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Methodological challenges for patient safety

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Background

- Consistent evidence of failure of poor quality and safety
  - 30-40% patients do not get treatments of proven effectiveness
  - 20–25% patients get care that is not needed or potentially harmful
- Suggests that ensuring quality and safety is a fundamental challenge for healthcare systems to optimise care, outcomes and costs

Schuster, McGlynn, Brook (1998). *Milbank Memorial Quarterly*

Grol R (2001). *Med Care*

Why evaluate quality and safety initiatives?

- Often the perceived imperative ‘to do something’ to improve quality and safety results in a failure to robustly evaluate quality and safety initiatives

‘Rushing to implement poorly tested interventions that target problems of unclear significance may do little to help and ultimately may even discredit the endeavour, an effect that all of us would hope to avoid.’

Forster (2005) CMAJ

Why evaluate quality and safety initiatives?

Findings 19 ASUs were randomly assigned to intervention (n=10) or control (n=9). Of 6564 assessed for eligibility, 1696 patients' data were obtained (687 pre-intervention; 1009 post-intervention). Results showed that, irrespective of stroke severity, intervention ASU patients were significantly less likely to be dead or dependent (mRS ≥2) at 90 days than control ASU patients (236 [42%] of 558 patients in the intervention group *vs* 259 [58%] of 449 in the control group, p=0·002; number needed to treat 6·4; adjusted absolute difference 15·7% [95% CI 5·8–25·4]). They also had a better SF-36 mean physical component summary score (45·6 [SD 10·2] in the intervention group *vs* 42·5 [10·5] in the control group, p=0·002; adjusted absolute difference 3·4 [95% CI 1·2–5·5]) but no improvement was recorded in mortality (21 [4%] of 558 in intervention group and 24 [5%] of 451 in the control group, p=0·36), SF-36 mean mental component summary score (49·5 [10·9] in the intervention group *vs* 49·4 [10·6] in the control group, p=0·69) or functional dependency (Barthel Index ≥60: 487 [92%] of 532 patients *vs* 380 [90%] of 423 patients; p=0·44).

Interpretation Implementation of multidisciplinary supported evidence-based protocols initiated by nurses for the management of fever, hyperglycaemia, and swallowing dysfunction delivers better patient outcomes after discharge from stroke units. Our findings show the possibility to augment stroke unit care.

Methods In the Quality in Acute Stroke Care (QASC) study, a single-blind cluster randomised controlled trial, we randomised ASUs (clusters) in New South Wales, Australia, with immediate access to CT and on-site high dependency units, to intervention or control group. Patients were eligible if they spoke English, were aged 18 years or older, had had an ischaemic stroke or intracerebral haemorrhage, and presented within 48 h of onset of symptoms. Intervention ASUs received treatment protocols to manage fever, hyperglycaemia, and swallowing dysfunction with multidisciplinary team building workshops to address implementation barriers. Control ASUs received only an abridged version of existing guidelines. We recruited pre-intervention and post-intervention patient cohorts to compare 90-day death or dependency (modified Rankin scale [mRS] ≥2), functional dependency (Barthel index), and SF-36 physical and mental component summary scores. Research assistants, the statistician, and patients were masked to trial groups. All analyses were done by intention to treat. This trial is registered at the Australia New Zealand Clinical Trial Registry (ANZCTR), number ACTRN12608000563369.

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Why evaluate quality and safety initiatives?

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Steven M. Asch
Michael Brode
Peg

Background: Organizationally
tive quality improvement effort
been subject to rigorous evaluati
Institute of Healthcare Improve
BTS) on quality of care for chronic heart failure (CHF).
Research Design: We conducted a quasi-experiment in 4 organiza-

Results: Participating and control patients did not differ significantly with regard to measured clinical factors at baseline. After adjusting for age, gender, number of chronic conditions, and clustering by site, participating sites showed greater improvement than control sites for 11 of the 21 indicators, including use of lipid-lowering and angiotensin converting enzyme inhibition therapy. When all indicators were combined into a single overall process score, participating sites improved more than controls (17% versus 1%, $P < 0.0001$). The improvement was greatest for measures of education and counseling (24% versus -1%, $P < 0.0001$).

Conclusions: Organizational participation in a common disease-targeted collaborative provider interaction improved a wide range of processes of care for CHF, including both medical therapeutics and education and counseling. Our data support the use of programs like the IHI BTS in improving the processes of care for patients with chronic diseases.

Why evaluate quality

Effects of
Care of Pa

Bruce E. Landon, MD,
Peter V. Marsden, Phl

Background: Mult
ment programs are
quality improvement
ment their effectiven

Objective: To eval
ment collaborative
infected patients.

Design: Controlled

Setting: Clinics rece
hensive AIDS Resour

Participants: 44
matched by location

Measurements: Ch
from medical record
patients at each study
effectiveness of antiretroviral therapy, screening and prophylaxis, and access to care.

Intervention: A multi-institutional quality improvement collaborative (the "Breakthrough Series").

Results: 9986 patients were studied. Clinical and sociodemographic characteristics of the intervention and control patients were similar ($P > 0.05$). Differences in changes in the quality of care were not statistically significant. The proportion of patients with a suppressed viral load increased by 11 percentage points (from 40.1% to 51.1%) in the intervention group compared with 5.3 percentage points (from 43.6% to 48.8%) in the control group, but this difference was not statistically significant ($P = 0.18$). In addition, rates of appropriate screening tests and prophylaxis did not differ between intervention and control sites.

Limitations: It was not possible to perform a pure randomized trial of the intervention or to assess other measures of quality, such as adherence and satisfaction.

Conclusions: This prospective, matched study of almost 10 000 patients found that a quality improvement collaborative did not significantly affect the quality of care. Additional research is needed to improve methods of teaching and implementing quality improvement programs to achieve better results.

Improvement programs to achieve better results.

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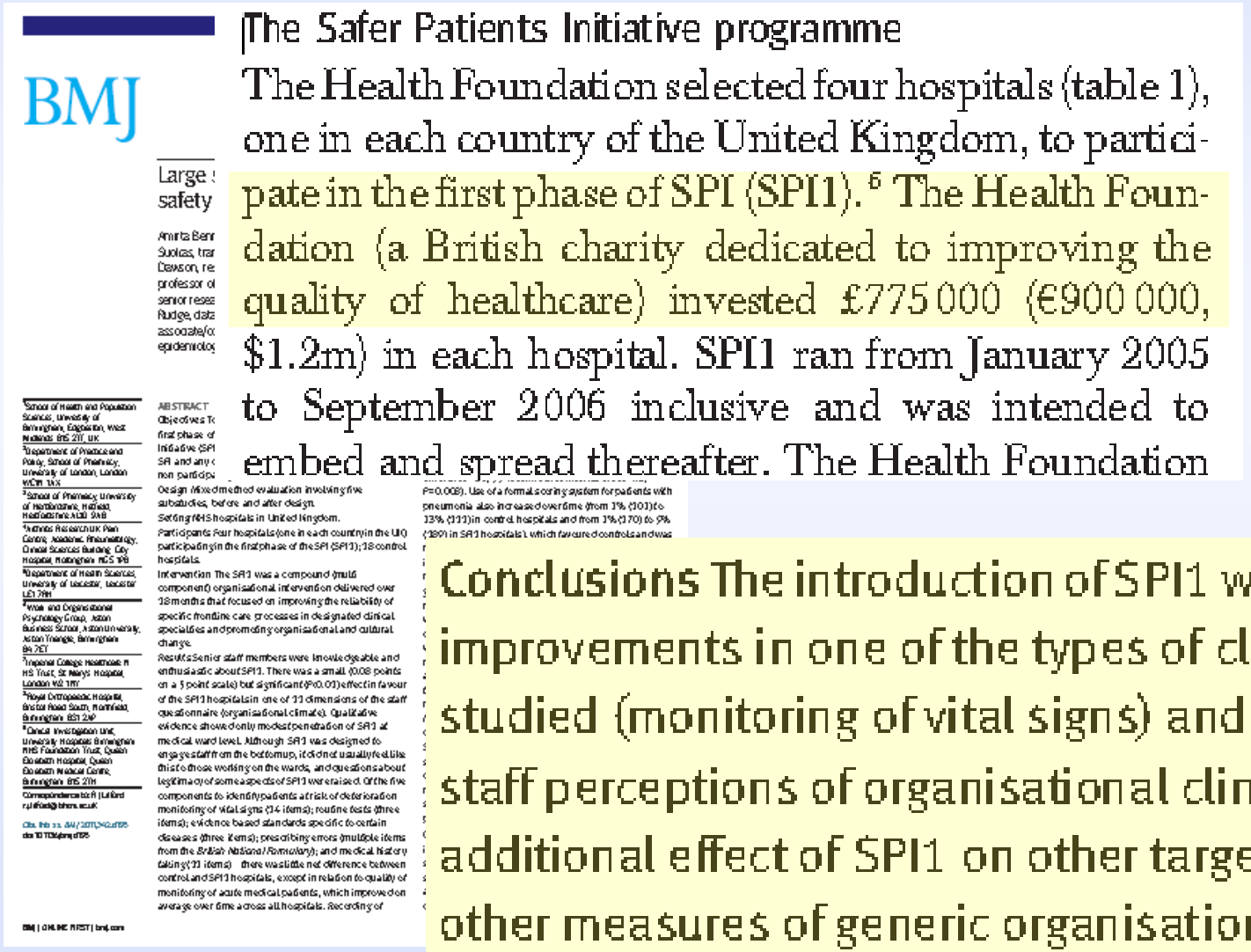
For author affiliations, see end of text.
See related article on pp 897-901.

Why evaluate quality and safety initiatives?



BMJ

Large
safety

The Safer Patients Initiative programme

The Health Foundation selected four hospitals (table 1), one in each country of the United Kingdom, to participate in the first phase of SPI (SPI1).[6] The Health Foundation (a British charity dedicated to improving the quality of healthcare) invested £775 000 (€900 000, $1.2m) in each hospital. SPI1 ran from January 2005 to September 2006 inclusive and was intended to embed and spread thereafter. The Health Foundation

ABSTRACT

Conclusions The introduction of SPI1 was associated with improvements in one of the types of clinical process studied (monitoring of vital signs) and one measure of staff perceptions of organisational climate. There was no additional effect of SPI1 on other targeted issues nor on other measures of generic organisational strengthening.

Why evaluate quality and safety initiatives?

- Observed effects relatively small
- Limited understanding of likely confounders
- Significant opportunity costs if health care systems adopt ineffective or inefficient quality and safety programs
- Results vary across studies (no magic bullets)
- Failure to evaluate leads to constant reinvention of the (square) wheel

Systematic reviews of quality and safety initiatives

- Rigorous (mixed method) evaluations provide best evidence of effects of individual quality and safety initiatives
- Systematic reviews of quality and safety initiatives:
  - Reduce the likelihood that decision makers will be misled by research (by being more systematic and transparent in the identification, selection, appraisal and synthesis of studies)
  - Increase confidence among decision makers about what can be expected from an intervention (by increasing number of units for study)
  - Allow decision makers to focus on assessing likely applicability of systematic reviews for their problem and context

Cochrane Effective Practice and Organisation of Care (EPOC) Group

- Cochrane Effective Practice and Organisation of Care (EPOC) group undertakes systematic reviews of interventions to improve health care systems and health care delivery including:
  - Professional interventions (e.g. continuing medical education, audit and feedback)
  - Financial interventions (e.g. professional incentives)
  - Organisational interventions (e.g. the expanded role of pharmacists)
  - Regulatory interventions

Bero, Eccles, Grilli, Grimshaw, Gruen, Mayhew, Oxman, Shepperd, Tavender, Zwarenstein (2006). *Cochrane Library.*

Cochrane Effective Practice and Organisation of Care (EPOC) Group

Progress to date

- 79 reviews, 44 protocols
- Professional interventions
  - Audit and feedback: effects on professional practice and health care outcomes
  - The effects of on-screen, point of care computer reminders on processes and outcomes of care
- Organisational interventions
  - The effectiveness of strategies to change organisational culture to improve healthcare performance
  - Lay health workers in primary and community health care for maternal and child health and the management of infectious diseases

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Progress to date – Methods

- EPOC reviews include broad range of designs (typically RCTs (including CRCTs), Controlled before and after studies, Interrupted time series)
- 79% of EPOC reviews include non randomised designs

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Progress to date – Methods

- Inclusion of these designs required methodological development:
  - Development of search strategies
  - Risk of bias assessment
  - Managing common errors
  - Synthesis approaches
- Inclusion of these designs have significantly increased workload for review group and review authors

Cochrane Effective Practice and Organisation of Care (EPOC) Group

Intervention	# of trials	Median absolute effect	Interquartile range
Audit and feedback (Ivers 2011)	140	+4.3%	+0.5% - +16%
Educational meetings (Forsetlund 2009)	81	+6%	+3 – +15%
Financial incentives (Scott 2011)	3	NA	NA
Hand hygiene (Gould 2010)	1	NA	NA

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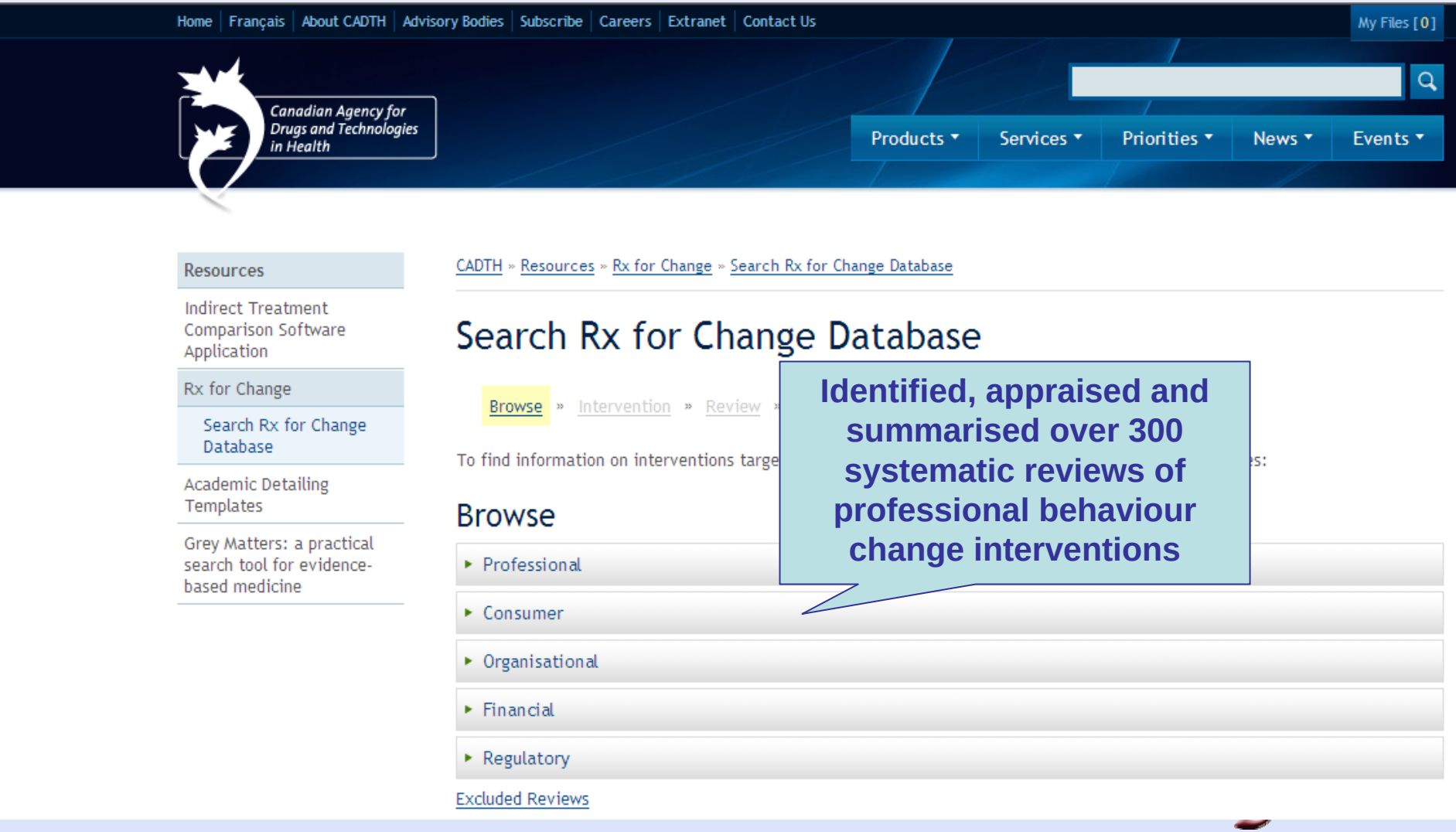

Summary

- Healthcare systems struggle to provide effective and safe care
- Imperative ‘to do something’ often results in a failure to evaluate quality and safety initiatives
- Quality and safety intervention programs should be based upon systematic reviews of the global research literature

‘Evidence based evidence should be complemented by evidence based implementation’

Grol (1997) BMJ

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- Rx for Change database of appraised reviews of professional behaviour change - www.rxforchange.ca
- KT Canada - http://ktclearinghouse.ca/ktcanada

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APPLICATION DES CONNAISSANCES CANADA