Patient Safety: Raising the Bar

G. Ross Baker, Ph.D.
Health Policy, Management & Evaluation
University of Toronto
September 13, 2004

Overview

* Implications of the Canadian Adverse Events Study
* Patient Safety Strategies
  - Key elements
  - Setting priorities
  - Improving Performance
* Raising the Bar
Canadian Adverse Events Study

- Reviewers examined 3776 charts in 20 hospitals and found 289 AEs
- After weighting for the sample frame, the overall AE rate was 7.5% [CI 5.7 -9.3] – this means 1 in 13 had an AE
- 2.8% of patients had one or more preventable AEs [CI 2.0 – 3.6] (i.e. 37.3% of AEs are preventable)
- 65% of AEs resulted in either no disability or minimal and moderate impairment with recovery within 6 months

40 patients who had a total of 46 AEs died

- An estimated total 1.6% of people hospitalized in Canadian hospitals in 2000 had an AE and died [CI =0.9 to 2.2%]
- Assuming an average LOS of 3.5 days and 95% occupancy, then a 500 bed Canadian hospital would have an average of 100 preventable AEs per month
  - Based on a large hospital estimate of 2.5% of patients with preventable AEs [CI= 1.7 to 3.3%]
Impact of CAES

- Considerable interest in results
  - Despite the embargo violation during the May long weekend, the study received heavy press coverage
  - 25,000 downloads of CMAJ article in first four days
- Federal election call shortened media interest
- More recent concern with sustainability and federal-provincial negotiations on waiting lists and increases in federal contributions have appeared to push patient safety into the background

“The pessimist complains about the wind; the optimist expects it to change; the realist adjusts the sails”

William Arthur Ward
Policy Developments

- National professional organizations released policy statements identifying patient safety goals
- CAES provided an impetus to the early work of CPSI
- Accreditation standards underway
- Patient Safety performance indicators likely
- Ontario Ministry of Health invests in patient safety efforts
  - Similar efforts elsewhere including strong efforts in Saskatchewan, Winnipeg, Calgary and Vancouver among other areas
- Number of supportive efforts from OHA, ISMP Canada and others

CCHSA Will Follow JCAHO

- US Joint Commission has articulated a number of patient safety goals
  - Improve the accuracy of patient identification
  - Improve the effectiveness of communication among caregivers
  - Improve the safety of using high alert medications
  - Eliminate wrong site, wrong patient, wrong procedure surgery
  - Improve the safety of infusion pumps
  - Improve the effectiveness of clinical alarm systems
  - Reduce the risk of health care-acquired infections
Patient Safety Indicators

- AHRQ funded the identification of PS indicators that can be derived from administrative data
- Efforts to identify similar indicators are underway in Canada

AHRQ Patient Safety Indicators

- Anaesthesia complications
- Death in low mortality DRGs
- Decubitus ulcer
- Failure to rescue
- Foreign bodies left during surgery
- Iatrogenic pneumothorax
- Infection due to medical care
- Post op hip fractures
- Post op hemorrhage or hematoma
- Post op physiologic or metabolic derangement
- Post op respiratory failure
- Post op thromboembolism
- Post op septicemia
- Post op abdominopelvic wound dehiscence
- Accidental puncture or laceration
- Transfusion reaction
- Birth trauma
- Obstetric trauma
Possible Future Patient Safety Hospital Report Measures

- Clinical outcomes
  - Complications
  - Type 2 codes
- Patient viewpoint
  - Patient views of safety
- Financial
  - Investments in safety oriented systems
- System Integration and Change
  - Human resources
  - Programmatic efforts

So What Should Healthcare Organizations Do To Improve Safety?
FIGURE 2: A Conceptual Model of Strategies for Making Healthcare Safer

Measurement
- Reliable
- Valid
- Cost effective
- Accepted timely

ERROR REDUCTION
- Culture
  - Non-blaming
  - To err is human
  - Learning
  - Leadership
- System Tools & Change Strategies
  - Improvement
  - System thinking
  - Redesign processes
  - Rapid cycle
  - Near miss

FMEA
HACCP

Prioritization

Rapid Cycle Testing

Deployment and Implementation

Injury and Near Miss Detection

Successful Change Ideas From Elsewhere

Institute of Medicine, 2004
Injury and Near Miss Detection

- First key issue is determining current performance and deciding where to focus our efforts
- Improving data collection to identify adverse event areas is challenging
  - Most organizations have poorly used incident reporting systems
  - Sustained efforts to increase reporting typically yield an 8 to 12 fold increase in reports
  - Barriers are complex and include substantial cultural resistance to improved reporting

You’ve made a mistake

- Will it show?
  - Yes
    - Can you hide it?
      - Yes
        - Conceal it before anyone finds out
      - No
        - Can you blame someone else, or special circumstances?
          - Yes
            - Get in first with your version of events
          - No
            - Could an admission damage your career prospects?
              - Yes
                - Sit tight and hope the problem goes away
              - No
                - Problem avoided
  - No
    - Bury it
Some Vulnerabilities Must Be Surfaced

- Risk prioritization exercises
  - HIROC risk assessment
  - Winnipeg Regional Health Authority process
  - Solicit input from knowledgeable staff
Identifying Priorities

◆ Solicit input from many stakeholders
  - “what keeps you up at night?”
  - Where are we vulnerable?
◆ Evaluate available safe practices
  - Evidence of effectiveness
  - Feasibility and measurability
  - Potential impact
◆ Stakeholder committee selects two or three
◆ Working groups assigned to manage projects

Adapted from Leape, 2003

Examples of High Risk Areas That Deserve Special Attention

◆ Many and varied interactions with diagnostic or treatment technology; many different types of equipment being utilized
◆ Multiple individuals involved in the care of individual patients; many handoffs
◆ High acuity of patient illness or injury
◆ Ambient atmosphere prone to distractions or interruptions
◆ Need for rapid care management decisions; care givers subject to time pressures
◆ High volume and or unpredictable patient flow
◆ Use of diagnostic or therapeutic interventions having a narrow margin of safety; including high risk drugs
◆ Communication barriers with patients and/or other coworkers
◆ Instructional setting for care delivery, with inexperienced caregivers

Institute of Medicine, 2004
How Can We Learn From the Errors and Near Misses?

- First stories are rarely complete
- Hindsight bias makes the way the incident happened seem inevitable and predetermined
- System factors are often difficult to uncover
- There is rarely one “root cause” but rather a series of conditions and untimely combination of events that leads to failure
After Brent James
Intermountain HC

**Patient Injuries**

- **Frequent events**
  - ADE
  - Hospital acquired infections
  - Falls and restraints
  - Decubitus ulcer

- **Rare events**
  - Wrong side surgery
  - Suicide
  - Device failure

- Prospective expert case finding using triggers
- Voluntary reports in a blame free culture

- **Recognize causes**
- **Unusual Cause**
- **Root cause analysis**
- **Record and monitor**
- **Target Improvements**
- **Risk management & improvement**

---

**The Incident**
KCl used to flush Central line

**Prior Action**
Remove K From floor

**Root Cause Analysis**

- 4th incident in 12 mo
- 8 other ‘push’ problems in last 6 weeks

**Environment**

**Policy**

**Teamwork**

**Staffing**

Calgary Health Region
Policy
- The critical incident committee had passed policy to remove KCL from wards 18 months before

Staffing
- One nurse short and no pool nurse was available the day of the incident

Teamwork
- The pharmacists are not involved in the inventory control or use of stock floor medications
Root Cause Analysis

- A set of tools and an approach to determine
  - What happened?
  - Why did it happen?
  - What do you do to prevent it from happening again?
- RCA is based on the premise that people do not come to work to do a bad job or make an error, but given the right set of circumstances any of us can make a mistake.
- It forces us to look past the easy answer that it was someone’s fault - to answer the tougher question as to why the error occurred.
  - It is seldom a single reason

Root Cause Analysis is

- Interdisciplinary, involving experts from the frontline services
- Involving of those who are the most familiar with the situation
- Continually digging deeper by asking why, why, why at each level of cause and effect
- A process that identifies changes that need to be made to systems
- A process that is as impartial as possible
HFMEA

- Health Care Failure Mode and Effect Analysis is a hybrid prospective analysis model that combines FMEA and other tools with root cause analysis (RCA) to improve healthcare processes.
- Developed by VA National Center for Patient Safety in US in collaboration with Tenet Health System.

HFMEA for IV Patient Controlled Analgesia (PCA)

Source: ISMP

Assess patients → Choose Analgesic & Mode of delivery → Prescribe Analgesic

- Failure mode: 1. Inaccurate pain assessment
- Failure mode: 1. Wrong analgesic selected
- Failure mode: 1. Wrong dose, route, frequency
- Failure mode: 2. Proper patient monitoring not ordered
- Failure mode: 3. Prescribed for wrong patient
- Failure mode: 4. No order received

Prepare med → Produce label → Enter order Into computer → Send order To pharmacy

- Failure mode: 1. Wrong drug
- Failure mode: 2. Wrong diluents Concentration
- Failure mode: 1. Label inaccurate
- Failure mode: 2. Label unclear
- Failure mode: 3. Label not printed
- Failure mode: 1. Order misunderstood
- Failure mode: 2. Order entered incorrectly
- Failure mode: 3. Entered for wrong patient
- Failure mode: 1. Order not received
- Failure mode: 2. Delay in receiving
System Fixes to Improve Safety

Epidemiological Analyses

Process Analyses
- FMEA
- HACCP

Injury and Near Miss Detection

Successful Change Ideas From Elsewhere

Prioritization

Rapid Cycle Testing

Deployment and Implementation

Holding the Gains

Institute of Medicine, 2004

Safety Tools

- Education
  - Staff orientation
  - Continuing education
- Simulation
- Teamwork and communication skills
- CPOE
- Medication safety tools
  - Bar coding
  - MAR
- Clinical practice guidelines
- Standardization of equipment
- Human Factors review of equipment
- Review of high risk areas
- Quality improvement
- Local problem solving
- Organizational collaboratives
Patient Safety Challenges

◆ Most healthcare organizations are treating adverse events as a technical challenge
◆ The real challenge is transforming the work and the patterns of behavior that have developed around the work
◆ Improving patient safety is primarily a cultural change, not a technical change

Safety Culture

◆ Safety cultures underlie safe performance by individuals and teams but are hard to achieve
◆ Key values of safety cultures
  – Informed
  – Just
  – Flexible
  – Learning
  – Reporting
  – Mindful

Reason, 1997; Marx, 2001; Weick and Sutcliffe, 2001
**Systemic Migration to Boundaries**

*VERY UNSAFE SPACE*

ACCIDENT

‘Illegal normal’
Real life standards

BTCUs
Border-Line tolerated
Conditions of Use

Usual Space
Of Action

Safety Regs
& good practices
Certification/ accreditation standards

Expected safe
space of action
as defined by
professional
standards

Adapted from R. Amalberti

---

**Advice on Helping To Shift Cultures**

1. Track down bad news
2. Clarify the onus of proof
3. Stalk the anomalous
4. Define the near miss
5. Consolidate your explanations
6. Don’t underestimate the power of social influence
7. Examine how your culture treats feedback
8. Act your way into new values
9. Don’t ignore the “heart” of culture
10. Encourage people to paraphrase
11. Crystallize the culture into symbols
12. Exercise control through culture
13. Think safety first!
14. Treat culture as an investment in resilience
15. Arm yourself for guerilla warfare

*Weick and Sutcliffe, 2001*
Tools for Safety Culture and Leadership

- Conversations and structured readings
- Surveys
- Appoint “Safety Champions”
- Executive Walk Rounds
- Safety Briefings
- Provide Feedback to Frontline Staff
- Accountability principles
- Disclosure Policies

Patient Safety Executive Walkrounds

- Senior executives conduct weekly visits to different areas of the organization
- Focus on asking staff about adverse events and near misses
- Solicit ideas from front line staff on improving safety and quality
- Raise awareness
- In the Calgary Health Region and Partners Healthcare (Boston) events are entered into a database and analyzed in terms of contributing factors and used to identify QI projects

Frankel, et al., 2003; Brenda Fisher, Calgary Health Region
Safety Briefings

- Based on experiences in other industries
- Goal is to raise safety awareness among staff in a non-punitive fashion
- Encourage staff to share experiences and identify common safety issues
- Can be designed and carried out by staff with limited guidance from management

Accountability

- Accountability requires clarification of responsibility, lines of reporting and specific areas of responsibility
- Accountability is not “who’s to blame?” but “how do we make it happen?”

Adapted from IHI.org
Accountability Principles

- Meaningful accountability is collaborative, supportive and reciprocal
- Safety is everyone’s responsibility
- The goals of safety trump personal preferences
- Accountability is rooted in legal, moral and professional responsibilities

Adapted from Leape, 2003

Disclosure Policies

- Public and professionals both agree that patients should be told when errors are made in their care
  - US data (Blendon, 2003)
    - Physicians 77%
    - Patients 89%
  - Alberta data are similar
Tracking Culture Change

- Several culture surveys have been developed to stimulate reflection and monitor progress
- Views of culture vary between the front line and the front office
- Changing culture requires addressing patterns of behavior and expectations

Raising the Bar

- Competing priorities will limit efforts to make healthcare safer
- Can we launch a “Toyota” project in Canada to create a model for safe healthcare?
- If you always do what you’ve always done...you’ll always get what you always got

Raising the Bar

It is impossible to know what a truly safe healthcare organization will look like, but based on work on high reliability organizations in other industries we can create some good predictions
High Reliability Organizations

- Accidents can be prevented through good organizational design and management
- Safety is the priority organizational objective
- Redundancies enhance safety
- Decentralized decision-making is needed to permit prompt, flexible field-level responses
- A “culture of reliability” will enhance safety by encouraging uniform and appropriate responses by field level operators
- Continuous operations, training and simulators can create and maintain high reliability operations
- Trial and error learning can be supplemented by anticipation and simulation

D. Gaba, modified from S. Sagan, 1993

How Do We Create HROs?

- Two projects that provide models
  - IHI Pursuing Perfection
  - UK Health Foundation Safer Patients Initiative
IHI Pursing Perfection project

- $21 million (US) project funded by Robert Wood Johnson Foundation
- Managed by IHI
- Goal is to create models of excellence at a select number of provider organizations that are redesigning all of their major care processes
- 13 participating organizations in the US, England, the Netherlands and Sweden

Cincinnati Children’s Hospital

- Wait time for Same Day Surgery patients was reduced from 67 to 35 minutes using an expedited outpatient process
- Instrument processing time for general surgery reduced by 51 percent, allowing for more timely surgery
- Hospital admission rates for several common childhood illnesses reduced by 15 percent.
- Adolescents hospitalized with cystic fibrosis customize their own inpatient schedules to meet their individual needs
- The average wait time for infants with a fever of uncertain source to receive antibiotic treatment after arriving in the Emergency Department has been reduced by over 53 percent.
Safer Patients Initiative

- £4 million initiative launched by the Health Foundation (UK) with the objective of making hospitals safer for patients
- Any NHS acute care organization that has the greater part of its resources in general acute and/or tertiary acute services is eligible to apply
- The program provides
- In depth support to develop goals, implement changes to improve patient safety, monitor progress and share their learning
- Financial support for trusts to help build capability and capacity for improving patient safety.
- Financial support to help trusts develop as leading centres in improving the safety of patients. Institutions will become exemplars in patient safety, building learning partnerships with other organizations and providing opportunities to allow open access for others to learn from their success.
- Award holders will work with an expert team from the Institute for Healthcare Improvement (IHI), based in Boston, USA, and noted safety experts from all over the world.

Conclusion

- Patient safety has become an important issue in the Canadian health care system
- Developing patient safety initiatives will require dedicated resources and leadership
- Competing priorities are likely to make progress slow
- Selecting a small number of organizations to focus on increasing safety might offer a way to advance the overall performance of the system