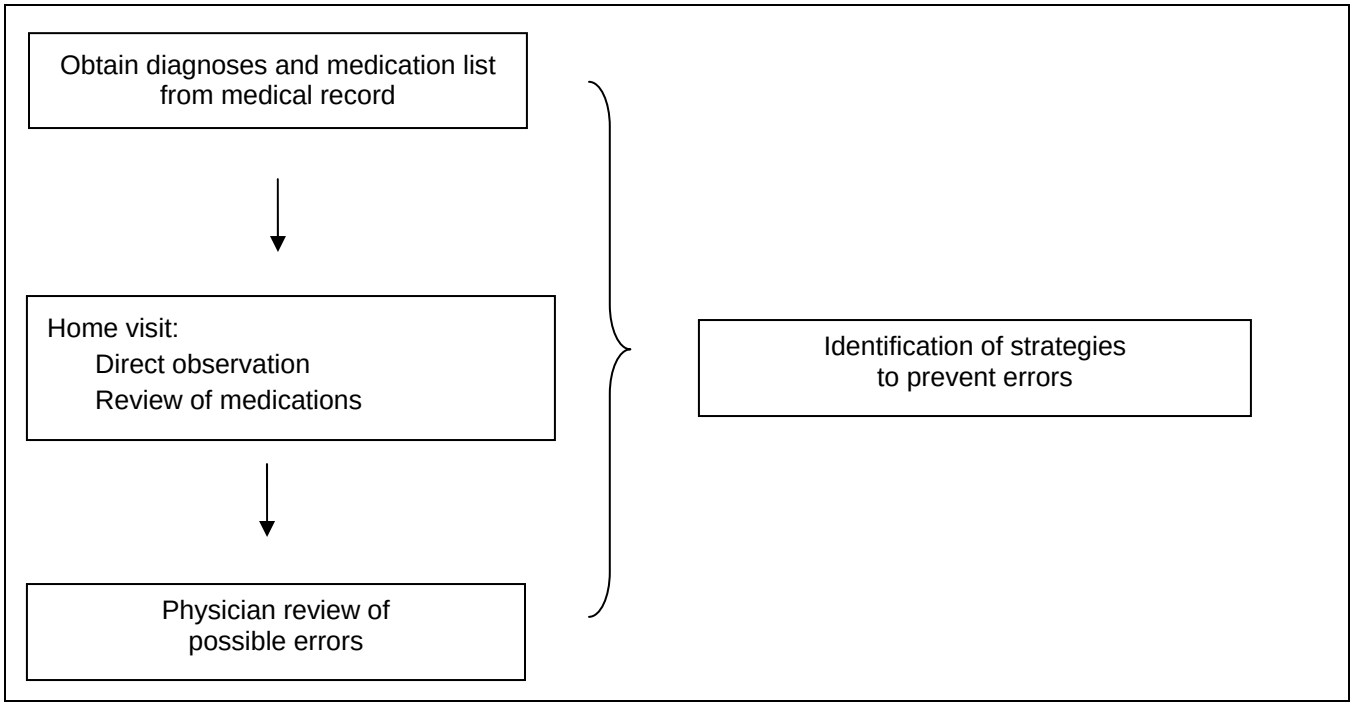

Figure 1. Home visit methods.

The administration of each medication is observed and detailed, and notes are recorded in a study diary. In addition to medication administration, medication preparation—such as pouring nutritional formula into a gastrostomy tube—and related procedures—such as flushing lines or giving medication with food—are observed as described by Flynn and colleagues in the inpatient setting.[10] As in hospital-based studies, observations and documentation are both quantitative and qualitative.[11, 12] Qualitative data include detailed field notes taken in diaries, which are recorded immediately after observation.

Quantitative data include specific details about medication administration, such as which measurement tool is used and what quantity of medication is given. Quantitative data are recorded on the home visit data collection form (Appendix A), along with demographics, allergies, the medication list, dispensing errors, and administration errors. The allergy section and medication list are completed prior to the home visit, using data obtained from the patient's medical record. Any other medications being taken by the child that are not on the medical record medication list are added during the home visit. After direct observation, for each error noted, the type of administration error is recorded on the medication list. The medication label is reviewed, and any dispensing error noted is recorded on the medication list. Pill counts or volumes and fill and expiration dates are recorded. A detailed description of any error noted during the home visit is written on an error reporting form (Appendix B).

Errors that potentially place the patient at risk that are detected by the research nurse but not noticed by the administering parent are intercepted prior to medication administration. The study nurse then contacts the prescribing physician to inform the physician of the error and ask for orders on how to handle the situation.

Medication Review

All medication labels are reviewed for dispensing errors. In addition, to detect missed dose errors, pill counts are taken for pills and volumes for liquid medicines. The percent of doses taken, the primary outcome for this part of the study, is calculated in the following fashion:

$$\text{\% doses taken} = \frac{\text{(\# pills dispensed – \# left in bottle) x 100}}{\text{(\# days between dispense date \& home visit date) (\# doses per day) (\# pills per dose)}}$$

or

$$\text{\% doses taken} = \frac{\text{(volume dispensed – volume in bottle) x 100}}{\text{(\# days between dispense date and home visit date) (\# doses per day) (volume per dose)}}$$

Prior research demonstrates that pill counts are 93 percent sensitive and 52 percent specific at detecting patients who miss more than one in four doses of medication.[46]

In order to assess accuracy of the outpatient medical record medication list compared to which medications the patient is actually taking—which is a Joint Commission goal[47]— the medications the child is taking in the home are compared with the medical record medication list. After observation of medication administration and pill counts, the labels of all medications in the home are compared to a list of home medications obtained from the chart, and the parent is asked about any discrepancies. The primary measure for this portion of the study is percent of home visits where the prescription medication list is accurate. Discrepancies between the medication list and the home medication regimen are not counted as errors because, based on prior research, we expect more than half of medication lists to be inaccurate.[37, 38, 39, 48, 49] However, any discrepancy considered by the study nurse to be potentially dangerous is recorded as a possible error.

In-depth Interviews

In-depth, qualitative interviews are conducted as the final step during home visits. The purpose of the interview is to identify parents' perception of barriers to effective home use of medications for their child(ren) with chronic disease and to describe possible prior medication errors occurring in the clinic or in the home. Parents are also asked for recommendations for systemic changes that would help them to avoid outpatient and home medication errors in the future. Questions were developed from a clinic-based pilot survey of parents of children with chronic conditions and were refined in pilot home visits (Table 3). Interviews are audiotaped, transcribed, and reviewed for themes. Themes are grouped in broad categories that reflect types of medication delivery system failures (e.g., use of the wrong measurement device or failure to complete the entire course of the medication) or categories of error-prevention strategies. Knowledge gaps and misconceptions that may contribute to parents' errors, parents' perceptions of barriers to using medications exactly as prescribed, and parents' recommendations for changes that would facilitate their giving medications exactly as prescribed are carefully considered.

Table 3. Questions for in-depth parent interviews

Repeat questions for each medication:
1. Why does your child take this medication?
2. How much of the medication are you supposed to give and how often?
3. Have you had any trouble giving it?
4. When was the last time, prior to now, that your child took this medication?
5. How often does your child miss medication at home? Why? Tell me more about this.
6. Has your child ever had a problem from the medication that you didn't expect? Tell me more about this.
7. Often, parents make adjustments in how they follow the physician's instructions at home. Some parents might feel that their child doesn't need a particular medication any longer; others might feel that their child is having more problems, and so might increase the dose. Have you ever made any adjustments like that?
8. Often, parents give their child's medication one way, and then realize later on that the doctor had meant for them to give it some other way. Have you ever had that experience?
9. Has your child ever had an error in her care? Tell me more about this.
10. Was there any harm to your child from the error? Any extra medicines or tests?
11. How do you think the error could have been avoided?

Physician Review and Event Classification

All possible medication errors detected during observation, medication label review, and potentially dangerous errors in medication reconciliation are recorded on a standardized error reporting form. This form is an adaptation of forms utilized in outpatient adults and inpatient children, with modifications based on results of the literature review and pilot work[30, 50] (Appendix B). The error reporting form provides space for a detailed description of the incident, including information about any systems failures that may have caused the error and any patient injury that resulted from the error. Additional sections support this description, by naming the system failures that occurred and possible improvements to the system that may have prevented the error.

Possible medication errors are subsequently reviewed by two trained study physicians. Physician reviewers independently classify each possible error in one of the following four categories:

1. A medication error causing injury to the patient (preventable adverse drug event).
2. Medication error that had the potential to cause injury but did not injure the patient (serious medication error without injury).
3. Medication error with little potential for injury.
4. Not a medication error (excluded from the study).

A medication error is an error in drug ordering, dispensing, administering, or monitoring.[30, 32, 51] A serious medication error is a medication error that causes harm or has substantial potential to cause harm.[11] For example, if a mother administers twice the appropriate dose of methotrexate to her 5 year old with leukemia, this is a serious medication error because of the potential for injury, even if it does not cause any harm.

Failure to administer a prescribed medication is considered an error in medication administration.[10] For those incidents categorized as a preventable adverse drug event or a serious medication error without injury, severity of the error is also rated. Severity is rated as:

1. Clinically significant but not serious.
2. Serious. A serious medication error would be a failure to administer pneumocystis pneumonia prophylaxis to a patient with cancer for several weeks, due to confusion about the purpose of the medicine.
3. Life threatening.
4. Fatal.

Pilot Visits

In order to understand the feasibility of these methods, we performed 12 pilot home visits to children with chronic conditions taking at least one daily medication. One challenge we found in scheduling the visits is that home medication administration usually occurs before school or during evening hours for those children enrolled full time in school. One visit took place at 7:00 am, one at 3:00 pm, three at 10 am, and seven between 6:00 and 7:30 pm. Home visits lasted from 15 minutes to 2 hours, with a median duration of 20 minutes. During these 12 home visits, we observed the administration of 23 medications and reviewed the labels of 78 medication bottles.

Reliability

To test the reliability of these methods, two observers observed four medication administrations and reviewed eight medication bottles together during home visits; observers independantly detected the same three errors during the visit.

Interrater reliability of independent classification of events by physicians before coming to consensus was determined and expressed as a kappa statistic. For classification of an event as a preventable adverse drug event, serious error without injury, or error with little potential for harm, interrater reliability for the 16 events captured during the home visits was 0.72 (95 percent, CI 0.4 - 1.0). Interrater reliability for severity was not calculated due to the small sample size.

Preliminary Data

The rate of errors from our pilot work was surprisingly high. In 12 pilot home visits, 16 medication errors were detected, including seven serious medication errors. Errors detected during observation included the use of a twice-a-day medication once a day and carrying EpiPen®s for a nut allergy that were expired. Parents discussed problems with medication use such as using syringes where none of the markings were visible or a child taking and vomiting

twice-concentrated medication for 5 days before the family recognized that the medicine was incorrectly reconstituted.

When assessing an error-detection method, it is also important to consider whether the data collected during home visits will be valuable in developing systems-based improvements. Prior research compared observation to two other commonly used methods—chart review and incident report review—for the detection of medication errors in hospitals and skilled nursing facilities. Direct observation was found to be more efficient and accurate than chart review and incident reports.[10]

Limitations

One concern with the use of observation to measure error rates is the idea that people will avoid making errors when being observed (Hawthorne effect). However, in a study of direct observation of nurses for administration errors, Dean found no difference between observation and no observation periods in the percentage of omitted doses and no change in the error rates with repeated observations.[43] In addition, our literature review demonstrates that parents are frequently unaware that they are making errors and are therefore unable to consciously avoid making errors when being observed. Study nurses are trained in nonintrusive, nonjudgmental methods to avoid altering the normal pattern of home medication use. Our pilot work indicates that error rates, even with observers present, may be high in any case.

Researchers face unique ethical challenges in using direct observation to measure errors.[45] For instance, the researcher normally attempts to avoid altering the environment while observing it. In this setting, if the observer notices a potentially dangerous medication error that is about to negatively affect the patient, the observer is obligated to intercept the error prior to medication administration.

It is possible, however, that given a few more seconds, the parent may have intercepted the error himself or herself. In pilot testing, the research nurse never observed an error that required her intervention. In addition, home visits require a significant time commitment, compared with chart review or telephone survey methods. Nevertheless, in inpatient research, direct observation is considered a better method to detect administration errors.

Conclusion

In the outpatient setting, pediatric home medication errors have not been studied with sufficiently rigorous methods to provide the information needed to guide development of interventions to support self-management of medicines. Existing methods are not adequate to comprehensively capture home medication errors. Building on existing research, we described the use of home visits with observation of medication administration to identify pediatric home medication errors. Reliability of study methods—as measured by interobserver agreement and interrater event classification agreement—in pilot studies was good.

These home visit methods, designed to measure rates of home medication errors among children with chronic conditions, have several other possible applications. The home visit could be expanded to measure rates of errors in medication use among the entire family, rather than just

children with chronic disease. Similarly, other vulnerable populations—such as the elderly, Medicaid patients, or non-English-speaking patients—may benefit from this line of research. These home visit and ethnographic methods may aid those interested in cultural differences in medication use, compliance, and disease care. Health literacy could be evaluated during home visits to assess the relationship between parent health literacy and parent administration errors. Similar methods could also be used to understand medication use by children with chronic disease in schools. These methods may be used to develop and test interventions to prevent systems failures associated with serious medication errors in outpatient children with chronic disease.

In summary, little information is available about pediatric medication errors in the home, where the vast majority of pediatric medications are taken, in part because current research methods are not adequate for the home setting. Building on approaches utilized in outpatient adults and children and on prior inpatient observation studies of nurse administration, we developed home visit methods to detect pediatric home medication errors. These home visit methods may be used to understand and quantify home medication errors in many different patient populations, providing information needed to better support safe medication self-management.

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Appendix A: Home Visit Data Collection Form

To be completed for each home visit even if no possible error is detected.

1. Study ID number ____ ____ ____ ____

2. Date of home visit ____ ____ /____ ____/____ ____

3. Time of home visit ____ ____ : ____ ____

MILITARY TIME

4. Age: ____ ____

5. Weight: ____ ____ ____ pounds **OR** ____ ____ ____ kilograms

6. Height: ____ ____ ____ inches **OR** ____ ____ ____ centimeters

7. Gender: male female

8. Diagnoses at the time of the home visit:

a. _____

b. _____

c. _____

e. _____

f. _____

g. _____

h. _____

i. _____

k. _____

l. _____

m. _____

n. _____

h. _____

9. Persons participating in interview: _____

_____

_____

_____

10. Who administered medication during this visit?

Mother

Father

Child

Grandparent

Sibling

Visiting nurse

Other: _____

Table 11. Allergies to medicines and reaction

Medical record ☐ NONE		Interview ☐ NONE	
Drug	**Reaction**	**Drug**	**Reaction**
A.		A.	
B.		B.	
C.		C.	
D.		D.	
E.		E.	
F.		F.	
G.		G.	
H.		H.	

Med list from chart medication list. Verify against bottle label, note differences, observe medication administration, note errors.

Name	Conc.	Volume of dose or pill strength	Route	Freq. of dose	Fill date	Exp date	Medication label the same? (If no, write in letter from list 12b)	Administration Correct? (If no, write in letter from list 12c)
A.							Y: ____ N: _____	Y: ____ N: _____
B.							Y: ____ N: _____	Y: ____ N: _____
C.							Y: ____ N: _____	Y: ____ N: _____
D.							Y: ____ N: _____	Y: ____ N: _____
E.							Y: ____ N: _____	Y: ____ N: _____
F.							Y: ____ N: _____	Y: ____ N: _____
G.							Y: ____ N: _____	Y: ____ N: _____
H.							Y: ____ N: _____	Y: ____ N: _____
I.							Y: ____ N: _____	Y: ____ N: _____
J.							Y: ____ N: _____	Y: ____ N: _____
K.							Y: ____ N: _____	Y: ____ N: _____
L.							Y: ____ N: _____	Y: ____ N: _____
M.							Y: ____ N: _____	Y: ____ N: _____

Med list from chart medication list. Verify against bottle label, note differences, observe medication administration, note errors. (continued)

Name	Conc.	Volume of dose or pill strength	Route	Freq. of dose	Fill date	Exp date	Medication label the same? (If no, write in letter from list 12b)	Administration Correct? (If no, write in letter from list 12c)
N.							Y: ____ N: _____	Y: ____ N: _____
O.							Y: ____ N: _____	Y: ____ N:_____
P.							Y: ____ N: _____	Y: ____ N:_____
Q.							Y: ____ N: _____	Y: ____ N:_____
R.							Y: ____ N: _____	Y: ____ N:_____
S.							Y: ____ N: _____	Y: ____ N:_____
T.							Y: ____ N: _____	Y: ____ N:_____

12b. Label Differences:

a. No longer takes
b. Different concentration
c. Different volume
d. Different route
e. Different frequency
f. Different indication
g. Additional med not listed in medical record med list

12c. Administration differences

a. Administration
b. Wrong frequency
c. Wrong route
d. Wrong instrument (e.g., tablespoon instead of teaspoon)
e. Unable to see lines on syringe
f. Overdose
g. Underdose

Pill Count

a. Too many pills
b. Too few pills
c. Volume too small
d. Volume too large
e. Medication expired
f. Drug interaction

13. Was a possible error found? Yes____ No ____

If yes, please list the event # and complete an error- reporting form for each different event.

____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____ ____

Appendix B: Error Report Form

Only to be completed for index cases with possible errors

If a single index visit has more than one error, a separate form should be completed for each possible error

DESCRIPTION OF EVENTS INVOLVED IN ERROR

Please include period leading up to, during, and following the error. It is important to emphasize data that would help determine if: 1) an error in care occurred; 2) the error reached the patient or was intercepted before reaching the patient; and 3) the error injured the patient.

Brief Description of error _____

Date of error_____

Detailed Description of error

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

What was the final outcome of the error? _____

_____

_____

_____

_____

_____

DETAILS OF ERROR

2. Person primarily responsible for the error:

☐$_1$Oncologist ☐$_2$ Fellow ☐$_3$ Other physician ☐$_4$ Nurse practitioner

☐$_5$ Physician assistant ☐$_6$ Nurse ☐$_7$ Pharmacist ☐$_8$ Patient or family

☐$_9$ None ☐$_{10}$ Unable to determine ☐$_{11}$Other_____

3. At what level in the process did the *primary* failure occur? ____

4. Additional levels where failure occurred?

PROCESS LEVELS

1. Pharmacy prepares/dispenses
2. Medication administration
3. Monitoring for side effects
4. Other_____
5. Unable to determine

5. Was anyone notified of the error? (may select more than one)

☐$_1$Physician ☐$_2$ Fellow ☐$_3$ Nurse ☐$_4$ Physician assistant

☐$_5$ Pharmacist ☐$_6$ Patient or family ☐$_7$ None ☐$_8$ Unable to determine

☐$_9$ Other_____

6. Who initially discovered the error?

☐$_1$Physician ☐$_2$ Fellow ☐$_3$ Nurse ☐$_4$ Physician assistant

☐$_5$ Pharmacist ☐$_6$ Patient or family ☐$_7$ Secretary

☐$_8$ None ☐$_9$ Unable to determine ☐$_{10}$Other_____

OUTCOMES OF ERROR

7. Was any additional vital sign monitoring performed because of the error?

☐$_0$ No ☐$_1$ Yes

8. Was any additional medication given because of the error?

☐$_0$ No ☐$_1$ Yes

9. Was any additional blood work performed because of the error?

☐$_0$ No ☐$_1$ Yes

10. Was any additional radiologic test performed because of the error?

☐$_0$ No ☐$_1$ Yes

11. Was any additional invasive procedure (other than blood work and radiologic tests) performed because of the error?

☐$_0$ No ☐$_1$ Yes

12. Was any additional clinic visit made because of the error?

☐$_0$ No ☐$_1$ Yes

13. Was any additional outpatient consult made because of the error?

☐$_0$ No ☐$_1$ Yes

14. Was any additional emergency room visit made because of the error?

☐$_0$ No ☐$_1$ Yes

15. Was the patient admitted to the hospital because of the error?

☐$_0$ No ☐$_1$ Yes

16. Was the patient admitted to the intensive care unit because of the error?

☐$_0$ No ☐$_1$ Yes

17. Did the error injure the patient?

☐$_0$ No (*If no, please stop here)* ☐$_1$ Yes

Drug A

18. Name of drug involved _____

19. Dose of drug _____

20. Unit of drug dose:

☐$_1$ Drops ☐$_2$ Grams ☐$_3$ Kilograms ☐$_4$ International Units

☐$_5$ Liters ☐$_6$ Micrograms ☐$_7$ Milligrams ☐$_8$ Milliliters

☐$_9$ Units ☐$_{10}$ Other_____

21. Route of drug ordered:

☐$_1$ Central venous access ☐$_2$ Intramuscular ☐$_3$ Topical ☐$_4$ Oral

☐$_5$ Intravenous ☐$_6$ Subcutaneous ☐$_7$ Sublingual

☐$_8$ Other _____

22. Frequency of drug ordered_____

23. # doses received in the 24 hours previous _____

24. # doses received in last week _____

Drug B

Please complete only if there were more than one medication involved in the error being described. ***If there were two different medications involved in different errors complete a separate event identification form.***

25. Name of drug involved _____

26. Dose of drug _____

27. Unit of drug dose:

☐$_1$ Drops ☐$_2$ Grams ☐$_3$ Kilograms ☐$_4$ International Units

☐$_5$ Liters ☐$_6$ Micrograms ☐$_7$ Milligrams ☐$_8$ Milliliters

☐$_9$ Units ☐$_{10}$ Other_____

28. Route of drug ordered:

☐$_1$ Central venous access ☐$_2$ Intramuscular ☐$_3$ Topical ☐$_4$ Oral

☐$_5$ Intravenous ☐$_6$ Subcutaneous ☐$_7$ Sublingual

☐$_8$ Other _____

29. Frequency of drug ordered_____

30. # doses received in the 24 hours previous _____

31. # doses received in last week _____

Drug C

Please complete only if there were more than two medications involved in the error being described. ***If there were two different medications involved in different errors complete a separate event identification form.***

32. Name of drug involved _____

33. Dose of drug _____

34. Unit of drug dose:

☐$_1$ Drops ☐$_2$ Grams ☐$_3$ Kilograms ☐$_4$ International Units

☐$_5$ Liters ☐$_6$ Micrograms ☐$_7$ Milligrams ☐$_8$ Milliliters

☐$_9$ Units ☐$_{10}$ Other_____

35. Route of drug ordered:

☐$_1$ Central venous access ☐$_2$ Intramuscular ☐$_3$ Topical ☐$_4$ Oral

☐$_5$ Intravenous ☐$_6$ Subcutaneous ☐$_7$ Sublingual

☐$_8$ Other _____

36. Frequency of drug ordered_____

37. # doses received in the 24 hours previous _____

38. # doses received in last week _____

Developing a Community-Wide Electronic Shared Medication List

Ron Stock, MD; Eldon R. Mahoney, PhD; Dawn Gauthier, MIS; Linda Center; Mary Minniti, CPHQ; James Scott, MD; Marc Pierson, MD; Lori Nichols

Abstract

This study demonstrates the feasibility of developing a medication list e-tool from multiple medication data sources that is accessible to patients, caregivers, and health care practices and is "portable" or accessible wherever patients go. A single medication list was created electronically by integrating data from the Shared Care Plan, a Web-based personal health record, and clinic electronic medical records (EMRs) to create a single, Web-based view. The feasibility of sharing accurate, updated information with everyone involved in a patient's care was explored using innovative technology and training, while motivating health care professionals and patients to communicate medication regimen changes. Qualitative and quantitative evaluation methodologies were utilized to assess the impact of interventions among three outpatient clinic sites and 108 adult patients. Through extensive collaboration, clinic sites improved the accuracy of patient EMR medication lists, medication safety culture improved, and patients found the electronic medication list beneficial.

Introduction

Thousands of deaths and injuries occur annually in hospitals due to preventable medical errors, and preventable drug reactions are a leading cause of these errors.[1] An Institute of Medicine (IOM) report[2] suggests that medication errors leading to adverse drug events (ADEs) are as frequent or more frequent in the ambulatory setting. According to the report, a key approach to developing and maintaining a safe medication management system is to establish a strong clinician-patient relationship, improve patient medication self-management and availability of information, develop a culture of medication safety in the health care setting, and use health information technology to improve medication management. Only through engagement of multiple stakeholders in the medication management process will medication safety improve.

Despite the fact that medication prescribing is the most frequently used therapeutic intervention and that nearly two-thirds of office visits end with a prescription, relatively little is known about the ADEs that occur in the ambulatory clinic setting.[3] ADEs occur frequently in the outpatient clinical setting, and as many as a quarter of them are preventable.[4, 5] A recent survey using an ICD-9-CM code methodology[6] found that during the period 1995-2001, 2.5 to 3.7 per 1,000 physician office visits and 1.8 to 3.4 per 1,000 hospital outpatient visits involved ADEs.

In the outpatient setting, medication errors and subsequent ADEs can result from physician/provider-related, health system/practice process-related, or patient-related factors or a

combination of these factors. To understand these factors, it is important to examine the processes involved in each of these three domains. Although little is known about the processes and/or risks in all domains, probably the least known are patient-related processes and risks from the patients' perspective.

From the ambulatory practice perspective, it is assumed that management of an accurate medication list would result in fewer medication errors and, therefore, fewer ADEs across the continuum of care. A fundamental problem in the outpatient setting occurs when a clinician does not have immediate access to an accurate list of the medications a patient is taking. Lack of access to accurate information presents a serious gap that prevents providers from delivering optimal health care services and increases the risk of medical errors. Another challenge is to implement reliable medication safety practices in every outpatient clinical setting and across the care continuum. Discrepancies between medications recorded in clinical office files and patient-reported medications are common and involve all classes of medications, prescribed and over the counter. These discrepancies present a particular risk to older patients who are taking multiple medications.[7]

This project was based on the premise that creating an accurate medication list and making it available to patients and caregivers at each encounter within the broader health care system would enhance medication safety. We hypothesized that patient engagement is a critical component for maintaining an accurate medication list. Effective interactions between the health care system and patients, especially those on complex medication regimens, are uncommon in today's health care environment. The challenge is to implement reliable medication safety practices in every outpatient setting, with involvement of patients and all their caregivers across the care continuum.

Methods

The project's goals were accomplished through three objectives, to:

1. Develop a single, updated, and reconciled medication list and care plan that would be electronically and manually accessible to patients and their caregivers, physicians, alternative care practitioners, clinics, hospitals, home health aides, nursing homes, and others who participate in the care of each patient.
2. Develop a medication reconciliation process that involves the patient, clinic, and other health care providers or care settings.
3. Measure perceptions of patients and clinicians regarding safety and satisfaction with the new electronic tools; measure use of the electronic tool by patients and clinicians; measure the degree to which medication discrepancies occurred in the clinic setting; and use focus group interviews to analyze the impact of the process on culture change.

Quantitative and qualitative methodologies were used to assess the impact of the community-wide electronic shared medication list. Objective medication list accuracy outcomes and the perceptions of patients and clinicians on safety and satisfaction with the tools were explored.

Participants

PeaceHealth is a nonprofit, integrated health care system that operates hospitals and clinics in Washington, Oregon, and Alaska. In 1990, the PeaceHealth leadership set out to develop a sophisticated information management system that would support a standardized electronic medical record that was shared by each of its health care facilities. Over the past decade, PeaceHealth has developed new tools and software programs that can provide medical information accurately and efficiently.

In 2002, PeaceHealth, on behalf of the Whatcom County Community Health Improvement Consortium in Bellingham, WA, was awarded a Robert Wood Johnson Foundation Pursuing Perfection Initiative grant to create innovative chronic care services focused on strengthening patients' ability to manage their own care and to create a more effective community health care system. One outcome of that project was the Shared Care Plan (SCP), an online personal health record (www.sharedcareplan.org) designed with feedback from patients and health care professionals. One feature of the SCP is a medication list maintained by patients, who then share that information with their family and health care professionals.

Based on their interest in improving medication safety and experience in quality improvement projects, three ambulatory care clinics were chosen to participate in this project:

1. Senior Health and Wellness Center (SHWC), in Eugene, OR, with four geriatrician providers and two nurse practitioners.
2. Center for Senior Health (CSH), in Bellingham, WA, with seven adult medicine and geriatrician providers.
3. Health Associates at Peace Harbor (HAPH), in Florence, OR, with 13 adult care providers.

A medication safety quality improvement team—involving providers, nurses, administration, pharmacy, and patients—was formed at each pilot site. Adult patients were recruited from all practice sites to test the SCP and electronic medication management processes.

The Single, Updated, and Reconciled Electronic Medication List

The clinic medication process-mapping phase and technical development of tools occurred simultaneously. Technical design questions included:

1. How can technology support the medication reconciliation process?
2. How can existing medication data be shared?
3. How can PeaceHealth build on what has already been learned from existing electronic tools?

To answer these questions, a user-centered design methodology[8] was employed, in which the tasks, needs, wants, and limitations of the end users within each system were given attention at each stage of the design process. From as many source systems as possible, including the patient, the intent was to collect information on one page that would allow health care professionals to better identify and document within their systems exactly which medications each patient was taking.

Initially, a shared medication list functionality was developed within the SCP that provided medication information from the provider-managed electronic medical record (EMR) and the

patient's documentation via a single Web page. This Web page, called "Meds On Record" (MOR), was available within the SCP medication list function. Because of the recognized value in showing allergies and intolerances when prescribing medications, that information was also made available through the MOR. The medication list included both prescribed and nonprescribed medications. This project also developed functionalities within the SCP for patients to document their personal health goals and to store electronic copies of their advance directive.

"Meds On Record" Functionality

With patients entering medication data into their SCPs and health care professionals entering medication data into their EMRs, it was possible to build interfaces to the participating systems in order to create the Meds On Record view (Figure 1).

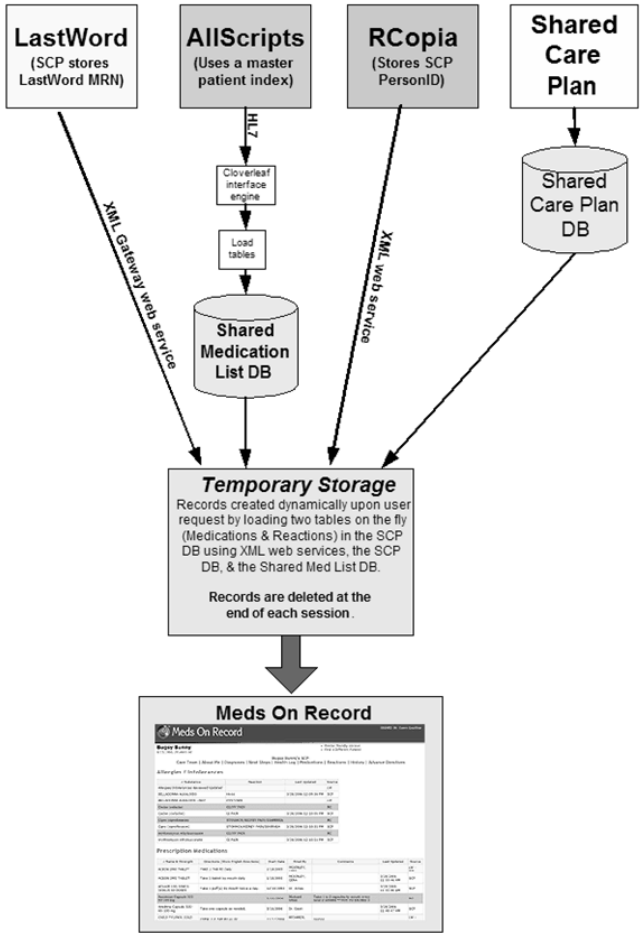

Figure 1. "Meds On Record" functionality diagram.

The participating health care entities and their respective clinical systems included:

- PeaceHealth, using GE/IDX LastWord.
- Oregon Cardiology, using AllScripts™ Medications.
- Three independent clinics in Whatcom County, Bellingham, WA, piloting Dr First[SM] Rcopia.

The LastWord and RCopia interfaces were built using XML Web service technology to pull real-time data from source systems instantly upon user request. The AllScripts interface utilized HL7 messages sent through an interface engine and then stored in a database each night. As a best practice for privacy and security, the database that brings together all of the sources for display in Meds On Record deletes all data after each individual user session.

To match patients among the different systems, an existing master patient index that included both PeaceHealth and Oregon Cardiology data was used to match patients among the SCP, LastWord, and AllScripts. RCopia used demographic data from the SCP to match patients in its system and then store the patients' unique SCP IDs in the RCopia system.

Patients accessed Meds On Record through their SCPs, while health care professionals accessed it from a Web link within their clinical systems. In the LastWord (EMR) system, health care professionals received notification by a pop-up alert whenever they activated the record of a patient who was participating in the project. This made it easier for clinicians to remember to implement the process of medication reconciliation using the Meds On Record tool for these patients. Patients could also print their medication list and personal health information in a wallet-sized format that they could carry with them.

The Ambulatory Medication Reconciliation Process

The three clinic pilot teams mapped current medication reconciliation processes at the beginning of the study, identified "best practices" in medication reconciliation as the goal, and worked toward achieving that goal. At the time of process mapping, the electronic tool was not used but was considered later for the best practices process design. The SHWC team was most successful using small steps of change. Newly defined processes were implemented at the practice level, with one provider and one nurse, plus full participation of the receptionists and patients. The HAPH group had been working on medication list reconciliation for 2 years, thus requiring integration into an already re-engineered medication process. The CSH was undergoing reorganization and a physical site move early in the study but by early summer 2005, was fully participating in process redesign.

As study participants, patients at the three sites were asked to maintain an accurate medication list in their SCPs. Through interview processes and participation from patients in the quality improvement teams, a better understanding of patient and caregiver use of the SCP and Medication List functionality helped the clinic team understand how to integrate the clinic's medication management process with patients.

Project Evaluation

The following quantitative and qualitative measures were utilized to evaluate the impact of interventions used in this project:

Ambulatory medication safety culture survey. An ambulatory-focused survey[9] measuring the degree to which a culture of medication safety was present in a clinic was developed using components from previously studied safety culture surveys, which were primarily hospital-based.[10, 11, 12] Baseline data from office staff were collected for the three clinics prior to intervention (June 2004 for two clinics, August 2004 for the third). A followup survey for all three clinics was carried out in June 2005.

Patient experience with the shared medication list (PESML) survey. Each clinic was asked to recruit 35 patients over the age of 18 as active participants in process improvement and design. After PeaceHealth System IRB approval, patients were identified and recruited to participate, and participant informed consent was obtained. Patients were registered into the SCP and trained in the use of the tool. A 19-question telephone survey (PESML) was conducted 60 days after patients signed up for the SCP to solicit information about their experiences using the shared medication list and SCP.[13]

Patient satisfaction survey. PeaceHealth regularly conducts patient satisfaction surveys with a probability sample of patients following an office visit. Two questions were added for patients from the participating clinics to evaluate their perceptions of medication safety in those clinics. These two questions were: (1) "I am confident that my primary provider knows all of the medications I am currently taking"; and (2) "I am confident that all of my health care providers other than my primary doctor know all of the medications I am currently taking."

Medication list discrepancy measure. The aim of this outcome was to measure the degree to which the medications a patient is taking are known by the primary care physician or practice where the patient receives care. A tool was developed to measure the extent of medication discrepancies between what the patient was taking and what was documented in the medical record. Using a standardized tool and process,[14] a sample of 15 to 30 patients at each of the three primary care clinics was randomly selected at baseline (pre-intervention), and then a new sample was chosen monthly to measure the percentage of medication discrepancies. One clinic (Clinic B) chose to obtain discrepancy data from all patients coming for an ambulatory visit during the post-intervention period. A percent of medication discrepancies was calculated for each patient by dividing the number of meds the patient was taking that were not on the med list, or the number of meds the patient was not taking that were still on the med list (discrepancies), by the total number of medications that would accurately reflect the patient's medication list.

Focus group and observational review. An experienced outside consultant was hired to query the Agency for Healthcare research and Quality (AHRQ) Leadership Oversight Group and document the leadership team's perceptions of this project and change as a result of the project. This group included the regional executive sponsors and leadership and project management (both technical and process). A baseline focus group was conducted September 15, 2004, with a follow up conducted June 15, 2005. Additionally, interviews and observations of patients, caregivers, health care professionals, clinic staff, and technical support staff were recorded throughout the study.

Results

Ambulatory Medication Safety Culture Survey

Staff, including physicians from all three pilot clinic sites, completed an online PeaceHealth Ambulatory Medication Safety Culture Survey[9] pre- and post-intervention. The total number of clinic staff completing the survey in the first administration was 62 (response rate = 60 percent; Clinic A: N = 20; Clinic B: N = 16; Clinic C: N = 26). In a second administration 12 months after the intervention, the total number of staff survey completions was 80 (response rate = 77 percent; Clinic A: N = 20; Clinic B: N = 28; Clinic C: N = 32). The 16-item survey showed good internal consistency reliability with minimal ceiling and floor effects. Cronbach alpha was 0.94 and 0.90, respectively, for the two administrations. The internal consistency reliability was maintained in all clinic sites (Clinic A = 0.96; Clinic B = 0.90; Clinic C = 0.94).

Item difficulty. Item difficulty is the degree to which a survey item is easy or hard to agree to. In this survey, the difficulty of the items has a hierarchical structure, since to have measurement of a culture of medication safety, there must be a sufficient range of item difficulties. Since the item difficulties indicate how difficult it is to put each item's referenced component in place in

building a culture of medication safety, information can be provided in terms of the developmental progress in building such a culture in the clinic environment. The most difficult item for staff to endorse was, "In this clinic we have defined protocols about reporting and discussing medication mistakes that almost happened and could have harmed a patient but did not." Nearly half of the staff felt a need for defined protocols for reporting and discussing medication mistakes. Approximately 20 percent of the staff would be concerned if a member of their family were a patient there due to concerns about possible medication errors.

Clinic differences and change over time. To evaluate differences among the three clinics and change over time in the culture of medication safety, a univariate general linear model analysis was conducted on survey scores. Clinic and year (2004, 2005) were fixed factors with no covariates. There was a significant between subject's effect for clinic ($F = 9.65$, $P < 0.0001$) and year ($F = 17.5$, $P < 0.0001$) and a significant clinic-by-year interaction ($F = 14.28$, $P < 0.0001$). The nature of the interaction was that Clinic A and Clinic B significantly improved in culture of medication safety from 2004 to 2005, while there was no significant change in Clinic C (95 percent CI). At baseline in 2004, there were no significant differences among the three clinics, but in 2005, Clinics A and B had a significantly higher culture of medication safety score than Clinic C (95 percent CI).

Patient Experience with the Shared Medication List (PESML) Survey

To assess patients' experience with the SCP medication list, 104 patients (Clinic A, N = 38; Clinic B, N = 34; Clinic C, N = 34) were recruited from the three pilot clinics. Of all consenting participants, 59 percent accessed their SCP within 60 days of signing up for participation (N = 61): Clinic A, N = 26; Clinic B, N = 18; Clinic C, N = 17). A completed telephone survey was obtained from 51 participants (response rate = 84 percent; Clinic A, N = 26; Clinic B, N = 10; Clinic C, N = 15). Only patients who had accessed their SCP were contacted for the telephone survey. Table 1 summarizes the telephone survey responses.

Patient Satisfaction Survey

Using a patient satisfaction telephone survey, 486 patients receiving care in the three pilot clinics answered two questions about their perception of providers' knowledge of the medications they were currently taking. Overall, 95.8 percent of patients agreed or strongly agreed with the statement, "I am confident that my primary provider knows all of the medications I am currently taking"; 62.1 percent of patients strongly agreed with this statement. Although lower than for the primary care provider, 92.6 percent of patients agreed or strongly agreed to, "I am confident that all of my health care providers other than my primary doctor know all of the medications I am currently taking"; 45.6 percent of patient responders strongly agreed with this statement. These rates of confidence did not differ significantly by clinic. Answers to these two confidence questions were not related to the patient's age or sex. Testing differences in mean confidence rating of patients surveyed in different months (January 2005 to June 2005) showed no difference in confidence rating by month ($F < 1$ for both questions).

Table 1. Summary of patient experience with shared medication list (PESML) telephone survey results

- A majority (61 percent) of patients reported going online to look at their medication list.
- A large majority of patients found the SCP easy to access and the medication list easy to use, to read (100 percent), and to print (94 percent).
- 96 percent of patients thought the medication list contained all the information they needed to understand what medications they were taking, when to take them, and how to take them.
- Patients were more likely to take a printed copy of the medication list to providers other than their primary care physician.
- An equal number of patients never took a printed copy of their medication list to a primary care physician visit or always took a printed copy to a primary physician.
- A majority (78 percent) of patients said that having a medication list made them confident that wherever they went for health care, the providers would know which medications they were taking, and they would not be given a medication they should avoid.
- Most patients said they would indicate on the medication list whether they were not taking a prescribed medication (92 percent) and would report herbals and other over-the-counter supplements (97 percent).
- A majority of patients felt that having a medication list made them more confident they were taking their medications correctly (78 percent), and they felt their primary care physician knew which medications they were taking (86 percent).
- 97 percent of patients said that having their medication list made it easier for them to take an active role in their health care.
- 90 percent of patients said that having a medication list improved the communication between themselves and their health care providers.
- 83 percent of patients said that having a medication list made them more aware of the possibility of medication errors; the same percentage said it reduced their fear that a medication mistake would be made.

Medication List Discrepancy Measure

It was hypothesized that the number (percent) of medication discrepancies between the practice medical record and what the patient is actually taking would decrease following the intervention. Using a standardized tool and process,[14] a sample of 15 to 30 patients at each of the three clinics was randomly selected at baseline (pre-intervention), and a new sample was chosen monthly at two clinics to measure the percentage of medication discrepancies over time. The third clinic (Clinic B) acquired discrepancy data from most patients daily during a 5-month postintervention study period. From the three primary care clinics, 903 patients provided medication use data (Clinic A, N = 178; Clinic B, N = 614; Clinic C, N = 111).

Change in medication discrepancy. To examine whether the clinics reduced medication list discrepancies over time, a statistical process control analysis was conducted for each clinic. The analysis first examined whether a process was in place, with a statistical process control analysis assessing whether the variability across the months following intervention was in control (2-sigma control limits). If the variability was out of control, there was no process in place, and it was not meaningful to see if the process was in control.

If the process was found to be in place, it was then determined whether it was in control and for how long by examining the mean percent medications discrepant by month using 2-sigma control limits. Clinic A developed and maintained a clear process until 10 months post-intervention, at which time the variability exceeded the control limits. In Clinic C, with the exception of months 9 and 10 post-intervention, the variability in percent medications discrepant was within control, and Clinic C did develop a process of medication reconciliation. Month 9 was characterized by excessive variability, which was followed by a sharp decline in process variability in month 10. In the pre-intervention month for Clinic C, the process was out of control, but there was an initial sharp decline in discrepant medications, and that decline continued steadily throughout the study period. Of the three clinics, Clinic B most definitively developed a process from month 1 onward and maintained that process in control for the same period. Figure 2 shows that all three clinics developed a process and reduced the percentage of medication discrepancies over the postintervention period.

Comparison of data at baseline and 3 months post-intervention. When all clinic data were combined at baseline and compared to 3 months post-intervention, the evidence indicated that the accuracy of medication lists improved. At baseline, 20 percent of medication lists examined in the three clinics reported no discrepancies (i.e., the patients' medication lists were the same as those listed in the office medical record). Three months after initiating the intervention, over 50 percent of the medication lists had no discrepancies, and the number of very large discrepancies declined considerably (Figure 3).

Focus Group and Qualitative Findings

Leadership oversight focus groups. The purpose of the focus group interviews was to qualitatively capture key lessons from the project. Key findings from the focus groups, as perceived by project and health system leadership include:

- Although leadership initially thought improvement in medication list accuracy required a technical solution, most came to realize the larger, more critical piece was the interpersonal communication between the clinic team, patient, and IT technicians.
- The importance of issues related to accountability, culture, and communication at various levels of staff involvement from providers to nurses to receptionists was acknowledged.
- The recommendation to include patients in team meetings and discussions on process improvement was believed to assure success.
- Patient participation in the development of the tool and the process work promoted a positive culture change in participating clinical practice groups.
- Patient electronic medication list functionality needs differ from the needs of health care professionals.

In summary, leadership observed that an organizational transformation occurred from fear of including patients on quality improvement teams to full participation and transparency of clinical challenges and processes. Much was learned about the key components to successful quality improvement, such as building infrastructure to support all participants, including patients and staff, stakeholder ownership and engagement in the process and development, utilizing small steps of process change, and finding value in continuous feedback from patients and staff.

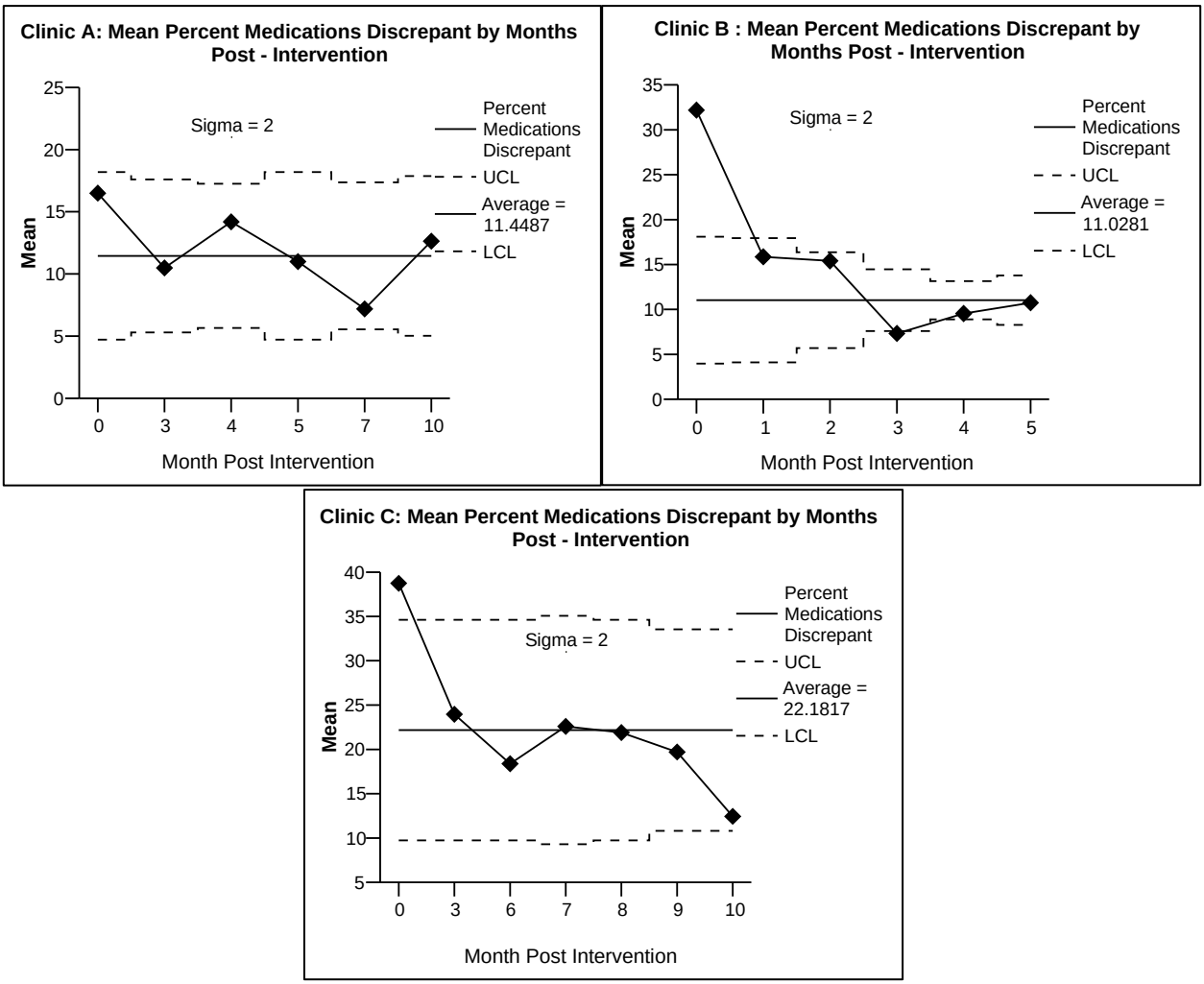

Figure 2. Postintervention mean percent medication discrepancies by clinic.

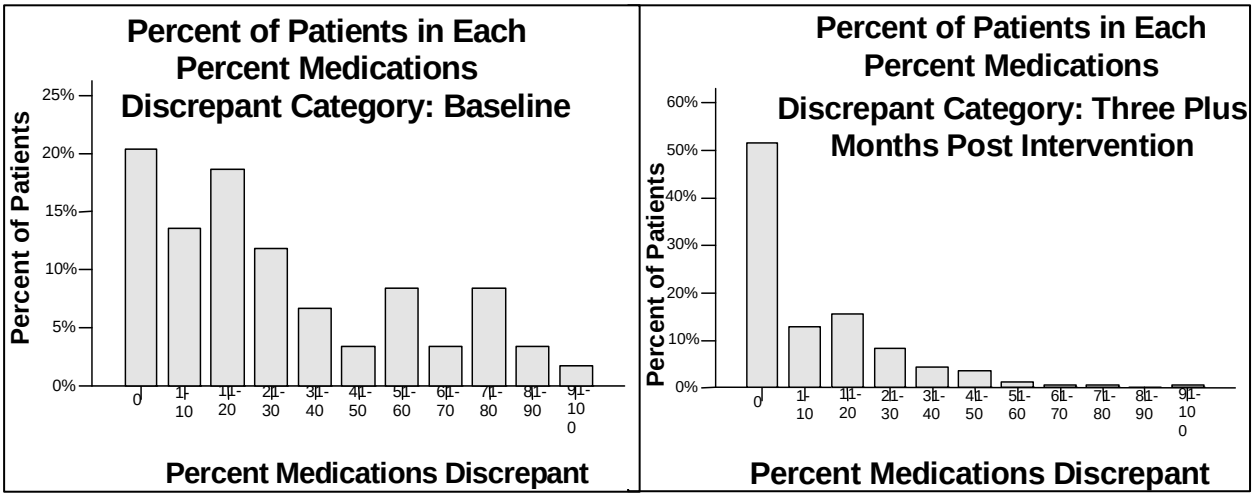

Figure 3. Baseline and postintervention medications discrepancy percentage for all participants.

Finally, there is still a need to address the use of multiple electronic tools in the health care system, to identify the tool(s) of choice, and/or to determine how they should work together.

Health care professional observations. Early discussions with providers and staff dealt with the definition of an "accurate" medication list, who would be accountable for maintaining the medication list, and which medications—prescribed or nonprescribed—belonged on the list. To many health care professionals, the accurate list was the one they documented in the EMR, which identified the medications they had prescribed. After much discussion, it was concluded that the dictionary definition of "accurate"—"conforming exactly to fact; errorless"—meant that knowing which medications patients chose to take was a critical component.

A consensus was reached that accountability for an accurate medication list needed to be shared between the health care system and the patient. It was agreed that the primary care physician or the "medical home" chosen by the patient was responsible for maintaining the EMR medication list. In addition, a need was identified to update EMR medication functionality. The EMR had been designed as a prescribing tool, but it does not easily support maintaining an accurate, continuity-based medication list that reflects which medications patients are actually taking.

It was evident that having team members who were participating in the study at the point of service led to improved outcomes. Engagement declined as team membership was removed from the actual patient/provider interface. For example, in one clinic the team included the pilot provider, a nurse, and two patients. At another site, where they did not have direct provider or patient participation, staff and provider engagement was perceived to be lower.

Patient participation on the clinic team was a new experience for everyone involved. Early on, concerns were raised about sharing internal process problems with patients. Qualitative feedback from some participating clinicians revealed a fear that patients might lose trust if they were aware of the challenges and complexity of our medication processes. However, patients involved with the team reported that they knew there were internal process problems, and they were glad to be asked to help resolve them. The patient trust level actually improved, and the team became comfortable with patient engagement.

Patient observations. Patients made assumptions about provider access to their information and about their ability to communicate problems. Patients' attitudes about communicating with their health care professionals were key to achieving an accurate medication list. Interviews revealed:

- Several patients were surprised at how complex prescribing and maintaining an accurate medication list could be, particularly when multiple providers in multiple care settings were involved.
- Most patients thought their doctor knew exactly which medications they were taking, regardless of whom in the community might have prescribed them.
- Patients often did not tell their doctor that they were not taking a prescribed medication due to its cost or because it made them ill. These patients were either afraid of "disappointing" the doctor or having the doctor "yell" at them.

Caregivers of more frail and vulnerable participants found the SCP to be a valuable information resource. Relatives or close friends assisting with patients' care were especially grateful to have a portable repository of personal health information. During an emergency, the SCP provided

them with the information they needed to communicate with the health care professionals providing care.

Discussion

The process of medication management in the ambulatory care setting was improved through a collaborative effort among patients, clinical practices, information technology support staff, and the health care system. Each partner experienced a unique set of "key lessons."

Patients

Patient involvement in the quality improvement process and technical development of tools was critical. This new relationship with health care providers led to clinical work practices that were more effective, efficient, and sustainable. Patients found the electronic medication list to be beneficial and desirable. The ability to see their EMR medication list alongside their own SCP list in the "Meds On Record" view made them feel safer and more confident that fewer medication errors would be made. Patients also felt the use of this tool improved communications with their providers. Tools such as the Healthwise® medication information software program, which was linked to the electronic medication list, created new opportunities for educating patients about their medications. Many patients assessed the value of the e-tools according to their perception of how much their participating clinician used it.

Patients perceive that their providers know more about their medications and have more confidence in the accuracy of their medication lists than is actually true. This was evidenced at baseline by high patient satisfaction scores despite a high degree of clinic site medication list discrepancy scores. Some patients do not fully understand the importance of maintaining an accurate medication list, and so, there was surprise when study participants realized its complexity. Patient engagement in the process is the only way to develop and maintain an accurate medication list. However, patients need to be educated and trained to maintain such an accurate list. This knowledge and the skill to effectively interact with the health care system will require focused attention to health literacy principles, something that is not commonly addressed in our health care system today. This is especially important for patients with complex medication regimens.

Only 59 percent of patients who signed up for the SCP in this study actually accessed their SCP within the first 60 days after signing up. Although this finding was somewhat low, there could be a number of explanations. For example, once patients' information was documented in the SCP, they might not have felt a need to access their data unless there was a change in meds or care plan. Many of the patients in this study were relatively healthy and functional, and so, changes to their care plan were probably infrequent and therefore presented no need to access their SCP. It has been observed subsequently that patients tended to access their SCP immediately prior to a health care encounter. So if these encounters were infrequent, then their access to the SCP would also be infrequent.

Patients might also be unaccustomed to accessing an electronic tool to maintain or share their medical information. Although most participants were comfortable using a computer, interacting with the health care system using this tool was new to them and would likely have required

training. Patients reported that they were likely to use the tool if they knew their health care provider was also looking at their information or engaged with the patient to use the information in their SCP. It could be that patients who perceived that their provider was not using or looking at their information might lead them to use the tool less often. Clearly, a more longitudinal evaluation of the SCP would provide meaningful information about usage of the tool.

There were some technical usability issues and fear of technology among patient participants. Many older adult participants were intimidated by the concept of recording and monitoring medications electronically. The SCP print feature, which produces a wallet-sized list of medications, was a successful tool for patients who preferred a paper record. As younger adults age, technical skills likely will improve, and these tools will be more acceptable.

Health Care Clinics

Two major improvements occurred in the clinic setting: (1) the clinic medication safety culture increased, and (2) the accuracy of the medication lists in the EMR improved. The Ambulatory Medication Safety Culture Survey proved to be an effective tool for providing feedback to clinic staff regarding the perception of medication safety in their work environment. Discussion among clinic staff about how they could make their clinic safer was an effective intervention.

Redesigning the process by which medications are managed in the clinic practice workflow led to more accurate medication lists. Staff and providers were highly motivated to raise the awareness of medication safety and to design more reliable processes to ensure accurate medication lists. Five key process components were developed to guide medication management at every ambulatory clinic encounter:

1. All patients are asked to provide a current list of their medications.
2. Clinic personnel review the list with the patient at the beginning of the office visit.
3. The patient's medication list and EMR medication list are reconciled and documented.
4. Any new prescribed medications are checked for interactions/conflicts with an updated, reconciled medication list in the EMR.
5. The patient is offered a paper copy of an updated, reconciled medication list at the end of the visit.

In one clinic, accuracy of medication lists improved through the process redesign, but the culture of medication safety did not. This raises the issue of whether improving care processes leads to improved safety culture or vice versa. It could be that providers and staff are good at making and following workflow process decisions regardless of the cultural context. Followup will be needed in that clinic to see whether the new workflow processes are sustained, since it is hypothesized that clinic culture might affect work process sustainability. It is also possible that improvement in the culture of safety at that particular clinic would require more than the 12-month period used in this study.

Some clinicians found that medication discrepancies could be reconciled faster using the e-tools, creating more confidence about knowing which medications patients were taking. Clinicians reported more discussions with patients about nonprescribed medications and an improved ability to assess how well patients understood their medications. Overall, clinicians felt this improved communication with patients.

Alternatively, there was a realization that a standardized, reliable medication management office workflow process requires more staff and provider time, which could be a barrier for many clinicians. Studies that demonstrate the downstream benefits and potential cost and time savings with safer medication management practices will be needed in the future.

Health Care System

This project received considerable support, both financially and through advocacy, from the highest levels of PeaceHealth leadership. There was a strong belief that safer medication practices in the ambulatory setting would lead to fewer errors and adverse events in the clinic, emergency department (ED), and hospital. Anecdotally, it was reported that more accurate medication lists reduced time spent in reconciliation within the ED and inpatient units, allowing clinicians to make expedient clinical decisions.

Patient involvement, both in participating in quality improvement projects and in engaging patients to be more actively involved in managing their medication lists, was a key feature that became more ingrained in the organizational culture. This study allowed further exploration and dissemination of patient involvement strategies across other regions in the organization. This level of involvement is now an expectation of all quality improvement projects in PeaceHealth.

The study confirmed the importance of user-centered design methodology in the development of electronic tools to support care, rather than the alternative of developing the tools and then making them work in existing practice workflow. Access to, and relationships with, clinic staff and patients led to a user-friendly tool that is more likely to be used and sustainable over time. Technical staff confirmed that a Web service approach is preferable to databases. Interface building with the three different data sources was resource-intensive, and data from prescribing software does not necessarily lend itself to an effective and efficient medication management process. A free Shared Care Plan CD and Developers Manual have been created for health care systems and entities interested in implementing these tools.[15]

Conclusion

This project demonstrated that it is possible to develop a medication list e-tool from multiple medication list data sources that is accessible to patients, caregivers, and health care practices and is “portable” for use wherever patients go. The process of medication management in the ambulatory setting improved through collaboration among patients, clinical practices, Web support staff, and the health care system. For over a decade, PeaceHealth has had a mission of developing an electronic community health record that would be accessible to all caregivers needing access to these data. This project added another piece to that endeavor and expanded an understanding of the technology and work processes necessary to implement such a record in the community. As a combination of the personal health record functionality found in the SCP and an EMR patient application, PatientConnection is the base concept of a new project to develop a patient portal. The portal work would provide patients and caregivers with an anytime/anyplace Web-based tool to facilitate active communication of accurate, specific information and patient requests or concerns.

Many of the issues, barriers, and successes experienced in this project will likely be repeated as regional health care information networks are developed. This will be particularly true as interfaces are built across disparate electronic systems, as new technologies and vendors emerge, as public-private relationships are formed, and as implementation occurs in systems of care that have different cultures and agendas.

Does a shared electronic medication list reduce medical errors and adverse drug events? Although it appears that medication list accuracy and practice culture improves, it is still not clear that primary clinical outcomes are affected by this intervention. Only through further research that randomizes patients or practices of care with a much larger population followed longitudinally will this question be answered. Also of interest would be whether some patient populations, such as those with more complex medication regimens or with multiple or specific chronic conditions, would reduce their risk of adverse events by participating in this model of care.

Creating medication management processes and improving the culture of medication safety in the ambulatory care setting are critical to improving patient safety. This study has explored, tested, and developed reliable, standardized processes and a tool to measure safety culture that other ambulatory clinics can replicate. These processes and tools can be implemented whether or not electronic tools are available.

Implementation of medication reconciliation and management processes is now occurring in all medical groups across all five PeaceHealth regions. Addressing medication management across the continuum of care has no doubt led to safer care of patients and has had a positive impact on clinic culture across the organization. However, it is a continuing challenge to work with nonaffiliated medical practice groups, specialty groups, pharmacies, long-term care facilities, and others who do not share the same culture or have competing priorities.

Throughout the implementation of this project, innovation and discovery continued to reveal important lessons about engaging patients, ambulatory medication management processes and the electronic tools necessary to support those processes, patients, and health care practices. The next step is to implement, further innovate, and test these tools and processes on a larger scale, such as across an entire community or health care system.

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