Patient Safety: 10 Years Later
Why is Improvement So Hard?

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Patient Safety: Strong Beginnings

- 1999 US Institute of Medicine Report: To Err is Human
- 2002 UK Report: An Organization with a Memory
- 2002 National Steering Committee on Patient Safety recommends creation of Canadian Patient Safety Institute
The Canadian Focus on Patient Safety Began in 2004

Considerable Efforts over Ten Years

- Safer Healthcare Now!
- Accreditation Canada Required Organizational Practices (ROPs)
- ISMP Medication Safety Initiatives
- Health Quality and Safety Councils
- Patient Safety Measurement
- Governance Initiatives
So Are Patients Safer Now?

Landrigan, et al. Temporal Trends in Rates of Harm Resulting from Patient Care, NEJM 2010
Adverse Events Rates Resist Improvement

- Netherlands studies of Adverse Events found no improvements between 2004 and 2008.
- AE Rate per 1000 days increases from 6.0 to 10.5 but preventable AE rate is stable.
- “The absence of improvements in preventable AE rates in these and our own study raises the question as to what extent it is possible to improve preventable AE rates.”

Baines, et al., BMJQS 2012

Growing Evidence of Safety Problems In Other Sectors

- Chart review of home care clients in MB, QC and NS using adaptation of acute care tools.
- The results indicate that 4.2% of home care clients experience an AE each year, the AE rate per client year was 10.1%, and 56% were preventable.
Why is Improvement So Hard?

• Is it the nature of the problems?
• Is it the difficulty of implementing and sustaining the improvements?
• Is it the broader healthcare environment that makes change difficult?
• Or, are we still learning how to make large scale change in complex systems?

Consider Three Key Initiatives

• Medication Reconciliation
• Safe Surgery Checklist
• Central Line Infections Bundle
Medication Reconciliation

- Adverse drug events are a major source of patient harm in all settings
- Transitions between settings create risks as medications are discontinued, started or changed
- Medication reconciliation provides an effective strategy for reducing these risks
- Standards for hospitals and other healthcare organizations require medication reconciliation at transitions

Impact of Medication Reconciliation

- There are few rigorously designed studies of medication reconciliation in comparison to usual care
  - Studies show consistent reduction in medication discrepancies (17 of 17 studies); potential adverse drug events (5 of 6 studies); and adverse drug events (2 of 2 studies); but inconsistent impact on post discharge healthcare utilization (2 of 8 studies show improvement)
- Key aspects of successful interventions include intensive pharmacy staff involvement and targeting to high risk population

Mueller, et al., 2012
Challenges for Effective Medication Reconciliation

• Unintended discrepancies are common but most are relatively minor

![Figure 2, Chapter 25. Median and interquartile range for the number of clinically significant unintentional discrepancies per patient for the 13 included interventions](image)

Challenges for Medication Reconciliation, 2

• Medication reconciliation can have a significant impact on these discrepancies but eliminating risk is difficult
  – Schnipper study (2009) showed a relative reduction of 28% in unintended discrepancies

• Three RCTs showed a pooled reduction in ED visits and hospital readmissions of 23%, but this result was largely the result of one study where Med Rec was one of several interventions aimed at reducing readmissions (Making Health Care Safer II, 2012)
Challenges for Medication Reconciliation, 3

- Medication reconciliation is a time consuming process in often busy environments
- Many clinicians see medication reconciliation as a superficial administrative task requiring completion of forms, rather than a critical step in patient admission and discharge
  - Many clinicians do not have formal training
- Pharmacists are ideally suited to lead MR as part of an inter-professional team, but
  - Many wards do not have clinical pharmacists
  - Many hospitals have insufficient resources to provide pharmacy expertise to all MR
  - If pharmacists lead then other professionals may not see the need to participate

**TABLE 1.** Medication reconciliation in varying levels of intensity, as seen in published studies

<table>
<thead>
<tr>
<th>Level</th>
<th>Key Components</th>
<th>Published Examples</th>
</tr>
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<tbody>
<tr>
<td>Bronze</td>
<td>BPMH with admission reconciliation</td>
<td>Cornish et al. 2005; Kwan et al. 2007</td>
</tr>
<tr>
<td>Silver</td>
<td>Bronze level + reconciliation at discharge by prescriber only + electronically generated discharge prescription</td>
<td>Schnipper et al. 2008; Wong et al. 2008</td>
</tr>
<tr>
<td>Gold</td>
<td>Silver level + discharge reconciliation is inter-professional (e.g., prescribing physician and pharmacist collaboration) + electronically generated discharge prescription</td>
<td>Cesta et al. 2006; Dedhia et al. 2009; Schnipper et al. 2009</td>
</tr>
<tr>
<td>Platinum</td>
<td>Gold level + attention to broader medication management issues (e.g., appropriateness of agents, safety and effectiveness assessment) + medication counselling prior to discharge (including discussion of medication changes) + provision of patient-friendly reconciliation medication schedules upon discharge</td>
<td>Al-Rashed et al. 2002; Dedhia et al. 2009; Makowsky et al. 2009; Murphy et al. 2009; Nazareth et al. 2001</td>
</tr>
<tr>
<td>Diamond</td>
<td>Platinum level + additional elements, such as post-discharge follow-up phone call to patient by hospital clinician (e.g., nurse or pharmacist) + communication of medication changes with rationale directly to community pharmacy and primary care physician</td>
<td>Gillespie et al. 2009; Jack et al. 2009; Karapinar-Cakkit et al. 2009; Schnipper et al. 2006; Walker et al. 2009</td>
</tr>
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BPMH = best possible medication history.

Fernandes and Shojania, 2012
Harm in Surgery

• Although surgery is an essential component of healthcare, there are considerable risks of complications and deaths
  – Most common event or procedure in the Canadian Adverse Events Study
  – Estimates from industrialized countries provide mortality estimates of 0.4 to 0.8% and major complication rates of 3 to 17%
  – Analysis of surgical events in US and Australia suggest that 50% or more are preventable
Perceptions of Teamwork in Surgery

Surgical Checklists

- Checklists are one of the key tools for creating safer care
- Checklists are used in many industries as a strategy for ensuring safety practices and clear communication among team members

Fig 1. Rating of teamwork with consultant surgeons

Sexton, et al., 2000

Sexton, et al., 2000
Surgical Checklist

- Studies of OR teamwork found multiple types of communication failures that may have patient safety implications – and that checklists help

A study of 8 hospitals in 4 countries found checklists were associated with reductions in mortality (1.5% to 0.8%) and in-patient complications (11.0% to 7.0%)
Recent review of literature on surgical checklists indicates:

“Checklist were associated with increased detection of potential safety hazards, decreased surgical complications and improved communication among operating staff.”

“Strategies for successful checklist implementation included enlisting institutional leaders as local champions, incorporating staff feedback for checklist adaptation and avoiding redundancies with existing systems for collecting information”

Treadwell, et al. , 2014
Baker, Flintoft, unpublished

**Impact of SSC use on OR function**

- **Percentage**
  - **Communication**: 78%
  - **Teamwork**: 21%
  - **Workflow in OR**: 44%
  - **Workflow between Cases**: 26%
  - **Patient Safety**: 61%

**Analysis of harm from surgery within 30 days for 101 Ontario hospitals, 3 months before and 3 months after checklist implementation**
Surgical Checklists Had No Impact

The adjusted risk of surgical complications within 30 days after the procedure was 3.86% before implementation of a checklist and 3.82% afterward. The only complication for which the risk significantly decreased was an unplanned return to the operating room (from 1.94% to 1.78%. DVT risk increased.

The likely reason for the failure of the surgical checklist in Ontario is that it was not actually used.

Lucian Leape
“While checklists are valid and useful we need in the longer term to think more in terms of designing teamwork in the same way as we design equipment.”

Charles Vincent
CR-BSI intervention

- Clinical protocols
  - Hand hygiene
  - Full-barrier precautions during insertion of central venous catheters
  - Cleaning the skin with chlorhexidine
  - Avoid the femoral site
  - Remove unnecessary catheters
Strategies to ensure adherence

- Education for clinicians on infection control and harm resulting from CR-BSIs
- A standardized central line cart with necessary supplies
- Checklist to ensure adherence to infection control practices
- Discussion of catheter removal at daily rounds
- Feedback regarding the number and rates of CR-BSIs at monthly and quarterly meetings
- Letters to CEOs to request that chlorhexidine was available

What Accounts for Keystone Success?

- Evidence based practice captured in the checklist was necessary, but not sufficient
- Key elements that supported improvement included:
  - Competitive pressure to improve
  - Sharing information among sites
  - Better data on infection rates shared among sites
  - Use of persuasion (soft tactics) and sanctions (hard tactics)

“Matching Michigan”

- Two year, four cluster, non-randomized study of the technical and behavioral interventions to prevent CR-BSIs in adult and pediatric ICUs in England
- 215 ICUs (of a total 223 in England) submitted data covering 438,887 CL patient days
- The mean CR-BSI rate was reduced over 20 months from 3.7/1000 CL patient days to 1.48 in adult patients and from 5.65 to 2.89/per 1000 CL patient days in pediatric patients

Adult ICU CL-BSI rates by Cluster
Local Context Explains Success

• A detailed review of the experiences of 17 English ICUs that participated in Matching Michigan found:
  – Previous efforts to improve infection rates, perceived as punitive, influenced engagement
  – Individual ICU experiences and histories were important, including:
    • Influence of local leaders in creating collaboration and consensus
    • Availability and use of data
    • Past experience with quality improvement

“Perhaps the single most important influence on program response by individual units— either in promoting or resisting change— was the extent of consensus and coalition among the senior medical and nursing staff on individual ICUs. The commitment, characteristics, and skills of local leads were pivotal. Transforming or boosting of efforts was most likely to occur when those locally charged with implementation were sincere in their beliefs about the value of the program, were able to create transdisciplinary alliances, had local credibility among peers, were prepared to tolerate debate but exercise firmness, and used multiple tactics including role modelling, persuasion, sanctioning, reminders, and constant feedback”

Dixon-Woods, Leslie, Tarrant and Bion, 2013
Characteristics of Setting

- Peer pressure
- External policy and incentives
- Culture
- Implementation climate
  - Tension for change
  - Relative priority and perceived importance
- Readiness for implementation
  - Leadership
  - Available resources
  - Access to information about the intervention and how to integrate it into work tasks

Damschroder, et al., 2009

Process of Implementation

- Planning
- Engaging
  - Opinion leaders
  - Formally appointed internal implementation leaders
  - Champions
  - External change agents
- Executing
- Reflecting and evaluating
Adaptive Versus Technical Change

“Resistance to adaptive change…is the classic error. Companies treat adaptive challenges as if they were technical problems. For example, executives attempt to improve the bottom line by cutting costs across the board. Not only does this avoid the need to make tough choices about which areas should be trimmed, it also masks the fact that the company’s real challenge lies in redesigning its strategy.”

Heifetz and Linsky, 2002

Effective Microsystems Need to be Part of Larger Systems that Can Deliver Reliable Care

“…quality improvement could help planners and policy makers think differently about how to improve the design of healthcare buildings and systems. It is important that this happens as there is little point of improving front line clinical delivery if it is embedded in a wider system that is dysfunctional. QI methods offer the chance to find innovative ways to solve some of the most intractable problems…”

N Edwards Qual Saf Health Care 2005;14:75
9 Success Factors for Clinical Microsystems

Nelson, Batalden, Huber, et al., 2002

Patient Safety Culture Results, 2012

<table>
<thead>
<tr>
<th>Positive response (%)</th>
<th>Canada (n=35,941 respondents)</th>
<th>Ontario (n=21,541 respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Safety Learning Culture</td>
<td>71</td>
<td>69</td>
</tr>
<tr>
<td>Senior leadership support for safety</td>
<td>67</td>
<td>67</td>
</tr>
<tr>
<td>Supervisory leadership for safety</td>
<td>58</td>
<td>58</td>
</tr>
<tr>
<td>Talking about errors/communication barriers</td>
<td>53</td>
<td>50</td>
</tr>
<tr>
<td>Overall perception of patient safety</td>
<td>66</td>
<td>67</td>
</tr>
</tbody>
</table>
Creating a Patient Safety Culture

• Effective strategies and techniques:
  – Executive walk-rounds
  – Interdisciplinary rounding
  – Unit based safety initiatives
  – Team training

• Effort that include both technical interventions and adaptive change may be most effective
  – Johns Hopkins Comprehensive Unit Based Safety Program (CUSP)

Safety Strategies Should Correspond to the Current Performance of the System

Rene Amalberti
Conclusions

• Despite the attention paid to patient safety, results in many settings have been limited
• The search for evidence-based practices provides an armamentarium of solutions
• But success lies as much in the implementation of these practices as their technical merits
• Creating local practice environments that support staff and create a culture of patient safety is the critical challenge facing those who want to reduce harm