

# Implementation Gap: When Health Policy Clashes with Research

## ***EVIDENCE-BASED EXPERTISE FOR BETTER POLICY-MAKING***

November 8, 2019  
Brussels, BE



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# Financial Disclosures

I have no relevant financial relations with any commercial interests



# Background

- Practicing Anesthesiologist and Surgical Intensive care expert
- Clinical Professor, Wayne State University/Children's Hospital; Visiting Professor, Sigmund Freud University, Vienna, Austria
- Married to busy Professor of Surgery, Father of 3 hyperkinetic boys
- Harvard University and Massachusetts General Hospital trained; Masters in Public Health and Health Services Research and Quality Improvement
- Harvard School of Medicine Josiah Macy Medical Education Scholar
- Board of International Academy for Design and Health; Chair, Patient Safety, World Society of Intravenous Anesthesia
- Member of the highest Anesthesia honorary Society, Association of University Anesthesia ( AUA)
- Former 5 years in military (retired) doing adverse event investigation, team training and simulation training
- Former Chief Quality and Risk officer, Associate Chief Medical Officer, Major Academic Medical Center University Administrator
- Former visiting professor, Utrecht Medical Center, Netherlands; University of Cork, Ireland; University of Oslo and Stavanger, Norway;
- Active health services researcher, \$14,000,000 in grants (EU; FP-7, Scientific Coordinator HANDOVER project; Erasmus); US (NIH; AHRQ; VA HSRD; HRSA), Netherlands ( ZonVw), UK ( NIHR); Norway ( NRC), Australia ( NHMRC, ARC), etc
- 45 graduate/PhD students including from Norway, Netherlands, Italy, UK.
- 250 publications, 5 books, 9930 citations, H=49
- Developed human factors and patient safety curriculum ( i.e, TeamSTEPPS)
- Former editor of UK based BMJ Quality and Safety Journal (IF=7.3)
- Consultant to governments ( i.e, Norway, Netherlands, UK, Canada, US, Jordan, Bahamas, Pakistan, Australia), European Union, World Health Organization
- Founder, and former Director of one of first simulation and skills training centers
- Former Head of Florida Patient Safety Authority; Co-Founder of Massachusetts Patient Safety Authority
- Cancer survivor





*"Honestly, if you learn to change  
you'll feel so much better."*

## The Clinician's Dilemma

- How do I treat the patient in front of me when there exists meaningful uncertainty about what to do in the real world circumstance for this actual patient?

Progress in Pediatric Cardiology 49 (2015) 20–26

Contents lists available at ScienceDirect

Progress in Pediatric Cardiology

journal homepage: [www.elsevier.com/locate/ppedcard](http://www.elsevier.com/locate/ppedcard)



Review

Towards a learning system for pediatric outcomes: Harvesting meaning from evidence

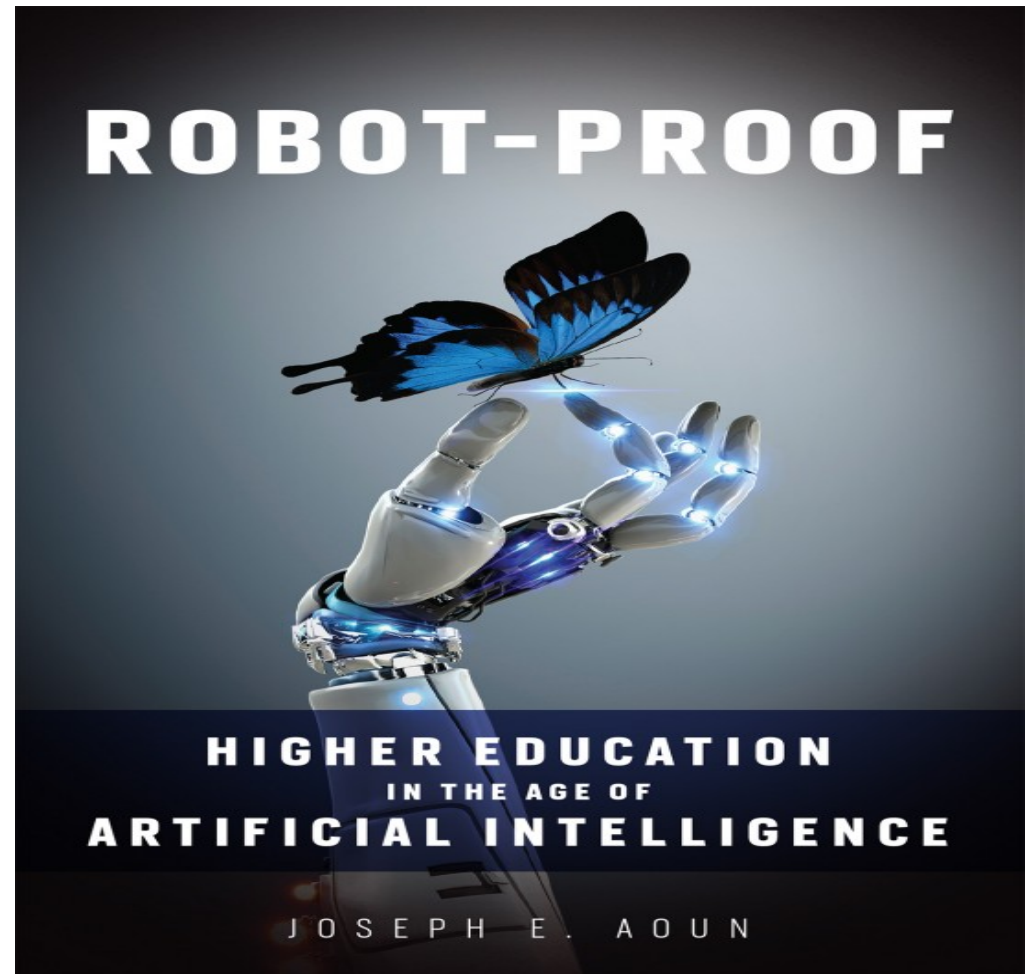
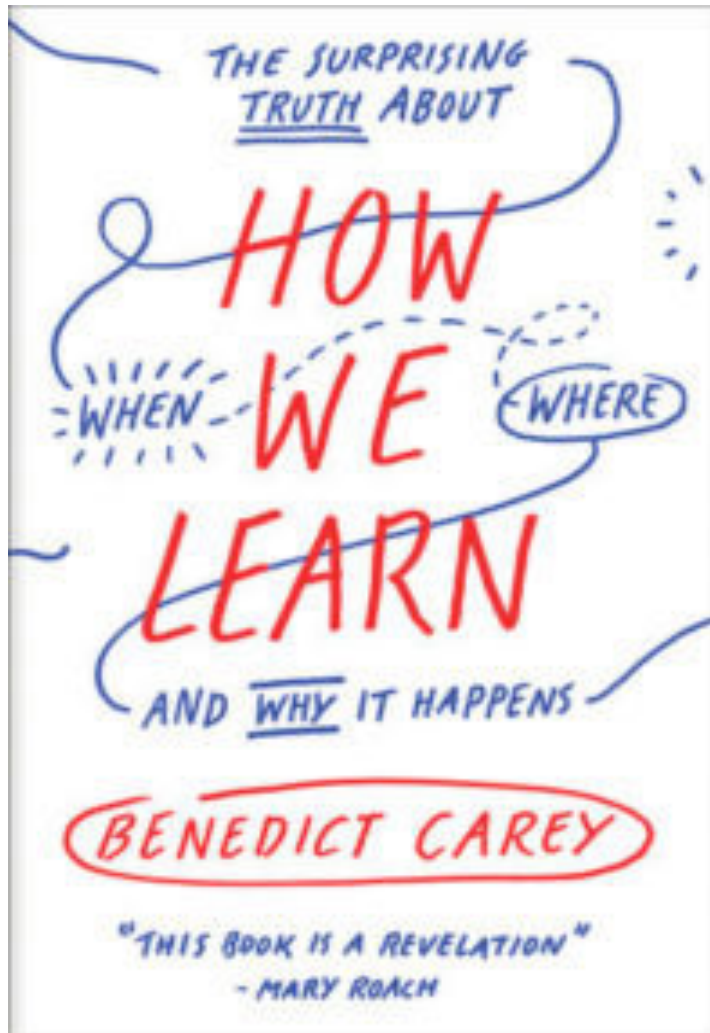
Lawrence C. Kleinman<sup>a</sup>, Paul Barach

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## How Can We Better Learn as a System?



2019

LIFESTYLE // HEALTH

# MD Anderson patient died after getting contaminated blood

Todd Ackerman | June 25, 2019 | Updated: June 25, 2019 10:20 p.m.



A view of the outside of the MD Anderson Cancer Center in Houston, Texas. Photo: Houston Chronicle

The event that triggered increased government oversight of MD Anderson Cancer Center was the death of a 23-year-old leukemia patient who received a contaminated blood product, according to a new report.

The report, issued Monday by the Centers for Medicare and Medicaid Services, notes the patient, a woman, died two days after receiving a transfusion tainted with a bacterial infection commonly acquired in hospitals but rarely found in blood transfusions. She had had serious complications prior to the transfusion,

The New York Times

# UNC Children's Hospital Suspends Most Complex Heart Surgeries

By Ellen Gabler

June 17, 2019

North Carolina Children's Hospital announced it would suspend heart surgeries for the most complex cases, some of which had a mortality rate approaching 50 percent in recent years, pending investigations by state and federal regulators and a group of outside experts.

In a statement on Monday, UNC Health Care, which runs the hospital and is affiliated with the University of North Carolina, also introduced several initiatives to "restore confidence in its pediatric heart surgery program." These include creating the external advisory board of medical experts to recommend improvements, and committing to publicly release mortality data for that program, which it has refused to do in past years.

The actions are in response to a New York Times investigation last month into the medical institution, where cardiologists, department leaders and even the former head of the children's hospital expressed concerns about patients faring poorly after heart surgery there. Secret audio recordings provided to The Times captured doctors talking openly, some even saying they might not feel comfortable allowing their own children to have surgery at the hospital.

# RaDonDa Vaught made at least 10 mistakes in fatal Vanderbilt medication error, prosecutors say

Scott Soliman and Arden Denhart for The Nashville Tennessean | Updated 7:11 p.m. CT March 27, 2019 | Updated 5:29 p.m. CT March 26, 2019

Prosecutors say at least 10 mistakes led on Vanderbilt nurse RaDonDa Vaught to accidentally give a patient a fatal dose of the wrong medication two years ago, including Vaught overlooking a boldfaced warning immediately before injecting the drug. Vaught also told investigators she was "distracted" by an unrelated conversation with a colleague when she grabbed the wrong drug from a medication cabinet, according to new prosecutorial documents filed Wednesday in Vaught's reckless homicide case. These documents offer the most detailed look yet into the evidence against Vaught. Prosecutors say she overrode a safeguard on the cabinet even though she wasn't treating an emergency and had not checked with the hospital pharmacy, then ignored four warnings or pop-ups about the medication she was withdrawing from the cabinet. Once the medication was in hand, Vaught then somehow didn't notice the drug was supposed to be a liquid but was instead a powder and therefore had to be mixed with fluid and shaken before it could be given to a patient. Finally, Vaught still injected the drug despite bold lettering on the medication bottle cap that said "WARNING: PARALYZING AGENT." Prosecutors said in the court records that Vaught would have had to "look directly" at the warning when sticking a syringe into the bottle before injecting the medication.



# Johns Hopkins promised to elevate All Children's Heart Institute.

## Then patients started to die at an alarming rate.

### INVESTIGATIONS

#### Top All Children's executives resign following Times report on heart surgeries

'The events described in recent news reports are unacceptable,' the hospital's parent company said.

By Kathleen McGrory and Neil Bedi Dec. 11, 2018



The CEO of Johns Hopkins All Children's Hospital and two other hospital administrators have resigned following a *Tampa Bay Times* investigation that found dramatic increases in the hospital's mortality rates for heart surgeries, Johns Hopkins announced Tuesday.

In a statement, the health system said All Children's CEO Dr. Jonathan Ellen, Vice President Jackie Crain and deputy director of the hospital's Heart Institute Dr. Jeffrey Jacobs had resigned.

### INVESTIGATIONS

#### A baby left All Children's with a needle in her heart

The prestigious hospital's Heart Institute acknowledged it's had "challenges" and said it has stopped some complicated procedures.

By Kathleen McGrory April 20



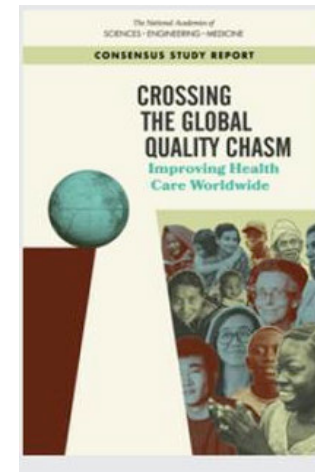
Amara Le thought her newborn daughter's surgery had gone well.

So it came as a shock when, at a followup appointment, a doctor alerted her to a serious complication: The baby had been released from Johns Hopkins All Children's Hospital in St. Petersburg with a needle in her heart.



# Implementation Gap 2019

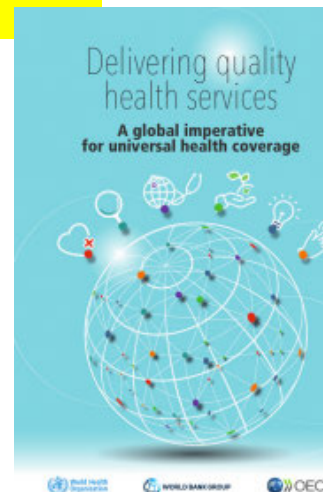
- Lack of coordination, with providers in silos, fragmented service models
- Patients inadequately trained to manage their illnesses
- Severe workforce issues
- 1 in 10 patients harmed in hospital care/ between 5.7 and 8.4 m deaths occurring annually from poor quality care
- 14 out of every 100 patients affected by HAI
- **2-5% patients subject to surgical complications for the 234 million surgical operations performed every year**
- 20-40% health spending wasted due to poor quality of care and failures
- 15% of hospital costs being due to patient harms caused by adverse events



Editorial

## THE ECONOMICS OF PATIENT SAFETY IN PRIMARY AND AMBULATORY CARE

Flying blind



## Putting quality and people at the centre of health systems

The burden of mortality attributable to poor care is lower than that of a lack of access to care. Significant gains were not made until the 1980s. Margaret Keck and colleagues' data show that 5 million lives could potentially be saved through quality improvements. Of the 5.6 million deaths per year in LMICs due to treatable conditions, the remaining 3.6 million deaths occur from lack of access. For expansion of LMICs will be ineffective unless quality is addressed.

Accountability, trust, and confidence in the health system are all people-led initiatives that will follow with quality improvements. Gaining people's trust takes time, and when health workers and policy makers choose to seek treatment in their own country's public institutions, a signal will be sent that the system can be trusted, and an assurance of safety made. While this lesson could be applied to many cultures and countries, the burden in LMICs is particularly acute, with the threat of poverty adding dangerous consequences to poor quality care.

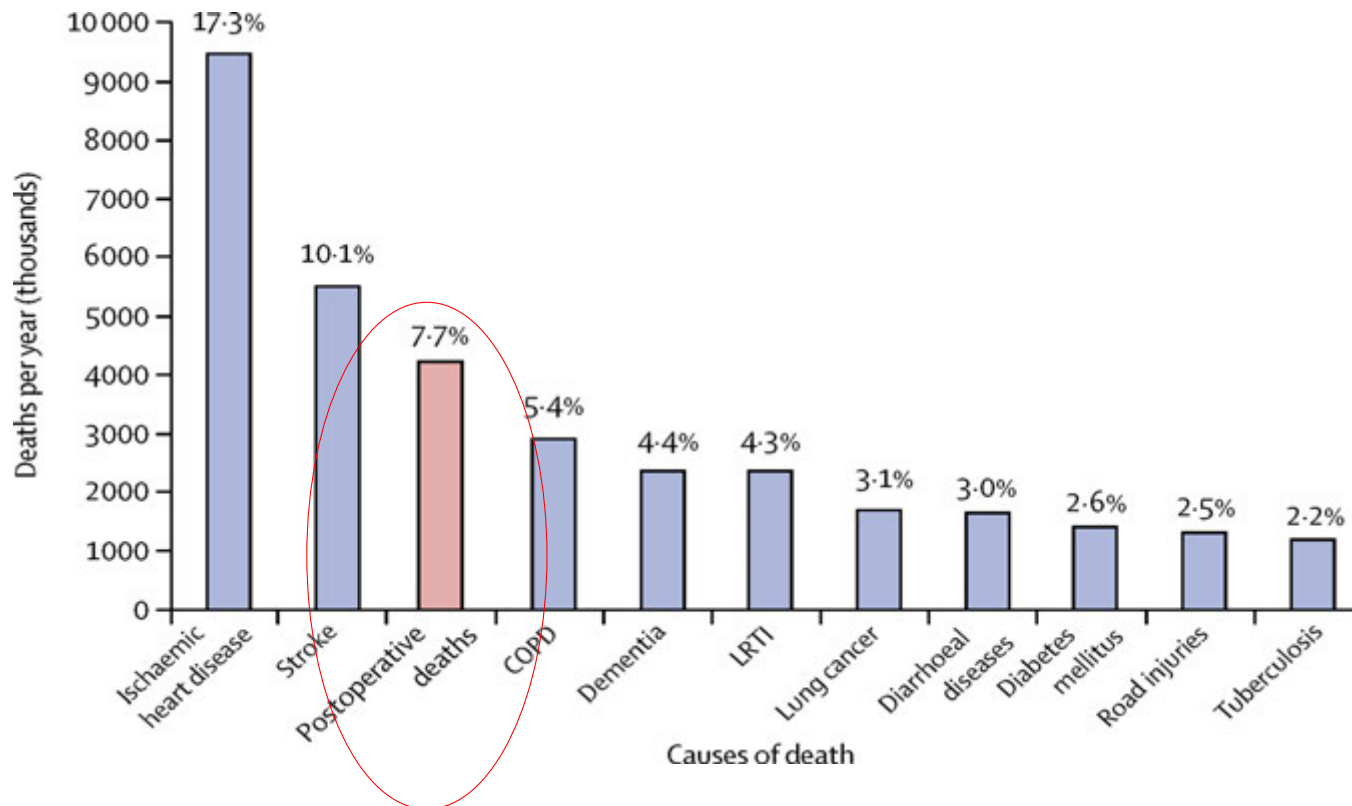
In both The Lancet Global Health's Commission and the research published in The Lancet, the authors acknowledge that there is no easy or single fix—the systems are complex and multifaceted, and their proposed mechanisms for building people's trust will take widespread cooperation with accountability and measurement placed at the core. Most quality improvement interventions have, until now, focused on provider-level activities, but today's publications confirm that these are merely peripheral adjustments rather than the complete overhaul of health systems that is needed to incorporate quality into the very fabric of these systems.

Findings from other substantial reports published this year support the findings of the Lancet Global Health Commission. In July 2018, Delivering Quality Health Services: A Global Imperative for Universal Health Coverage by WHO, the OECD, and the World Bank laid out policy plans for governments and countries. Last week, the US National Academies of Sciences, Engineering, and Medicine published a review of the state of quality in LMICs. Crossing the Global Quality Chasm: Improving Health Care Worldwide. Together, these reports have highlighted and assessed the challenges, provided new data and analyses, and proposed appropriate policy frameworks with people-led needs. The scenery and landscape have been thoroughly and clearly constructed—now the work to turn words into actions must begin. ■ The Lancet.



Editorial

## Global Surgery Burden of Postoperative Death-2019



*Lancet* 2019 393, DOI: (10.1016/S0140-6736(18)33139-8)

Ernest Codman, The Importance of Truth Telling, Transparency, and Trust for Patient Outcomes, 1915





June 19, 2019

# Association of Coworker Reports About Unprofessional Behavior by Surgeons With Surgical Complications in Their Patients

William O. Cooper, MD, MPH<sup>1</sup>; David A. Spain, MD<sup>2</sup>; Oscar Guillaumondegui, MD, MPH<sup>3</sup>; [et al](#)

» [Author Affiliations](#)

*JAMA Surg.* Published online June 19, 2019. doi:10.1001/jamasurg.2019.1738



# Safety Climate and Patient ICU Outcomes

- Observational, 48 h study in 57 ICU in **Austria, Germany, and Switzerland**, with self reporting of medical errors by ICU staff S Assessment of safety climate and workload
- For 795 observed patients, a total of 641 errors affecting 269 patients were reported = rate of 49.8 errors per 100 patient days
- (administration of medication, loss of artificial airways, and unplanned dislodgement of lines, catheters and drains)
- Conclusions:
  - A more highly safety climate score contributes to a reduction of medical errors.
  - Higher workload is associated with higher occurrence of errors

Intensive Care Med (2013) 39:391–398  
DOI 10.1007/s00134-012-2764-0

ORIGINAL

Andreas Valentin  
Michael Schiffinger  
Johannes Steyrer  
Clemens Huber  
Guido Strunk

**Safety climate reduces medication  
and dislodgement errors in routine intensive  
care practice**

The NEW ENGLAND JOURNAL of MEDICINE

MEDICINE AND SOCIETY

TEAMWORK — PART 2

Debra Malina, Ph.D., *Editor*

**Cursed by Knowledge — Building a Culture  
of Psychological Safety**

Lisa Rosenbaum, M.D.

2019

# BMJ Open

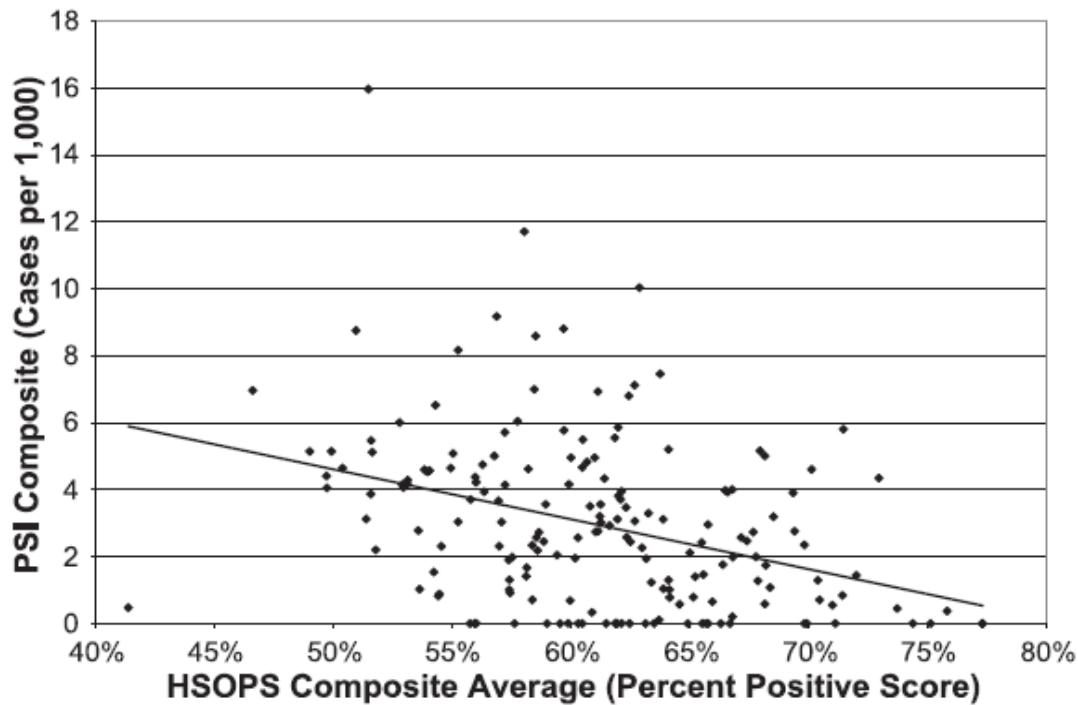
- 2.5 million patients
- 50% of Norway clinical interactions

## Associations between Work Satisfaction, Engagement, and 7-day Patient Mortality; a Cross-Sectional Survey

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-031704.R2
Article Type:	Original research
Date Submitted by the Author:	28-Oct-2019
Complete List of Authors:	Brubakk, Kirsten; Helse Sør-Øst RHF Svendsen, Martin ; Sykehuset Telemark HF, Department of Occupational and Environmental Medicine Hofoss, Dag; Lovisenberg Diaconal University College Hansen, Tonya; Folkehelseinstituttet Barach, paul; Wayne State University, Pediatrics; Jefferson College of Population Health Tjomsland, Ole; Helse Sør-Øst RHF
<b>Primary Subject Heading</b>:	Health services research
Secondary Subject Heading:	Health policy
Keywords:	Patient safety, Work environment, Patient outcome, Safety climate, Staff engagement, Safety culture

**Conclusion: 7-day mortality rates in hospital wards were negatively correlated with the nurse workload and manager engagement levels. A deeper understanding of the**

## Negative Correlation: Culture and Patient Safety Events



- Higher HSOPS scores are associated with fewer adverse events, which validates patient safety culture assessment as a meaningful indication of the safety of patients.

**FIGURE 1.** Scatter plot of PSI composite versus HSOPS composite average (N = 179).



SPECIAL ARTICLE

## Introduction of Surgical Safety Checklists in Ontario, Canada

David R. Urbach, M.D., Anand Govindarajan, M.D., Refik Saskin, M.Sc.,  
Andrew S. Wilton, M.Sc., and Nancy N. Baxter, M.D., Ph.D.

### ABSTRACT

#### BACKGROUND

Evidence from observational studies that the use of surgical safety checklists results in striking improvements in surgical outcomes led to the rapid adoption of such checklists worldwide. However, the effect of mandatory adoption of surgical safety checklists is unclear. A policy encouraging the universal adoption of checklists by hospitals in Ontario, Canada, provided a natural experiment to assess the effectiveness of checklists in typical practice settings.

#### METHODS

We surveyed all acute care hospitals in Ontario to determine when surgical safety checklists were adopted. Using administrative health data, we compared operative mortality, rate of surgical complications, length of hospital stay, and rates of hospital readmission and emergency department visits within 30 days after discharge among patients undergoing a variety of surgical procedures before and after adoption of a checklist.

#### RESULTS

During 3-month periods before and after adoption of a surgical safety checklist, a total of 101 hospitals performed 109,341 and 106,370 procedures, respectively. The adjusted risk of death during a hospital stay or within 30 days after surgery was 0.71% (95% confidence interval [CI], 0.66 to 0.76) before implementation of a surgical checklist and 0.65% (95% CI, 0.60 to 0.70) afterward (odds ratio, 0.91; 95% CI, 0.80 to 1.03;  $P=0.13$ ). The adjusted risk of surgical complications was 3.86% (95% CI, 3.76 to 3.96) before implementation and 3.82% (95% CI, 3.71 to 3.92) afterward (odds ratio, 0.97; 95% CI, 0.90 to 1.03;  $P=0.29$ ).

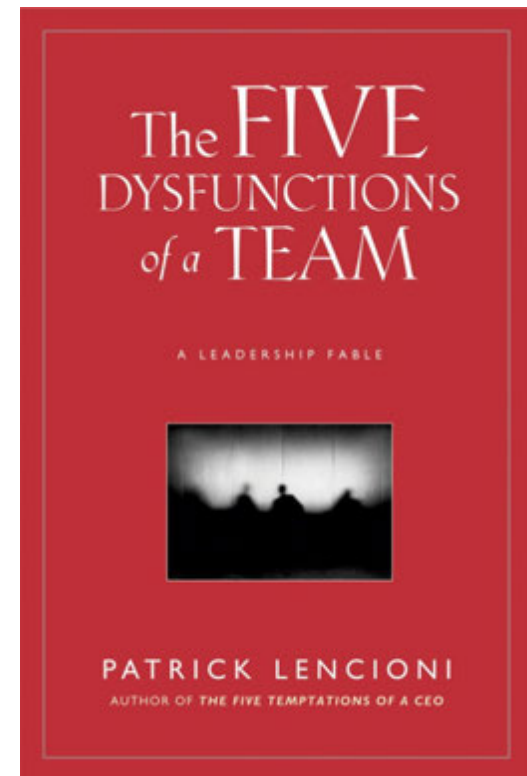
#### CONCLUSIONS

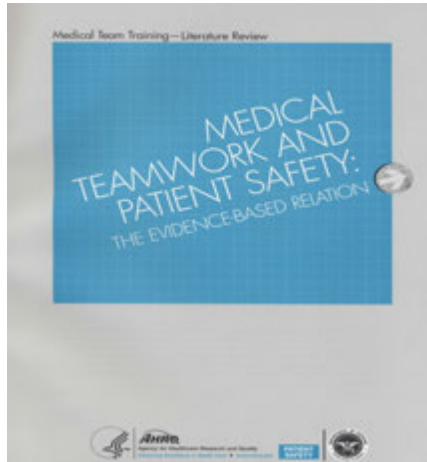
Implementation of surgical safety checklists in Ontario, Canada, was not associated with significant reductions in operative mortality or complications. (Funded by the Canadian Institutes of Health Research.)

- Checklists work when used as a social-technical tool to engage teams and raise situational awareness to complex patient and systems.

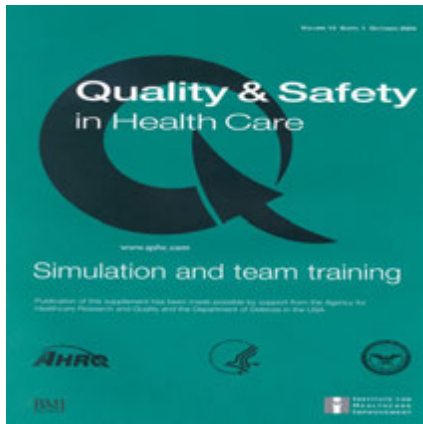
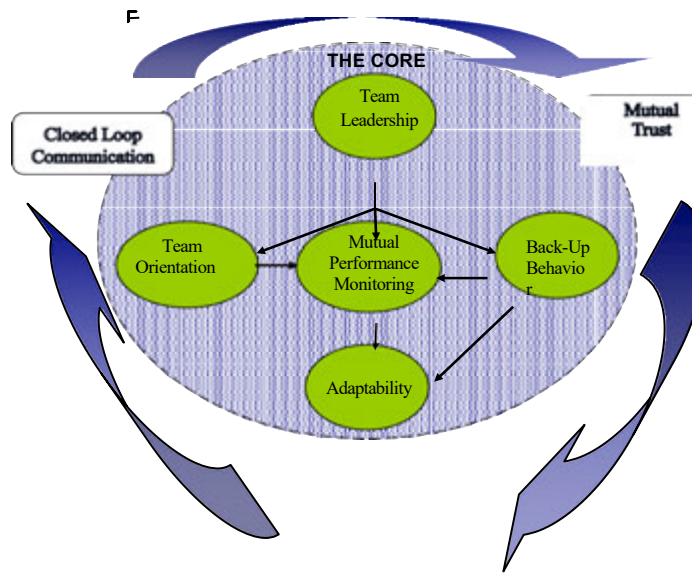
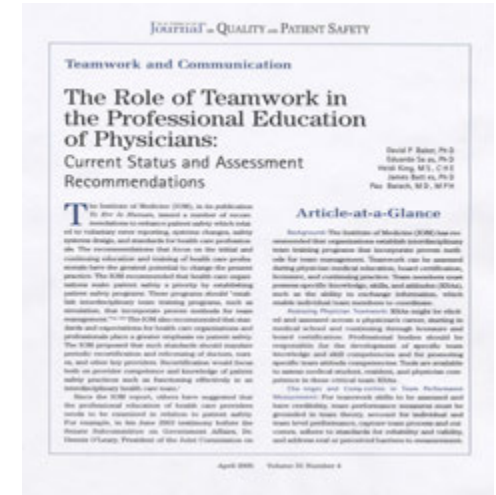
# Engage in Dialogue – Even Disagreement!

“When team members do not openly debate and disagree about important ideas, they often turn to back-channel personal attacks, which are far nastier and more harmful than any heated argument over issues.” (pg 203)





# TeamSTEPPS Model of “Big 5” Teamwork



Baker, Salas, King, Battles, Barach, 2006; 2007; Barach and Cosman, 2015

# Association Between Implementation of a Medical Team Training Program and Surgical Mortality

Julia Neily, RN, MS, MPH

Peter D. Mills, PhD, MS

Yinong Young-Xu, ScD, MA, MS

Brian T. Carney, MD

Priscilla West, MPH

David H. Berger, MD, MHCM

Lisa M. Mazza, MD

Douglas E. Paull, MD

James P. Bagian, MD, PE

**A**DVERSE EVENTS RELATED TO surgery continue to occur despite the best efforts of clinicians.<sup>1</sup> Teamwork and effective communication are known determinates of surgical safety.<sup>2-6</sup> Previous efforts at demonstrating the efficacy of patient safety initiatives have been limited because of the inability to study a control group.<sup>7</sup> For example, the use of the World Health Organization Safe Surgery checklist has been evaluated, but its overall efficacy remains uncertain because no control group was studied to clearly demonstrate this instrument's effectiveness.<sup>8</sup>

The Veterans Health Administration (VHA) is the largest national in-

**Context** There is insufficient information about the effectiveness of medical team training on surgical outcomes. The Veterans Health Administration (VHA) implemented a formalized medical team training program for operating room personnel on a national level.

**Objective** To determine whether an association existed between the VHA Medical Team Training program and surgical outcomes.

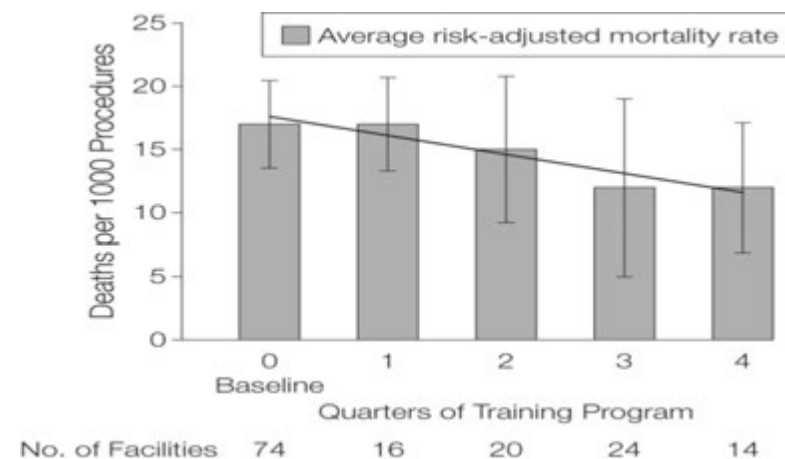
**Design, Setting, and Participants** A retrospective health services study with a contemporaneous control group was conducted. Outcome data were obtained from the VHA Surgical Quality Improvement Program (VASQIP) and from structured interviews in fiscal years 2006 to 2008. The analysis included 182 409 sampled procedures from 108 VHA facilities that provided care to veterans. The VHA's nationwide training program required briefings and debriefings in the operating room and included checklists as an integral part of this process. The training included 2 months of preparation, a 1-day conference, and 1 year of quarterly coaching interviews

**Main Outcome Measure** The rate of change in the mortality rate 1 year after facilities enrolled in the training program compared with the year before and with non-training sites.

**Results** The 74 facilities in the training program experienced an 18% reduction in annual mortality (rate ratio [RR], 0.82; 95% confidence interval [CI], 0.76-0.91;  $P=.01$ ) compared with a 7% decrease among the 34 facilities that had not yet undergone training (RR, 0.93; 95% CI, 0.80-1.06;  $P=.59$ ). The risk-adjusted mortality rates at baseline were 17 per 1000 procedures per year for the trained facilities and 15 per 1000 procedures per year for the nontrained facilities. At the end of the study, the rates were 14 per 1000 procedures per year for both groups. Propensity matching of the trained and nontrained groups demonstrated that the decline in the risk-adjusted surgical mortality rate was about 50% greater in the training group (RR, 1.49; 95% CI, 1.10-2.07;  $P=.01$ ) than in the nontraining group. A dose-response relationship for additional quarters of the training program was also demonstrated: for every quarter of the training program, a reduction of 0.5 deaths per 1000 procedures occurred (95% CI, 0.2-1.0;  $P=.001$ ).

Neily J: JAMA 304: 1693-700, 2010

“The 74 facilities in the training program experienced an 18% reduction in annual mortality (rate ratio [RR], 0.82; 95% confidence interval [CI], 0.76-0.91;  $P=.01$ ) compared with a 7% decrease among the 34 facilities that had not yet undergone training (RR, 0.93; 95% CI, 0.80-1.06;  $P=.59$ )”.





## Learning System Lessons Should Take from Aviation--2000

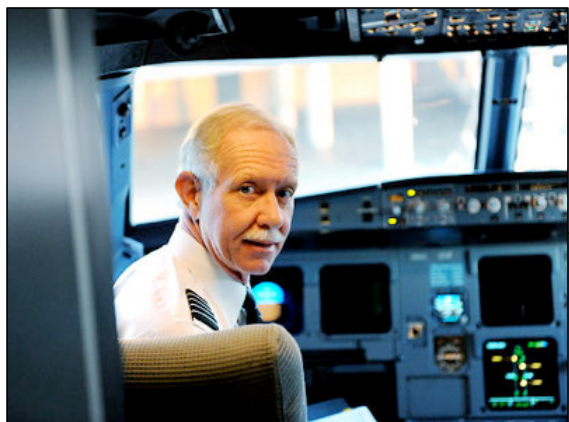
- Safety Science
- Systems/Human factors
- Communication and coordination
- Team based training
- Culture of safety
- Reporting/near miss culture
- Simulation-technical/non- technical(LOSA)
- Audio/Video blackbox
- Doctor wellness
- Transitions of care
- Room and equipment design

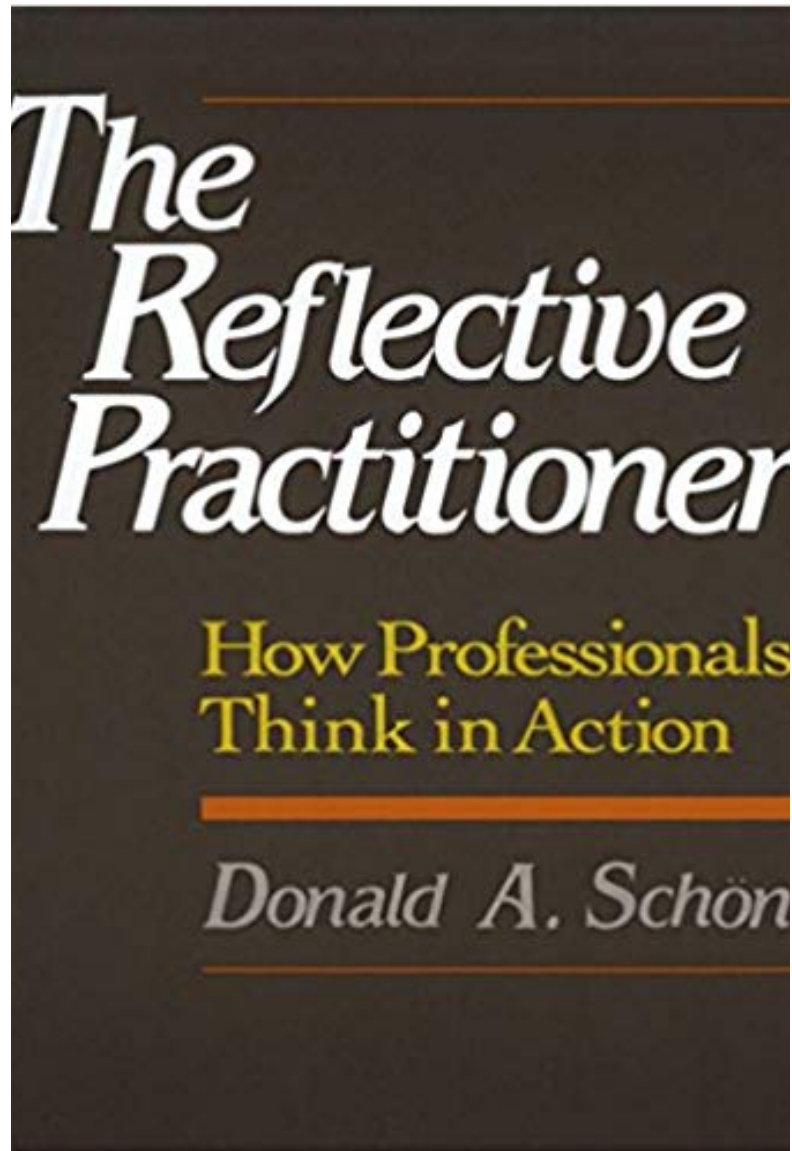
Barach P, Small S, 18 March 2000



## Miracle on the Hudson

Intuition or evidence-based decision?





## Evidence Base Policy Making

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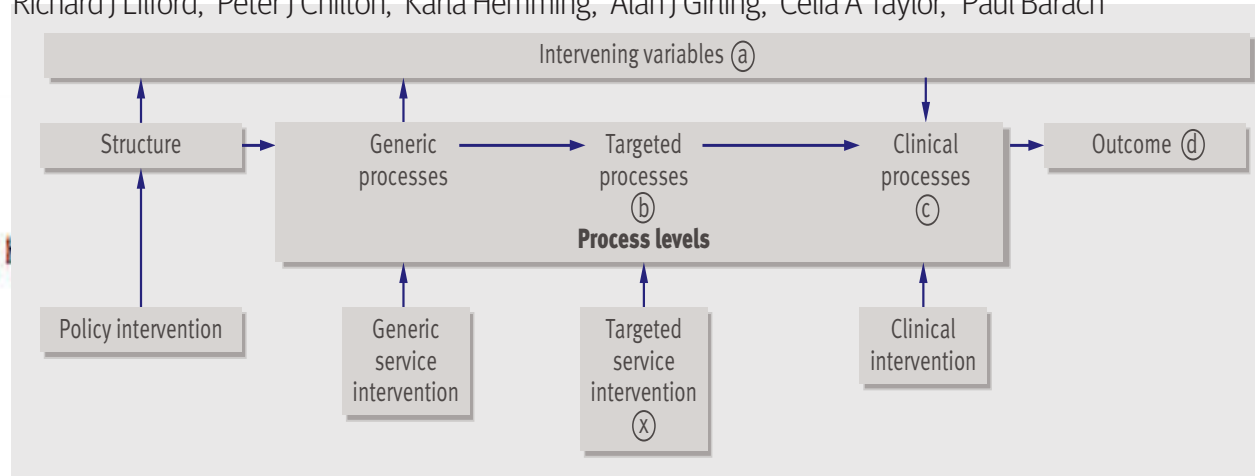
Distinction between:

- 'high ground wherein practitioners make effective use of research-based theory and technique'
- 'swampy lowland' where situations are confusing messes incapable of technical solutions' (Schon (1983, pp.43-43))

Schon, D. (1983) *The Reflective Practitioner*. New York: Basic Books

# Evaluating policy and service interventions: framework to guide selection and interpretation of study end points

Richard J Lilford,<sup>1</sup> Peter J Chilton,<sup>1</sup> Karla Hemming,<sup>1</sup> Alan J Girling,<sup>1</sup> Celia A Taylor,<sup>2</sup> Paul Barach<sup>3</sup>



**Fig 1 | Modified Donabedian causal chain.** Interventions at structural (policy) and generic service level can achieve effects through intervening variables (such as motivation and staff-patient contact time) further down the chain. For example, an intervention at (x) produces effects (good or bad) downstream at (a), (b), (c), and (d)

## Outcome

The end-results results of care.  
 Outcomes are not only what happens to the patient's health, but how he/she experiences the care and derives satisfaction.







# Managing the Risks of Organizational Accidents

JAMES REASON



# THE DESIGN OF EVERYDAY THINGS

SPRINGER HANDBOOK OF THE PSYCHOLOGY OF EVERYDAY THINGS

DONALD A. NORMAN



# A Safety Science and Human Factors Approach to Improve Health Outcomes

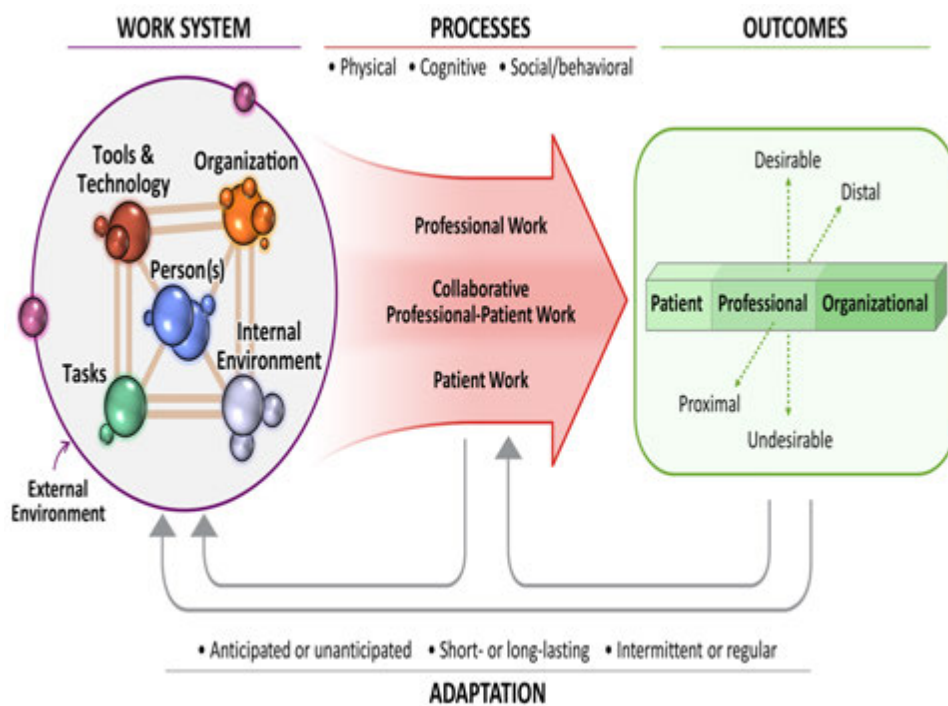


Figure 1. SEIPS 2.0 model.



A few examples of potential future reports


## Surgical Safety and outcomes--Worldwide Problem

**Worldwide 230 Million Adults  
have Major Non-Cardiac Surgery Each Year**

*Current Systems for Monitoring Patients Post-operatively,  
on Surgical Wards and after Transition to Home are Inadequate  
resulting in higher costs, lost revenue, preventable patient harm  
and unnecessary deaths.*

*10% of adults undergoing surgery (23,000,000) have preventable adverse  
post op events (harm).*

## Hospital Ward/ Home Monitoring

- Mortality in the 30 days *after* surgery is 1000 times higher than intraoperative mortality
- 41% of in-hospital cardiac arrests occur on the general ward : and outcomes of these are invariably catastrophic
- Current standard of ward monitoring same as 40 years ago: Intermittent vital sign checks every 4-6-8 hours
- However, patients are not the same as 40 years ago: They are much older, sicker (multiple morbidities), are undergoing more risky surgery
- Most ward hypoxemia and hypotension is missed due to lack of monitoring
-  "Failure to rescue"

RESEARCH ARTICLE

Open Access

### Crisis checklists for in-hospital emergencies: expert consensus, simulation testing and recommendations for a template determined by a multi-institutional and multi-disciplinary learning collaborative

Christian P. Subbe<sup>1\*</sup>, John Kellett<sup>2</sup>, Paul Barach<sup>3</sup>, Catriona Chaloner<sup>4</sup>, Hayley Cleaver<sup>5</sup>, Tim Cooksley<sup>6</sup>, Erik Korsten<sup>7</sup>, Elish Croke<sup>8</sup>, Elinor Davis<sup>9</sup>, Ashley JR De Bie<sup>7</sup>, Lesley Durham<sup>9</sup>, Chris Hancock<sup>10</sup>, Jilian Hartin<sup>11</sup>, Tracy Savjin<sup>1</sup>, John Welch<sup>11</sup> and on behalf of the Crisis Checklist Collaborative

#### Abstract

**Background:** 'Failure to rescue' of hospitalized patients with deteriorating physiology on general wards is caused by a complex array of organisational, technical and cultural failures including a lack of standardized team and individual expected responses and actions. The aim of this study using a learning collaborative method was to develop consensus recommendations on the utility and effectiveness of checklists as training and operational tools to assist in improving the skills of general ward staff on the effective rescue of patients with abnormal physiology.

**Methods:** A scoping study of the literature was followed by a multi-institutional and multi-disciplinary international learning collaborative. We sought to achieve a consensus on procedures and clinical simulation technology to determine the requirements, develop and test a safe using a checklist template that is rapidly accessible to assist in emergency management of common events for general ward use.

**Results:** Safety considerations about deteriorating patients were agreed upon and summarized. A consensus was achieved among an international group of experts on currently available checklist formats performing poorly in simulation testing as first responders in general ward clinical crises. The Crisis Checklist Collaborative ratified a consensus template for a general ward checklist that provides a list of issues for first responders to address (i.e. 'Check In'), a list of prompts regarding common omissions (i.e. 'Stop & Think'), and, a list of items required for the safe "handover" of patients that remain on the general ward (i.e. 'Check Out'). Simulation usability assessment of the template demonstrated feasibility for clinical management of deteriorating patients.

**Conclusions:** Emergency checklists custom-designed for general ward patients have the potential to guide the treatment speed and reliability of responses for emergency management of patients with abnormal physiology while minimizing the risk of adverse events. Interventional trials are needed.

**Keywords:** Rapid response teams, Crisis, Reliability, Patient safety, Simulation, Learning Collaborative

\* Correspondence: csbbe@hotmail.com  
<sup>1</sup>Ysbyty Gwynedd & Bangor University, Penrhosgarneidd, Bangor LL57 2PW, UK  
Full list of author information is available at the end of the article



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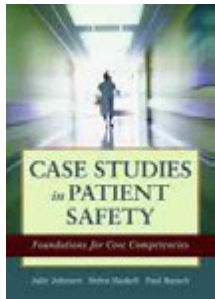
PI	Mark Coburn
Centers/countries	223/21
Primary Outcome	30-Day Mortality
Secondary Outcome	Functional Outcome
Patients included	9670/7500



[www.pose-trial.org](http://www.pose-trial.org)



## Co-Design and Co-Production of Health Services (PROM/PREM)



World Health Organization  
Regional Office for Europe

Exploring patient participation in reducing health-care-related safety risks

ISSN: 978-92-916-5264-1  
WHO/EURO number: 9484.4  
Original: English

World Health Organization  
Regional Office for Europe  
Schlegelweg 8  
DK-2100 Copenhagen Ø  
Denmark  
Tel.: +45 39 17 17 17  
Fax: +45 39 17 18 18  
Email: [contact@prom.euro.who.int](mailto:contact@prom.euro.who.int)  
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*"When we want your opinion,  
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HANDOVER

## Organizational Culture

### An Important Context for Addressing and Improving Hospital to Community Patient Discharge

Gijs Hesselink, MA, MSc,\* Myrra Vernooij-Dassen, PhD,\*†‡ Loes Pijnenborg, MD, PhD,§  
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Lisette Schoonhoven, PhD,\* Hub Wollersheim, MD, PhD,\* and on behalf of the European  
HANDOVER Research Collaborative

Ratray et al. *BMC Medical Education* .#####  
<https://doi.org/10.1186/s12909-018-1350-8>

BMC Medical Education

RESEARCH ARTICLE

Open Access

## Content counts, but context makes the difference in developing expertise: a qualitative study of how residents learn end of shift handoffs



Nicholas A. Ratray<sup>1,2,3\*</sup>, Patricia Ebright<sup>4</sup>, Mindy E. Flanagan<sup>1</sup>, Laura G. Militello<sup>5</sup>, Paul Barach<sup>6</sup>, Zamal Franks<sup>1</sup>, Shakaib U. Rehman<sup>7,8</sup>, Howard S. Gordon<sup>9,10</sup> and Richard M. Frankel<sup>1,3,11</sup>

Original article



**The Handover Toolbox: a knowledge exchange and training platform for improving patient care**

Hendrik Drachler,<sup>1</sup> Wendy Kicken,<sup>1</sup> Marcel van der Klink,<sup>1</sup> Slavi Stoyanov,<sup>1</sup> Henny P A Boshuizen,<sup>1</sup> Paul Barach,<sup>2,3,4</sup>

The Joint Commission Journal on Quality and Patient Safety 2018; 44:485-493

## "Workin' on Our Night Moves": How Residents Prepare for Shift Handoffs

Laura G. Militello, MA; Nicholas A. Ratray, PhD; Mindy E. Flanagan, PhD; Zamal Franks, BS; Shakaib Rehman, MD; Howard S. Gordon, MD; Paul Barach, MD, MPH; Richard M. Frankel, PhD

**Background:** Poor-quality handoffs have been associated with serious patient consequences. Researchers and educators have answered the call with efforts to increase system safety and resilience by supporting handoffs using increased communication standardization. The focus on strategies for formalizing the content and delivery of patient handoffs has considerable intuitive appeal; however, broader conceptual framing is required to both improve the process and develop and implement effective measures of handoff quality.

**Methods:** Cognitive task interviews were conducted with internal medicine and surgery residents at three geographically diverse US Department of Veterans Affairs medical centers. Thirty-five residents participated in semistructured interviews using a recent handoff as a prompt for in-depth discussion of goals, strategies, and information needs. Transcribed interview data were analyzed using thematic analysis.

**Results:** Six cognitive tasks emerged during handoff preparation: (1) communicating status and care plan for each patient; (2) specifying tasks for the incoming night shift; (3) anticipating questions and problems likely to arise during the night shift; (4) streamlining patient care task load for the incoming resident; (5) prioritizing problems by acuity across the patient census, and (6) ensuring accurate and current documentation.

**Conclusion:** Our study advances the understanding of the influence of the cognitive tasks residents engage in as they prepare to hand off patients from day shift to night shift. Cognitive preparation for the handoff includes activities critical to effective coordination yet easily overlooked because they are not readily observable. The cognitive activities identified point to strategies for cognitive support via improved technology, organizational interventions, and enhanced training.

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BMJ Quality & Safety Online First, published on 30 October 2012 as 10.1136/bmjqs-2012-001164

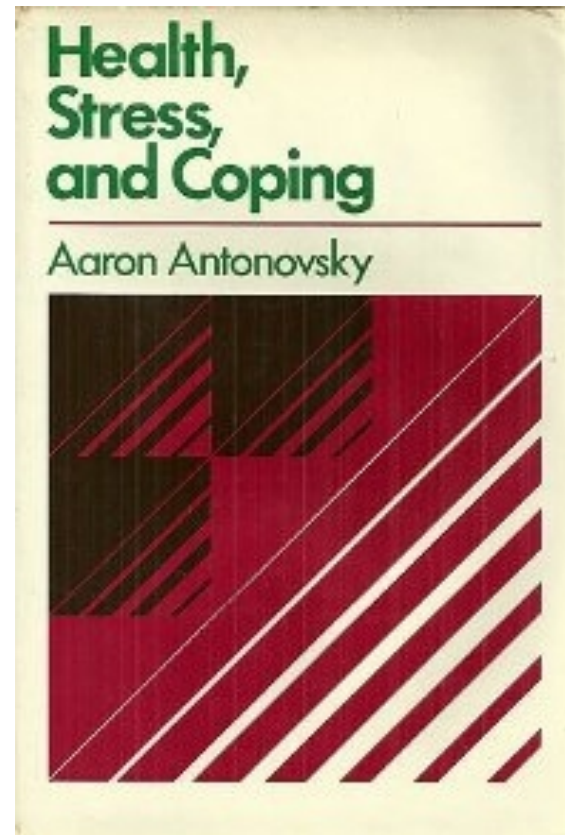
Original research

## Handover training: does one size fit all? The merits of mass customisation

Wendy Kicken,<sup>1</sup> Marcel Van der Klink,<sup>1</sup> Paul Barach,<sup>2,3,4</sup> HPA Boshuizen<sup>1</sup>



*Theory of Health and  
Salutogenesis*





# The Impact of the Built Environment

- Has large impact on quality outcomes, staff burnout, cost of services, and must be part of the holistic evaluation of health systems evaluation

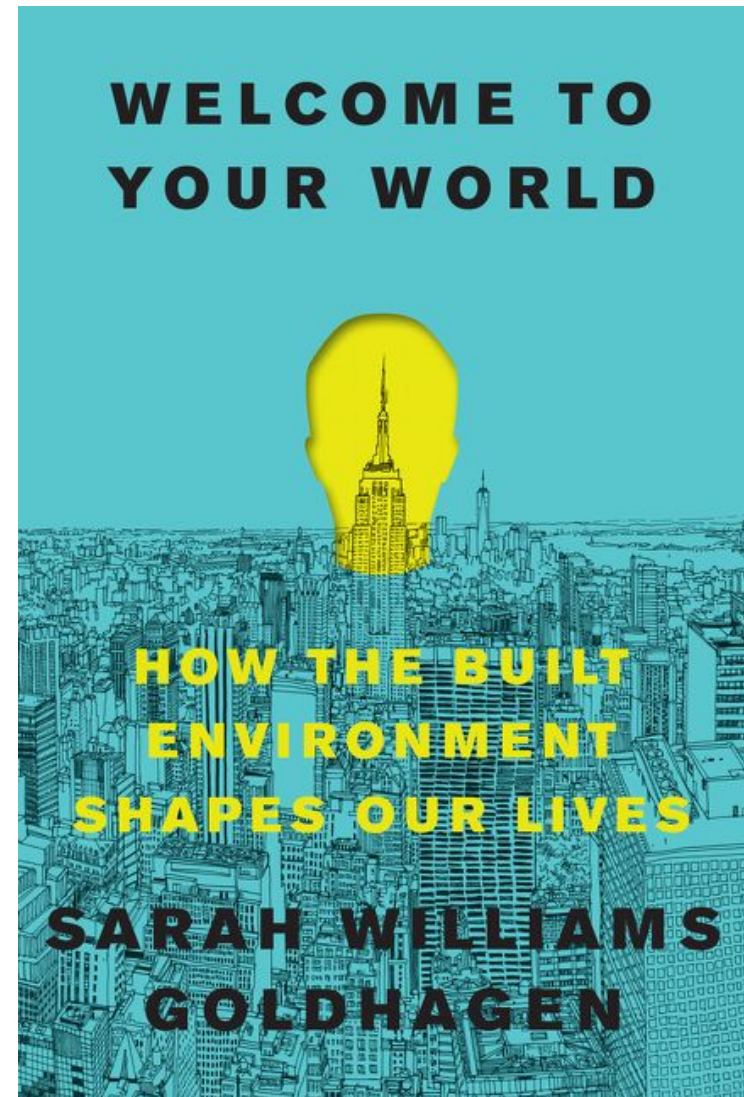
ORIGINAL RESEARCH



**One size fits all? Mixed methods evaluation of the impact of 100% single-room accommodation on staff and patient experience, safety and costs**

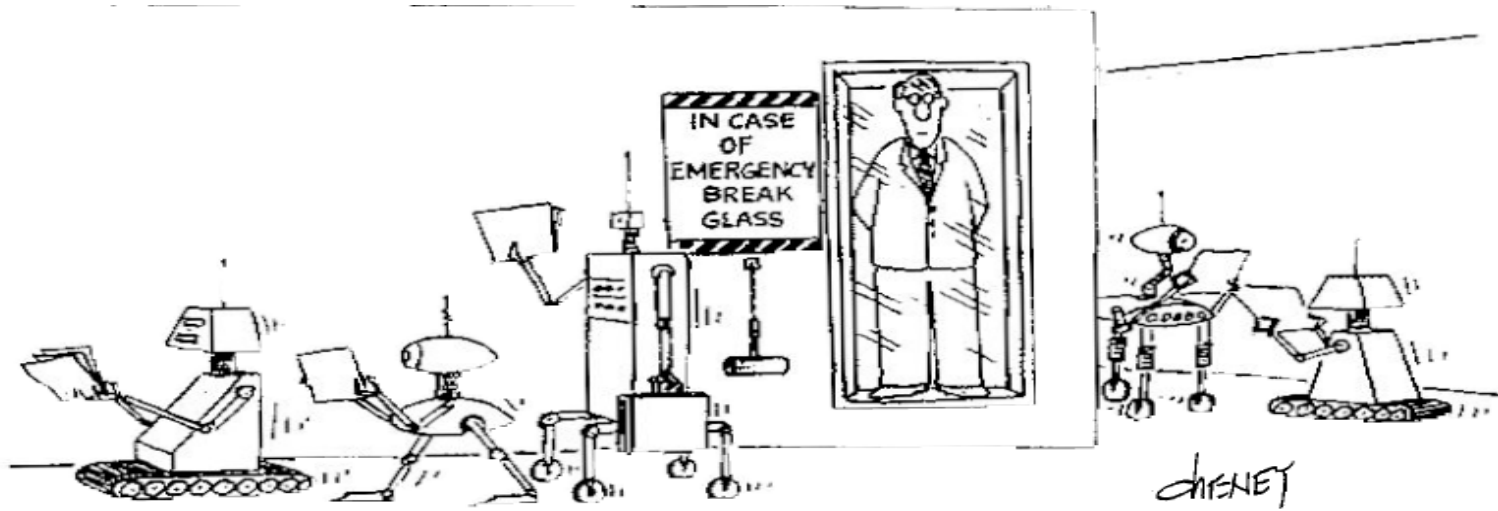
Jill Maben,<sup>1</sup> Peter Griffiths,<sup>2</sup> Clarissa Penfold,<sup>1</sup> Michael Simon,<sup>3,4</sup> Janet E Anderson,<sup>1</sup> Glenn Robert,<sup>1</sup> Elena Pizzo,<sup>5</sup> Jane Hughes,<sup>6</sup> Trevor Murrells,<sup>1</sup> James Barlow<sup>7</sup>

**Design & Health**  
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How do we get beyond a state of “technology will save me” and “technological determinism”?



**FIGURE 3.5**

Ultimate functional allocation when using a “capability” criterion. (Source: Cheney, 1989. New Yorker Magazine, Inc.)

DECLARATION



The Seoul Declaration: A Manifesto for Ethical Medical Technology\*

Preamble

Intersection of medicine, humanity and technology

It is often held that technology itself is incapable of possessing moral or ethical qualities, since “technology” is merely tool making.<sup>1</sup> But many clinicians and researchers believe that each piece of healthcare technology is endowed with affordances that can impact and challenge ethical values and commitments all the time. The technology’s “values” and artificial intelligence are embedded in the devices and implements by those that design them, and those that decide how it must be made, marketed and used. This is at the heart of the moral challenges surrounding the use of medical devices, AI and information technology.

We recognize that unsafe medical technology and avoidable patient harm represent a serious challenge to health care service delivery globally. The significant level of preventable human suffering, the considerable strain on health system finances, and the loss of trust by patients and society in health systems and in their governments is of great concern. The recent related reports around unsanctioned gene editing of embryos, biased AI data algorithms, and the Food and Drug Administration (FDA) and CE flawed certifications of devices often based on false or incomplete information provided by the vendors, raises many legitimate and ethical questions about medical device oversight systems. These reports extend from vaginal meshes to hip replacements to surgical endoscopes and more, make it seem that the oversight mechanisms are bent too far toward making it easier for industry rather than making protection of public health the primary goal.<sup>2,3</sup> The International Consortium of Investigative Journalists reported that “Health authorities across the globe have failed to protect millions of patients from poorly tested implants that can damage organs, deliver errant shocks to the heart, rot bones and poison blood, spew overdoses of opioids and cause other needless harm.”<sup>4</sup>

Sadly, technology companies do not police themselves nor learn in a systematic and transparent manner and often only do the minimum of what the legislation demands. Recent reports suggest that the FDA granted medical device makers special “exemptions” creating a vast and hidden repository of reports on device-related

injuries and malfunctions hidden from doctors and from public view.<sup>5</sup> Since 2016, at least 1.1 million incidents have flowed into this internal “alternative summary reporting” repository including deaths, serious injury and malfunction reports for about 100 medical devices, many implanted in patients or used in countless surgeries including minimally invasive and robotic-assisted. For example, the FDA has just alerted clinicians about an increasing number of medical device reports (MDRs) associated with the use of surgical staplers for internal use and implantable surgical staples reporting from 41,000 individual MDRs including 366 deaths, more than 9000 serious injuries, and more than 32,000 malfunctions. These reports speak to a profound crisis of public confidence in how medical devices and AI technologies are regulated.

New AI technologies and automation now entering health care as outlined in the MITAT AI special issue 2019 how to best raise questions about the downsides of all the automation, voice our concerns constructively, design more thoughtful technology assessments and experiments done under real world conditions, and demand more transparency about financial conflicts of interest and device failures during the development, marketing and post marketing surveillance periods. Patient safety isn’t just a matter of the technical risk, it is also about the public perception of risk. The recent Boeing Max 737 suggest that as with aviation, in AI and widespread automation acceptance depend on the public trusting the industry and in some cases that requires us to be extra cautious. Ultimately, regulators and policy makers will force upon medicine a more rigid and onerous risk avoidance accountability if we do not appreciate and actively address the highly coupled intersection of medicine, humanity and technology.

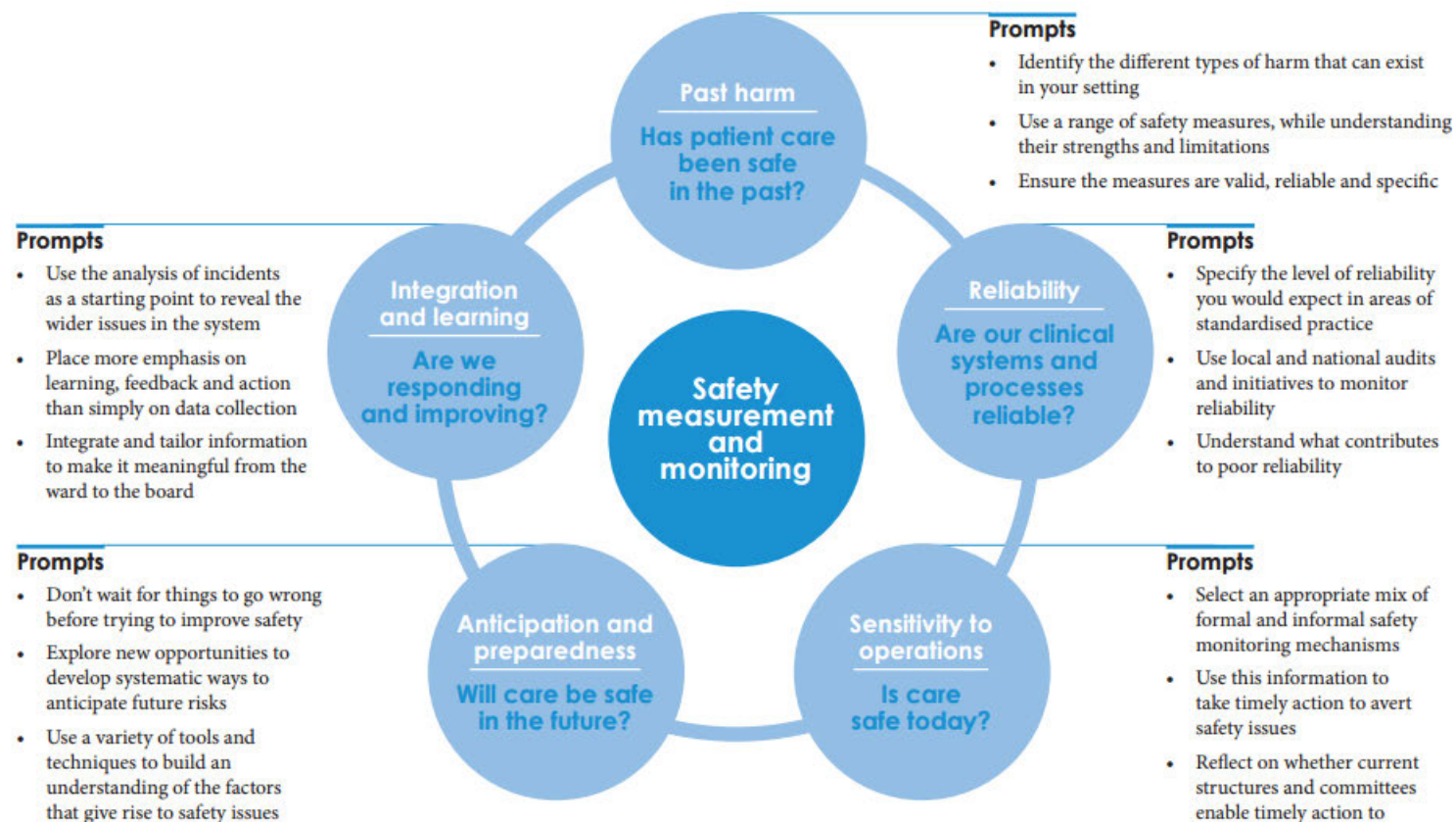
The goal of the *Seoul Declaration: A Manifesto for Ethical Medical Technology* is to be a clarion call for the ethical, research and policy issues that surround the development and implementation of new medical and AI technologies. We mean to not scare anyone from promoting and implementing new technologies based on sound human factors design that promotes patient safety and can improve service delivery systems, at all levels of health care and in all health care settings. We believe there is a global and urgent need for a robust public debate to address the trade-offs of automation vs safety

## Ethics and Quality of Medical Technology Innovation



# Safety Management and Investigative Systems

## A Framework for Learning (Measuring and Monitoring Safety)\*



\* Health Foundation

## Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program

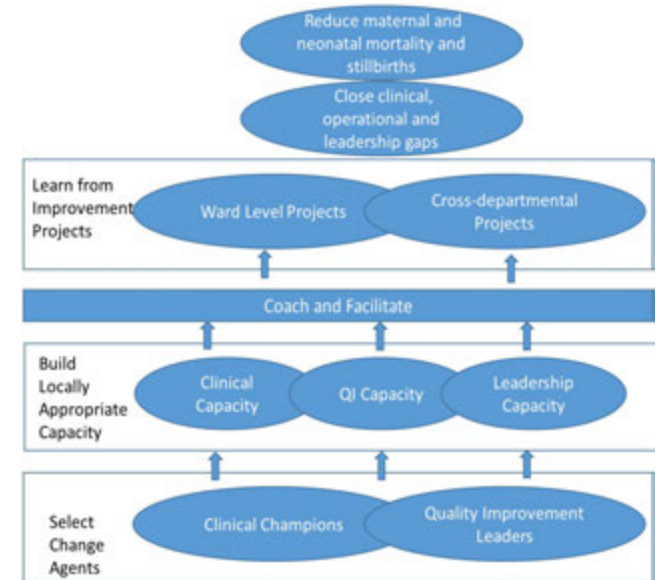
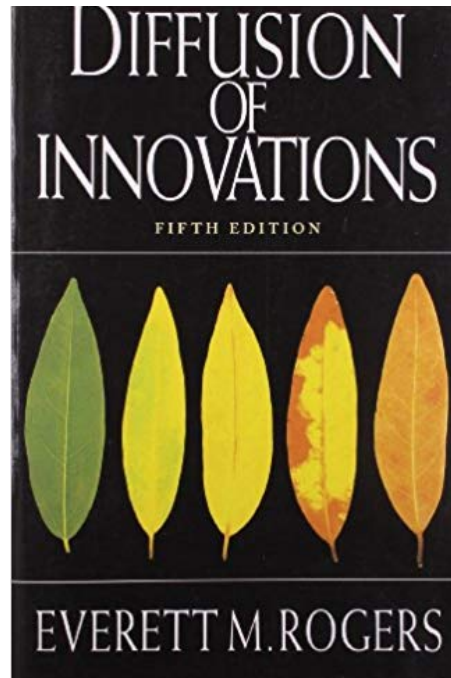
MARY DIXON-WOODS, CHARLES L. BOSK, EMMA LOUISE AVELING, CHRISTINE A. GOESCHEL, and PETER J. PRONOVOST

*University of Leicester; University of Pennsylvania; Johns Hopkins University*

**Context:** Understanding how and why programs work—not simply whether they work—is crucial. Good theory is indispensable to advancing the science of improvement. We argue for the usefulness of ex post theorization of programs.

**Methods:** We propose an approach, located within the broad family of theory-oriented methods, for developing ex post theories of interventional programs. We use this approach to develop an ex post theory of the Michigan Intensive Care Unit (ICU) project, which attracted international attention by successfully reducing rates of central venous catheter bloodstream infections (CVC-BSIs). The procedure used to develop the ex post theory was (1) identify program leaders' initial theory of change and learning from running the program; (2) enhance this with new information in the form of theoretical contributions from social scientists; (3) synthesize prior and new information to produce an updated theory.

**Findings:** The Michigan project achieved its effects by (1) generating isomorphic pressures for ICUs to join the program and conform to its requirements; (2) creating a densely networked community with strong horizontal links that exerted normative pressures on members; (3) reframing CVC-BSIs as a social problem and addressing it through a professional movement combining "grassroots" features with a vertically integrating program structure; (4) using several interventions that functioned in different ways to shape a culture of



# Theory of Change



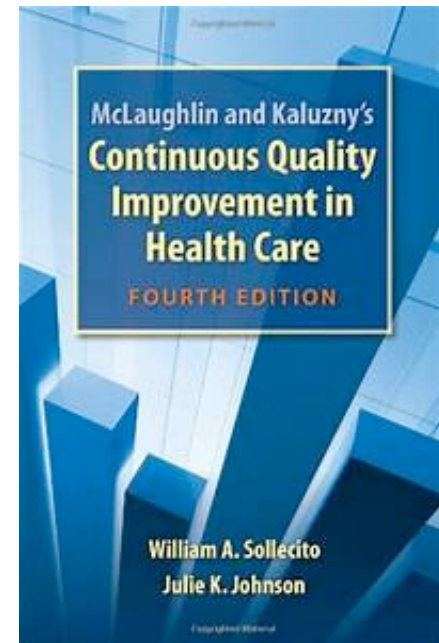
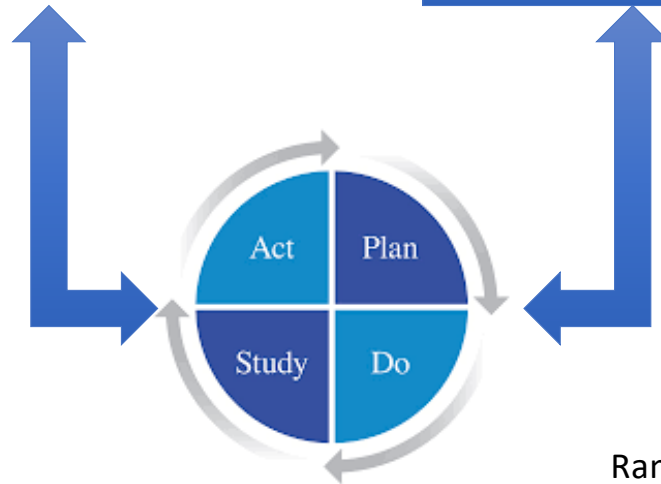
# MODEL FOR IMPROVEMENT AND IMPLEMENTATION

## Improvement Questions

- What are we trying to accomplish?
- How do we know that a change is an improvement?
- What change can we make that will result in improvement ?

## Implementation Questions

- What implementation outcomes are critical to implementing the change ?
- What factors impede the achievement of these outcomes ?
- What implementation strategies are the most appropriate to address these factors?



Ramaswamy R, Barach P, 2019

# Reverend Bayes and Prior Science

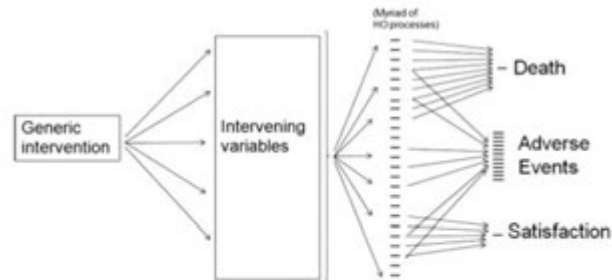
- Bayes' theorem tells us that what we learn from data formally depends upon what we already knew (and how confident we are in it)

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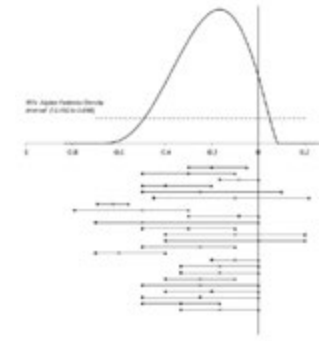
Original research

## Evaluation of a predevelopment service delivery intervention: an application to improve clinical handovers

Guiqing Lily Yao,<sup>1</sup> Nicola Novielli,<sup>1</sup> Semira Manaseki-Holland,<sup>1</sup> Yen-Fu Chen,<sup>1</sup> Marcel van der Klink,<sup>2</sup> Paul Barach,<sup>3,4,5</sup> Peter J Chilton,<sup>1</sup> Richard J Lilford,<sup>1</sup> on behalf of the European HANDOVER Research Collaborative\*



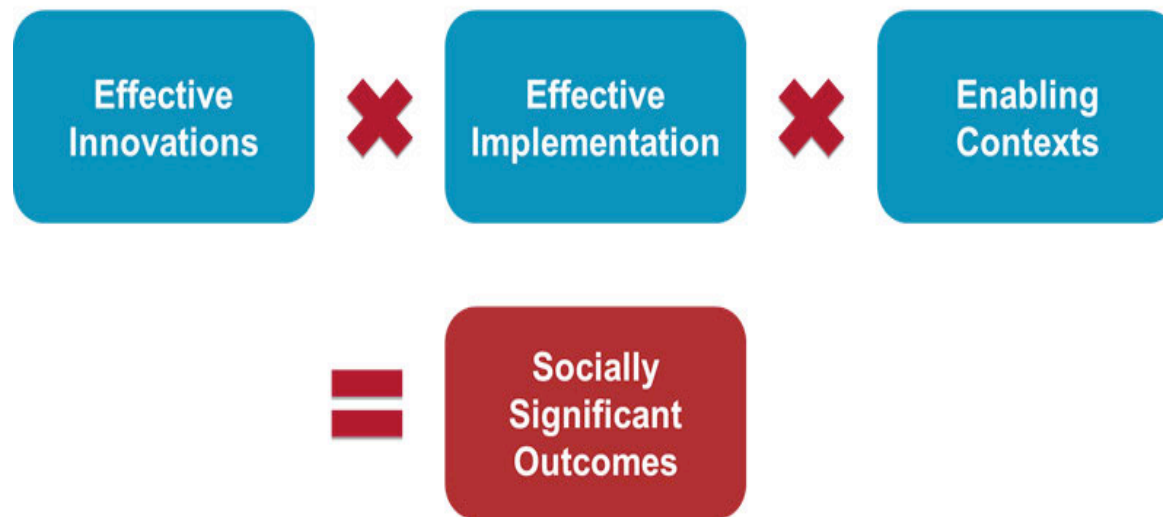
**Figure 1** Representation of the widespread effects of a generic intervention. Endpoints such as mortality, or those measuring satisfaction partially measure the effect of the intervention. A sensible grouping of adverse events allows the measurements of different dimensions of effectiveness.



**Figure 2** Results of the exercise to elicit experts' estimates on expected effectiveness. Above the x-axis, pooled expert opinion on the relative reduction of the attributable risk of adverse events as a result of the implementation of a proposed intervention to improve the quality of handover (mean =0.21 (21% reduction) and 95% Higher Posterior Density Interval [-0.492 to 0.048]). Below the x-axis: Best estimate (v), lowest (L) and upper (A) plausible values of the relative reduction of the attributable risk of adverse events as a result of the implementation of a proposed intervention to improve the quality of handover, as elicited from each of the 24 experts.

A corollary of these findings is that studies to detect minimum magnitude of effects that justify their cost need to be very large to avoid type 2 error—that is, a false null result. Studies demonstrating that adverse events can be reduced from a baseline of 19% to a rate of 17.7% (ie, the 1.3% reduction posited in the base case) would require 14 000 observations, both before and after the intervention at an alpha of 0.05 and a beta of 0.8. A less biased study with contemporaneous controls would require a much larger sample size,<sup>34</sup> and would be difficult to organise given the clustered nature of the data. Likewise, detecting the less than 0.5% absolute improvement level at which the intervention becomes cost-effective would be a totally quixotic undertaking. Even after full implementation, the cost-effectiveness of inexpensive interventions may have to be modelled, rather than estimated directly from observations of improved outcome for patients. The model developed at the outset can be repopulated as development proceeds and information of various sorts gradually accumulates.<sup>3</sup> This evidence may be surrogate evidence for patient outcomes. Such evidence is collated at the system level, upstream of the patient, as described elsewhere.<sup>8</sup> While evidence on effectiveness may be very difficult or impossible to obtain, other potential inputs to economic models, such as prevalence rates of adverse events and costs, can be obtained at lower cost and/or with less difficulty.

# Formula For Success



Ramaswamy R, Barach P, in press, 2019

### Five System Barriers to Achieving Ultrasafe Health Care

René Amalberti, MD, PhD; Yves Auroy, MD; Don Berwick, MD, MPP; and Paul Barach, MD, MPH

Although debate continues over estimates of the amount of preventable medical harm that occurs in health care, there seems to be a consensus that health care is not as safe and reliable as it might be. It is often assumed that copying and adapting the success stories of nonmedical industries, such as civil aviation and nuclear power, will make medicine as safe as these industries. However, the solution is not that simple. This article explains why a benchmarking approach to safety in high-risk industries is needed to help translate lessons so that they are usable and long lasting in health care. The most important difference among industries lies not so much in the pertinent safety toolkit, which is similar for most industries, but in an industry's willingness to abandon historical and cultural precedents and beliefs that are linked to performance and autonomy in a constant drive toward a culture of safety. Five successive systemic barriers currently prevent health care from becoming an ultrasafe industrial system: the

need to limit the discretion of workers, the need to reduce worker autonomy, the need to make the transition from a craftsmanship mindset to that of equivalent actors, the need for system-level (senior leadership) arbitration to optimize safety strategies, and the need for simplification. Finally, health care must overcome 3 unique problems: a wide range of risk among medical specialties, difficulty in defining medical error, and various structural constraints (such as public demand, teaching role, and chronic shortage of staff). Without such a framework to guide development, ongoing efforts to improve safety by adopting the safety strategies of other industries may yield reduced dividends. Rapid progress is possible only if the health care industry is willing to address these structural constraints needed to overcome the 5 barriers to ultrasafe performance.

*Ann Intern Med.* 2006;142:756-764.  
For author affiliations, see end of text.

www.ama-assn.org

More than 5 years ago, the Institute of Medicine report "To Err Is Human: Building a Safer Health System" highlighted the need to make patient safety a major priority for health care authorities (1). Since then, the pressure to increase patient safety has continuously grown in western countries. Priority has focused on identifying and reducing preventable events. Important changes have already been made to the accident and incident reporting system, and the associated techniques of analysis (2-6). However, the upper limit of harm prevention is unclear (7). Many investigators have proposed that adapting the success strategies and tools of ultrasafe systems, such as those used in the aviation and nuclear power industries, will lead to comparable successes and safety outcomes in health care (8, 9). The reality is probably more complicated. Many complex industries—for example, the chemical industry or road safety—have adapted the safety tools of advanced systems and made important gains in the past 2 decades. However, the safety results from most of these efforts top out well before the level reached by the civil aviation and nuclear power industries (10). This limit does not seem to be due to insufficient tools, low competence among workers, or naive safety strategies. For the most part, it seems to be the consequence of a conscious tradeoff among safety goals, performance goals, and the organization of the specific profession. Becoming ultrasafe may require health care to abandon traditions and autonomy that some professionals erroneously believe are necessary to make their work effective, profitable, and pleasant.

A comparative analysis of industry behavior demonstrates that becoming an ultrasafe provider requires acceptance of 5 overall types of constraints on activity. This

analysis is based on the screening of various socio-technical professions, such as the aviation, nuclear power, chemical, and food industries; road transportation; and health care. The benchmark analysis aims to associate specific traits of these industries with their safety performance. We then describe 5 high-level organizational dimensions derived from the general literature on risk and safety (11-15), each of which is associated with a range of values: type of expected performance (from daily routine work to highly innovative, and standardized or repetitive), interface of health care providers with patients (from full autonomy to full supervision), type of regulations (from few recommendations to full specification of regulations at an international level), pressure for justice after an accident (from little judicial scrutiny to routine lawsuits against people and systems), and supervision and transparency by media and people in the street of the activity (from little concern to high demand for national supervision).

We consider the value of a given dimension to become a barrier when it is present for all work situations that entail equal or less safety and it is absent for all work situations that entail greater safety. The barriers can be ranged along a safety axis by considering the average safety

See also:

Print

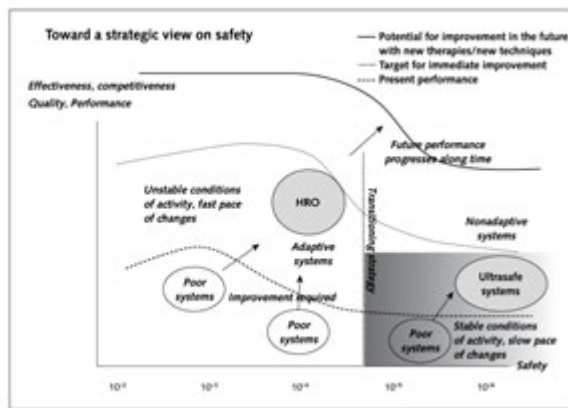
Key Summary Points ..... 757

Web-Only

Conversion of figures and table into slides

Improving Patient Care is a special section within *Annals* sponsored in part by the U.S. Department of Health and Human Services (DHHS) Agency for Healthcare Research and Quality (AHRQ). The opinions expressed in this article are those of the authors and do not represent the position or endorsement of AHRQ or DHHS.

Figure 2. A strategic view of safety in health care.



# Barriers to “Evidence-Informed” Policy Priorities

- There’s too much evidence.
- There’s not enough good evidence.
- The evidence doesn’t quite apply.
- People are trying to mislead you.
- You are trying to mislead you.
- The side effects outweigh the cure.
- Stories are more persuasive anyway.
- Evidence generally is agonistic to culture and context.

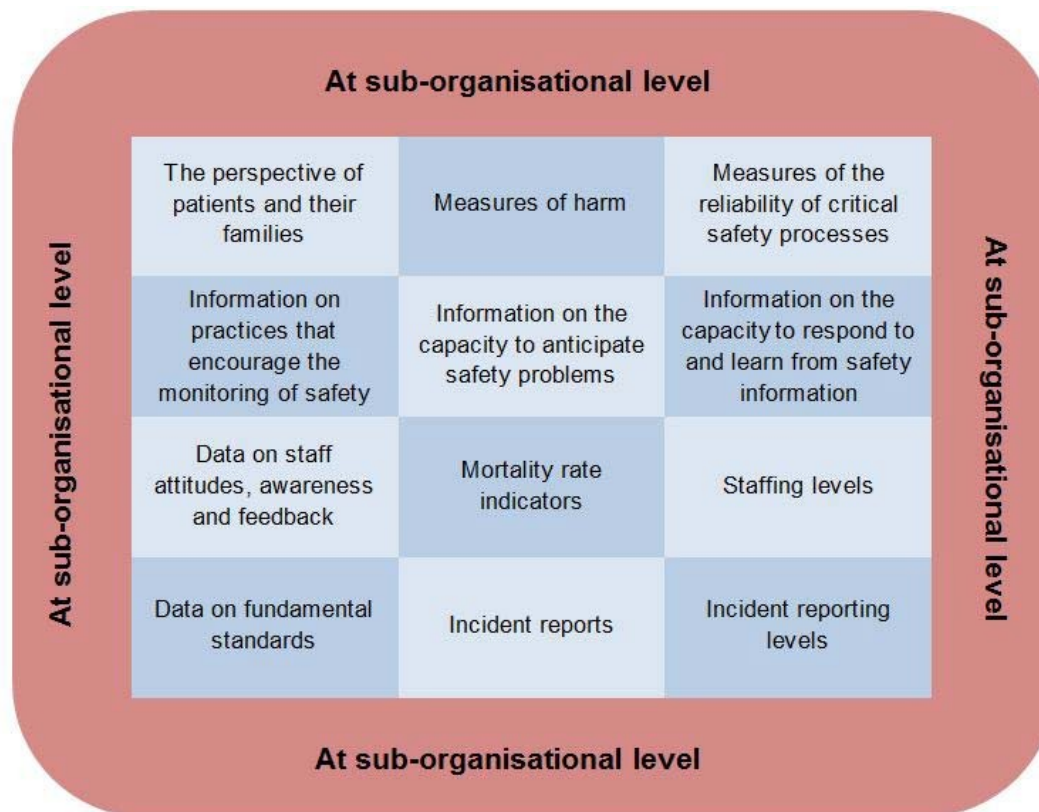
Almaberti A, Army, Berwick D, Barach P, 2006

## Outcomes Measurement and Transparency

- Transparency should be **complete, timely and unequivocal**. All non-personal data on quality and safety, whether assembled by government, organisations, or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the **public**.
- All organisations should seek out the **patient and carer voice** as an essential asset in monitoring the safety and quality of care.



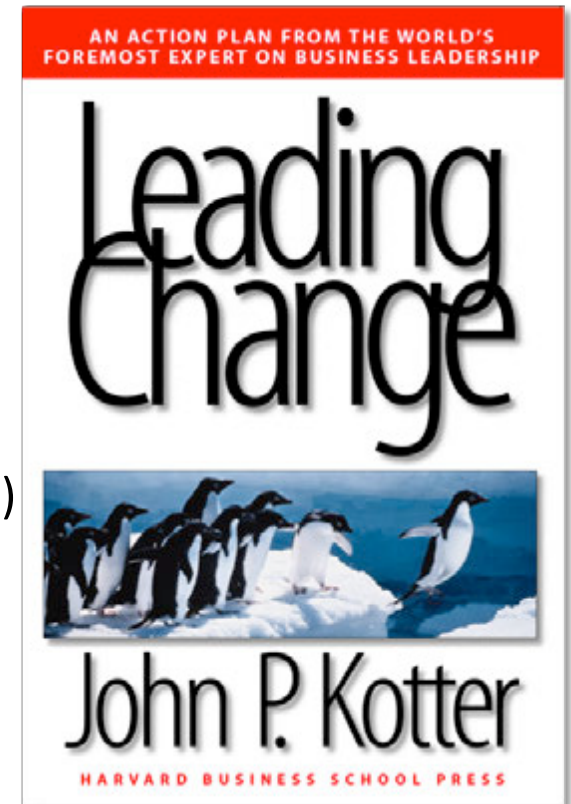
# Indicator Dashboard that should be used to assess safety improvement and reduce variation



Berwick et al. 2015

## Why Health Policy Transformation Efforts Fail?

- Lack of **urgency** (complacency)
- Fail to create a powerful **coalition**
- Failure to create a compelling **vision**
  - Competing visions (money vs safety; frontline vs leadership)
- Failure to **communicate** the vision clearly
- Failure to **remove obstacles**
- Failure to achieve **early wins**
- Declaring **victory** too soon
- Failure to **anchor change** in the culture



# Suggested Improvement Skills





## In Captian Sullenberger's Own Words...

---

*"One way of looking at this might be that for 42 years, I've been making small, regular deposits in this bank of experience, education and training.*

*And on January 15, the balance was sufficient so that I could make a very large withdrawal."*

## How does EC Health Policy Protect THESE CORE VALUES?

- Empathy
- Compassion
- Kindness
- Engagement
- Altruism
- Harmony
- Joy
- Loyalty



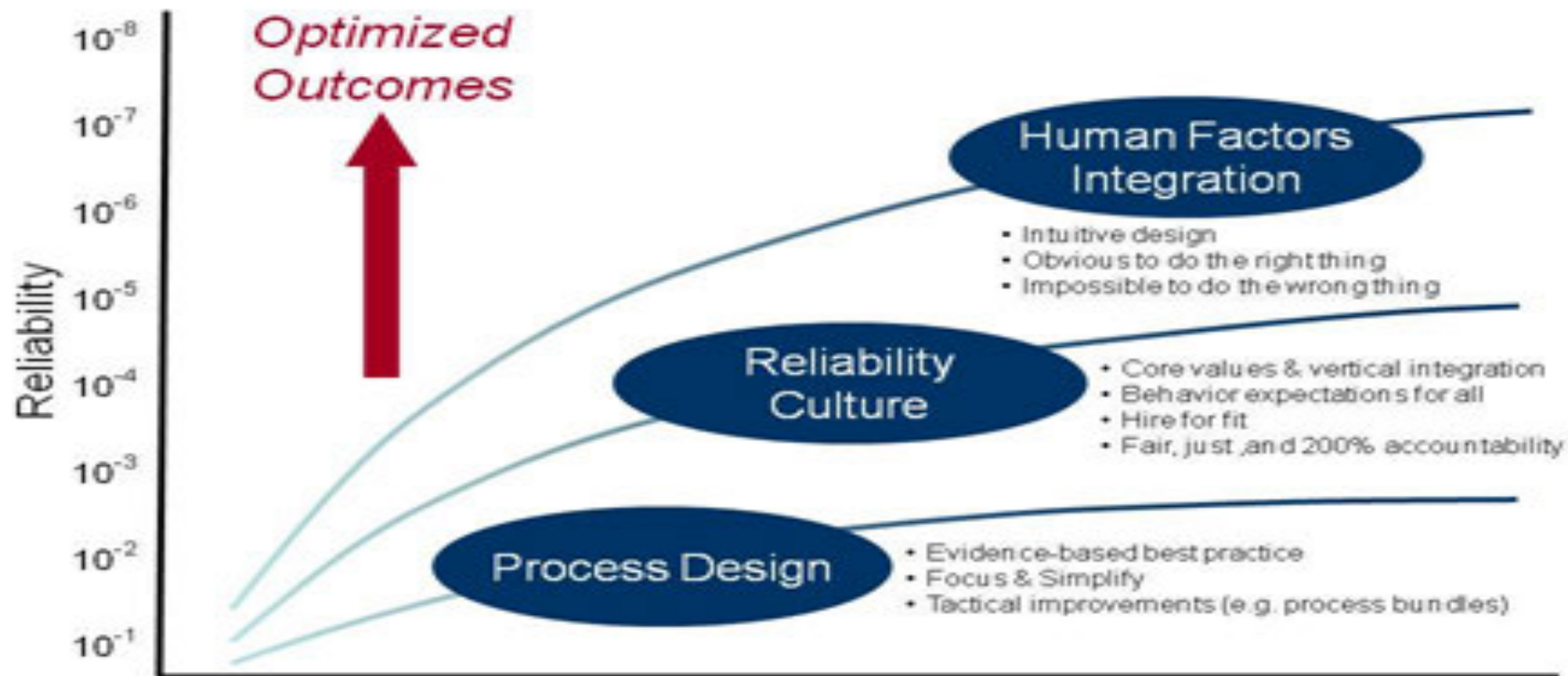
## Conclusions

- We must create care physical and organizational environments that support patient and provider's needs to support professional and respectful interactions.
- Engaging clinicians, patients and the community in the design and operational process remains the biggest obstacle in addressing the growing implementation gap in providing cost effective and reliable care.
- Facility design affects the design of how people work, and what processes, systems and technologies they will require to support the functioning of the work environment ( "Culture").
- Challenging individuals without also engaging their values and their overall care environment is not sustainable.

Slide: 56

**Culture Eats Strategy"—Peter Drucker**

# Journey to Reliability – The Next Zero



## “The Secret of Health Quality (Competency) is Love”

- “Systems awareness and systems design are important for health professionals but are not enough.
- They are enabling mechanisms only.
- It is the **ethical dimension** of individuals that is essential to a system’s success. Ultimately, the secret of quality is love...
- **If you have love, you can then work backward to monitor and improve the system.”**

**Avedis Donabedian**

