To Err is Human: Is Patient Safety an Issue for Palliative Care?

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Objectives

1. Describe the extent of the issue of patient safety
2. Define patient safety and error and give examples
3. Describe resource documents
4. Discuss issues of safety in home care
5. Discuss ways of looking at safety issues
6. Make recommendations about further action
Key Messages

1. Safety is everyone’s concern & is an integral part of quality
2. Safety involves more than errors, mortality & serious morbidity but is a source of suffering
3. Palliative care environments are not necessarily safe
4. Blaming someone does not solve the problems
5. Safety issues are system issues
Why discuss this issue?

• In the last 2 weeks, how many of you remember an incident of patient safety or medical error?
Magnitude of the Issue

• Medical care has potential to cause harm
  – However, acknowledgment that much iatrogenic injury may be due to human error or system failures has been slower to emerge

• Every day, thousands of errors occur in the Canadian health care system
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<thead>
<tr>
<th>Study Author</th>
<th>Adverse Events</th>
<th>Adverse Events Determined to be Preventable</th>
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<tr>
<td>(Baker et al., 2004) Canada</td>
<td>7.5%</td>
<td>36%</td>
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<td>(Thomas et al., 2000a) Utah, Colorado</td>
<td>2.9%</td>
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<tr>
<td>(Wilson et al., 1995) Australia*</td>
<td>16.6%</td>
<td>51%</td>
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<td>(Thomas et al., 2000b) analyzing Thomas et al., 2000a and Wilson et al., 1995</td>
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<td>(Leape et al., 1991; Brennan et al., 1991) New York</td>
<td>3.7%</td>
<td>48%</td>
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<td>(Vincent et al., 2001) London</td>
<td>10.8%</td>
<td>37%</td>
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<tr>
<td>(Davis et al., 2002) New Zealand*</td>
<td>12.9%</td>
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Magnitude of the Issue

• One Canadian study
  – Error rate of 7.5/100 admissions
  – 37% of errors preventable and 21% were fatal!

• Over 4000 persons die annually in Canada because of adverse events

• Most HPC occurs in the community & most discussions of safety are based on hospital care
Examples-Medication Orders

• For every 10,000 medication orders
  – 530 medication errors
  – 35 close calls
  – 5 preventable adverse drug events

• 100 errors for each adverse drug event

• 7 close calls for each adverse drug event
  • Bates D. JGIM 1995;10:199-205
Pain as the neglected adverse event
Why discuss this issue?

• HPC has entered the mainstream of care
  – Integrating into the current health care system means we need to be as concerned as the rest of the system about issues of quality & safety

• Considerable evidence of lack of safety within the system but little discussion in palliative care
Why discuss this issue?

• We cannot make assumptions that we are providing safe care in HPC (or even quality care!)

• Patients should not be harmed by care that is supposed to help them

• Achieving a higher level of safety essential 1st step in improving overall quality of care
Why discuss this issue?

• We cannot hide from this issue and assume we do not cause harm
Five Settings for Error

1. Recognition and treatment of symptoms
2. Advance care planning
3. Addressing goals of care
4. Impact of family members
5. Team involvement
Case Vignettes
Vignette 1

• Patient of a home palliative care service admitted to hospital for episode of CHF
• Receiving hydromorphone liquid 0.25 mg (ml) p.o. q4h for severe hip pain
• Deteriorates quickly ➔ LOC
• Review of medications reveals that RNs have been using parenteral 10mg/ml HM
Vignette 2

• Patient with advanced lung cancer on Percocet for pain in his hip
  – Develops increasing back pain & abdominal pain

• Admitted for control of pain

• MD orders HM Contin 18mg q8h to control the pain with 4mg BT

• Patient develops nausea, agitation, confusion, ↓ LOC
Vignette 3

• 38 year old man with non-Hodgkin’s lymphoma has abdominal pain
• History of nausea with opioids
• Started on morphine for pain along with prochlorperazine
• Develops acute dystonic reaction
Vignette 4

• 62 year old woman with advanced uterine cancer is at home
• Developing bowel obstruction with nausea & vomiting
• MD switching her from oral opioids to CSCI + adding octreotide
  – Orders to pharmacy at 1300h, equipment delivered 1600h, nurse booked for 1800h but fails to show up
  – Agency says no one available
Vignette 5

- 67 year old woman with untreated metastatic renal cell cancer presents with spinal cord compression
- Family physician admits her for control of pain which is mostly incident pain
- CSCI instituted at HM 3mg/h and 2 days later midazolam at 2mg/h for “palliative sedation”
- Patient now comatose & nurses very concerned
Vignette 6

• 62 year old man with myeloma, vertebral collapse & right sided sciatica
• Intractable pain controlled with methadone
• Physician prescribes an antidepressant duloxetine
• Wife of patient looks up meds on card given to them by pain physician & alerts psychiatrist to interaction issue
Vignette 7

- CSCI pumps especially CADD pumps have been used in the community for 20 years yet human engineering systems show us they are inherently unsafe
Important Resource Documents
To Err Is Human: Building a Safer Health System

- Report released by US Institute of Medicine in late 1999
- Captured widespread attention among healthcare providers, general public, governments
Crossing the Quality Chasm

- Report released by IOM 2 years later
- Broader look at quality problems and potential solutions
“Between the health care we have and the care we could have lies not just a gap but a chasm.”
Recommendation 1. Americans expect and deserve safe care. Improved information and data systems are needed to support efforts to make patient safety a standard of care in hospitals, in doctors’ offices, in nursing homes, and in every other health care setting. All health care organizations should establish comprehensive patient safety systems that:

- Provide immediate access to complete patient information and decision support tools (e.g., alerts, reminders) for clinicians and their patients.
- Capture information on patient safety—including both adverse events and near misses—as a by-product of care, and use this information to design even safer care delivery systems.
The Joint Commission’s National Patient Safety Goals: Implications for Home Care and Hospice Organizations
“There is an urgent need for research on safety in home care. Addressing safety in home care presents unique challenges and requires a major rethink of underlying assumptions and guiding frameworks that have been used to examine patient safety in the institutional environment.”
Canadian Patient Safety Dictionary

• “Patient safety be defined as the reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to optimal patient outcomes”

Definitions-Error

• Choice of an incorrect action to achieve an aim (i.e. error in planning) or the failure of a planned action to be completed as intended (i.e. error of execution)
  – Either case may include errors of commission or omission
Definitions-Adverse Event

• An injury (temporary or permanent discomfort or disability, physical or psychological) caused by medical management rather than underlying disease
  – Medical management includes all aspects of care, including diagnosis & treatment, failure to diagnose or treat, & systems & equipment used to deliver care
Definitions-Preventable AE

• Caused by an error or other type of systems or equipment failure
  – Need not need to be error committed by or attributable to a specific individual within a system
Definitions-Potential AE

• A serious error that has potential to cause an AE but fails to do so because of chance, not because of built in system safeguards
Definitions

• “Incidents” means patient safety events including: Adverse Events, Critical Incidents, and Near Misses; & “Incident” means any one of them

• “Close Call” means adverse event did not reach patient because of timely intervention/good fortune (the term is often equated with a near miss/hit
• “Critical Incidents” are incidents resulting in serious harm (loss of life, limb, or vital organ) to patient or significant risk thereof, that is, incidents are considered critical when there is evident need for immediate investigation & response

(Royal College of Physicians and Surgeons of Canada et al., 2003)
• **Harm** is an outcome that negatively affects a patient’s health or quality of life

• **Disclosure** is the process by which harm is communicated to a patient by HCPs
“Every system is perfectly designed to get exactly the results it gets.”

Paul Batalden MD
Home Care Safety

• Evidence suggest that home care has characteristics that suggest an increased incidence of AEs (Woodward 2002)

• AEs in home care represent system wide issues that need to be addressed by all stakeholders (Masotti et al 2009)
• Themes
  – inextricably linked relationships
  – communication among clients/families & caregivers/providers
  – unregulated and uncontrolled settings, autonomy and isolation
  – multidimensionality of safety (physical, emotional, social, functional)
  – diminishing focus on prevention, health promotion & chronic care
  – challenges of human resources and maintenance of competence
Why a setting for error?

• Complex care
  • Multiple goals of care
    – Lots of meds, off label
    – Conflicting goals
  • Lots of caregivers

• Interdisciplinary teams

• Sensitivity to multiple domains of suffering
  • Lots of stress
Differences in HC

• Key assumptions in defining systems often do not apply in HC
• Comprised of providers from various organizations & sectors who must create interface for coordination & communication that has different dimensions of complexity than that within an institutionalized setting
Differences in HC

• Care & safety of clients in HC settings cannot be attended to without including the family, caregivers, & providers in equation

• Unlike paid employees working under the auspices of a “supervised institution,” most of care provided in the home is by family and/or caregivers under indirect “supervision” of a HCP
Differences in HC

• Infrastructure required for assembling performance indicators for family &/or caregivers & unregulated workers is not evident within home care

• Multiple stakeholders (client, family members, friends, caregivers) who may or may not agree on the way to proceed provides a more challenging scenario
Differences in HC

- Homes are designed for living, not for providing healthcare
  - Physical environment in institutionalized settings can be modified to provide protection for employees, mitigating their risk as healthcare workers
  - this is much more difficult to address in home care environment
Differences in HC

• Pertains not only to technology & supplies but to existing policies & procedures, as well as being able to run down the hall for collegial or supervisory assistance when necessary
The nature of safety problems among Canadian homecare clients: evidence from the RAI-HC reporting system

• 2º analysis of data collected through Canadian home care reporting system

• All HC clients who qualified to receive a RAI-HC assessment from ON, NS, Winnipeg RHA 2003–2007

• 238 958 cases available for analysis; 205 953 from ON
Risk

Polypharmacy
Decline in physical function
Polypharmacy and history of cognitive impairment
Decline in physical function and lives alone
Decline in cognition
History of two or more falls
Social isolation with distress
Hearing deficit
Unsafe housing
Decline in cognition and lives alone
Vision deficit
Decline in mental function
No medication review
Non-adherence to medication
Substance abuse
No medication review for clients with polypharmacy
    and/or history of cognitive impairment
Smoking and oxygen in the home

Family/caregivers
    Aggressive behaviours
    Smoking and others in the home
    Exposure to HIV or tuberculosis in
Caring for client with morbid obesity requires weight-bearing assistance for transfer
Making a System Safe
Traditional approach

• Look for most obvious explanation
• Individual human error identified as the cause
  – Easy to identify and fix
  – Uncover individual’s inaccurate assessments, decisions, judgments, actions
• Ignore contributing factors
Patient safety approach

• Human error is a symptom of broader issues with a poorly designed system
• Human performance and therefore errors are influenced by many factors in a system
• Assess individual’s actions within the context of the circumstances at the time
Hierarchy of Effectiveness

Forcing functions

Automation & computerization

Simplification & standardization

Checklists & double checks

Policies & procedures

Training & education
Effectiveness and efficiency of guideline dissemination and implementation strategies

RCTs showed median improvements in guideline adherence of:

- 14% for clinician reminders
- 8% for educational materials
- 7% for audit and feedback
- 6% for educational outreach

Grimshaw et al *Health Technol Assess* 2004
Disclosure of Error

• Achieving a culture of patient safety requires open & honest communication between HCPs & patients & families

• Need clear & consistent approach to disclosure of harm or safety issues
  – Regulatory authorities are demanding this

  – CPSI Report Canadian Disclosure Guidelines
Illustration A: Understanding Harm and no Harm Events

Event in Patient's Healthcare

Harm
- Harm results from underlying medical condition
- Harm results from the care and/or services provided to the patient
  - Inherent risks of investigation or treatment
  - System failure(s)
  - Provider performance
  - A combination of these

Potential for Harm/No Harm
- Event Reached Patient
- Close Call: The event did not reach the patient
  - No Harm
    - Potential for Harm Exists
    - No Potential for Harm
Illustration B: Determining the Type of Event and the Requirements for Disclosure

Event in Patient’s Healthcare
- Harm has occurred
- A Potential for Harm Exists or No Harm is Apparent

**INITIAL DISCLOSURE**
Initial communication required as soon as reasonably possible

Analysis
Harm is found to result from or be from a combination of:
- Natural progression of patient’s underlying medical condition
- Inherent risks of investigations or treatments*
- System Failure(s)
- Provider Performance

**POST-ANALYSIS DISCLOSURE**

Event Reached Patient
- Close Call***: The event did not reach the patient
- Generally need not be communicated unless ongoing safety risk for that patient, or patient already aware

Potential for Harm Exists
- Should be disclosed to the patient

No Potential for Harm
- Generally should be communicated
Disclosure in Palliative Care

• We pride ourselves in being good communicators in HPC

• Need to use that skill in disclosing harm despite concerns & fears we have
New Skills for
Getting to the bottom of the problem
.....
Problem definition

• Variety of methods:
  – Root cause analysis
  – Human factors engineering analysis
  – Failure mode & effects analysis
  – Process mapping
Root Cause Analysis
CPSI Canadian Root Cause Analysis Framework
• Analytic tool that can be used to perform comprehensive, system-based review of critical incidents
  – Includes the identification of root & contributory factors, determination of risk reduction strategies, & development of action plans along with measurement strategies to evaluate the effectiveness of plans
Root Cause Analysis

• Goals of a root cause analysis are to determine:
  – what happened;
  – why it happened; &
  – what can be done to reduce likelihood of recurrence.
Root Cause Analysis

1. Inter-disciplinary, involving experts from frontline services
2. Involves those who are the most familiar with situation
3. Continually digs deeper by asking why, why, why at each level of cause & effect
Root Cause Analysis

4. Identifies changes that need to be made to systems
5. Impartial, in order to make clear need to be aware of & sensitive to potential conflicts of interest
Human Factors Engineering

• HFE is the discipline that studies human & limitations & applies that knowledge to the design of safe, effective, & comfortable products, processes, & systems for the human beings involved
  – Concerned with understanding of interactions among humans & all other elements of a “work system” in which a human exists and is attempting to accomplish something
The Smith and Carayon work system model.
Human Limitations

• Physical environment
  – noise, climate, lighting

• Cognitive
  – short-term memory capacity, fatigue, how humans present, perceive, & process information, decision-making approaches & cues

• Organizational
  – job and task design
Important Limitations

• Limited memory capacity ➔ 5-7 pieces of information are typical for short-term memory

• Negative effects of stress & associated cognitive tunnel vision used to compensate & focus in highly intense situations
Important Limitations

• Negative influence of fatigue, sensory overload, & other physiological factors
• Overdependence on multitasking skills of staff in complex work environments
Safe Design

• Takes into account various human limitations that are outside control of the human being interacting with the design
• Categories of human limitations are related to physical, cognitive, & organizational limitations
Enhancing Healthcare Process Design with Human Factors Engineering and Reliability Science, Part 1

Setting the Context
Model for Improvement

• Safety is an important part of quality improvement

• Once you have a reasonable idea of what cause(s) are then you can begin a QI process
“All improvement will require change, but not all change will result in improvement!”

Activity does not mean change

- Planning
- Meeting
- Educating staff
- Creating a protocol or policy
- Assigning responsibility

*THESE MAY BE NECESSARY BUT NOT SUFFICIENT*
3 fundamental questions

1. What are we trying to accomplish?

2. How will we know that a change is an improvement?

3. What changes can we make that will result in improvement?
AIM: What are we trying to accomplish?

CHANGE: What changes can we make that will result in improvement?

MEASURES: How will we know if a change is an improvement?

Act
Plan
 Study
 Do
What can we do?

• Recognize that patient safety is an issue in palliative care & begin to address the issue in an effective quality improvement way
• Read some basic resources
• Develop & implement a process of disclosure
  – Get over our fears
What can providers do to prevent or diminish impact of AEs?

1. Enhance communication
2. Provide education to HCPs & patients and caregivers on best practices & risk factors
3. Increase measurement & data collection & develop benchmarks
4. Implement prompt reporting & collaboration
5. Develop an atmosphere of trust
What can we do?

• Develop a culture of quality improvement & safety into our HPC programs
  – This is more difficult in home care but not impossible
  – Develop skills
• Build an academic force in QI & safety
• Develop a matrix for quality EOLC
Research in QI & safety

• Different
• RCT may not be the only valid research structure
• Ethics approval may be necessary
  – Tools available like SQUIRE that will tell you whether ethics approval needed
Final Recommendations

• Understand the basis for a given quality problem and match the solution to the problem

• Balance enthusiasm for promising ideas with appropriate skepticism and rigorous evaluation.

But that’s OK - consistent, modest gains eventually produce major improvements, just as with the rest of biomedicine.
Summary

• To err is human
• The goal is for a safe system for all
• Safety is everyone’s concern & everyone needs to participate
• Safety in home care needs more attention
• Palliative care can sometimes be unsafe
• Learn more about safety
Resources

- www.ihi.org
- www.patientsafetyinstitute.ca
- www.accreditation.ca
- www.ohqc.ca
- The Improvement Guide. Langley et al
- The Science of Improvement. Robert Lloyd
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