


halifax The Department of Health Services

Introduction to the basics of Patient Safety

The Swiss Cheese Reception



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The Plan

Why do bad things happen?
The Swiss cheese model

Safety Management
Finding hazards and mitigating risk before harm occurs

Managing Serious (Potential) Adverse Events*
Steps to follow when the inevitable happens

* or substantial risk thereof (close calls)

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Why do bad things happen?

The Swiss Cheese Model

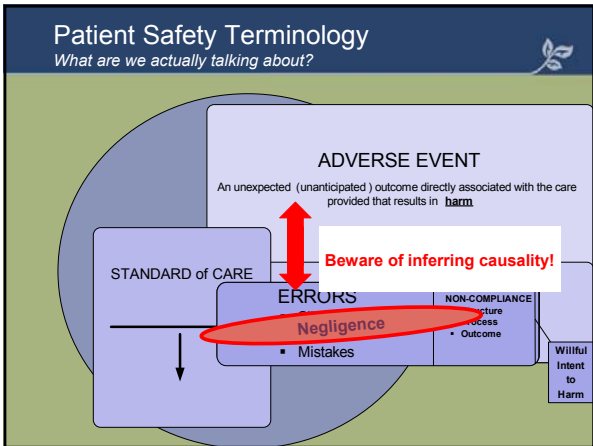


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Patient Safety Terminology

What are we actually talking about?

Harm
 Adverse Event
 Unsafe Acts
 Standard of Care
 Negligence
 Errors
 Active Failures
 Non-compliance
 Unanticipated



Why bad things happen

The usual explanation

HOW CAN ONE PERSON MAKE SO MANY MISTAKES IN ONE DAY?

I ALWAYS GET HERE AN HOUR EARLY!

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Why bad things happen
A better explanation

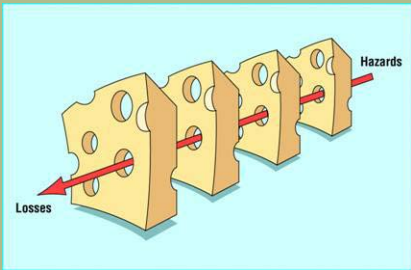


Man - a creature made at the end
of the week when God was tired.

Mark Twain

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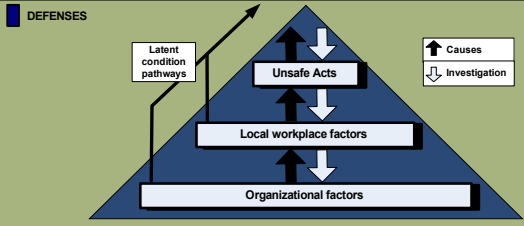
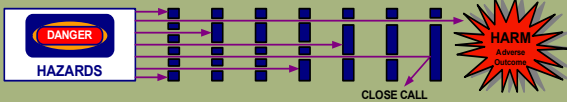
A Model To Understand
Adverse Events



James Reason

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Understanding adverse events



From: J. Reason; Managing the Risks of Organizational Accidents

How are your cognitive skills?



PARIS
IN THE
THE SPRING

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How does something like this happen?



Why do bad things happen?



Reason's Three Schools of Thought

1. Person Model
2. Engineering Model
3. Organizational Model

Person Model (#1)



Bad things ← Bad Mistakes ← Bad People

- Focus is on individual unsafe acts
- People are free agents freely willing to choose between safe and unsafe acts
- Errors are shaped by psychological factors
 - Inattention / Forgetfulness
 - Poor Motivation / Carelessness
 - Lack of Knowledge / Skills / Experience
 - Negligence

Countermeasures

- 'Fear Appeal' Poster Campaigns
- Rewards / Punishments
- Auditing of Unsafe Acts
- Writing Another Procedure

James Reason, *Managing the Risks of Organizational Accidents*, 1997

Person Model Reaction



SHAME & BLAME



systems. And she died because of one of the most dreadful medical mistakes ever revealed in Alberta, or all of Canada.

Person Model Reaction



BLAME & PUNISH



A head or heads have to roll. It's simply a matter of justice, of public safety and public confidence.

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What does this approach achieve?



We All Make Mistakes



Types of Healthcare Providers



1. Those who have committed an error → harm
2. Those who will

Paraphrasing James Reason



Engineering Model (#2)



- Safety Should be Engineered into the System
 - Safety expressed as Engineered Reliability
 - Human Errors ← Poor Human Engineering
 - Failure to Design Systems According to Cognitive Strengths / Weaknesses of Front-Line Workers
- **Countermeasures**
 - Redesign Systems → Make it Hard to Make Mistakes
 - Reminders
 - Alerts
 - Forcing Functions

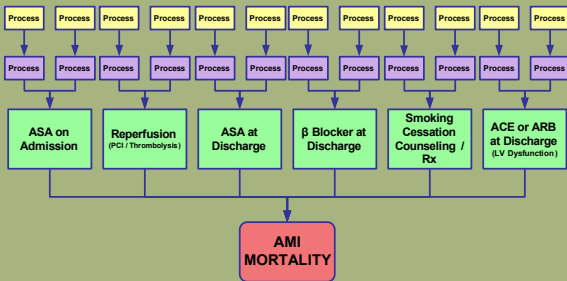
James Reason, Managing the Risks of Organizational Accidents, 1997

Institute for Healthcare Improvement



Designing for High Reliability

Improving AMI Outcomes



Improving Performance



10⁻¹

- No articulated common process
- Emphasis on training and reminders

10⁻²

- Process intentionally designed
- Tools and concepts based on principles of human factors engineering

10⁻³

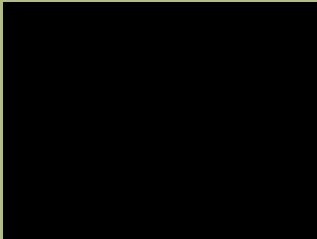
- Well designed system with attention to processes & structures and their relationships to outcomes

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Should we design humans out of the system?



Lest we think there is a technical solution to every problem



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Organizational Model (#3)



➤ Human Errors are a Consequence - Not a Cause

- Errors are Symptoms of Latent Conditions
- Need for Proactive Measures of Healthcare
- Similar thinking to TQM
- An Extension of the Engineering Model

Countermeasures

- Continual process redesign
- Measuring Key Process Indicators

James Reason, *Managing the Risks of Organizational Accidents*, 1997

Safety Management

Finding hazards & mitigating risk before harm occurs

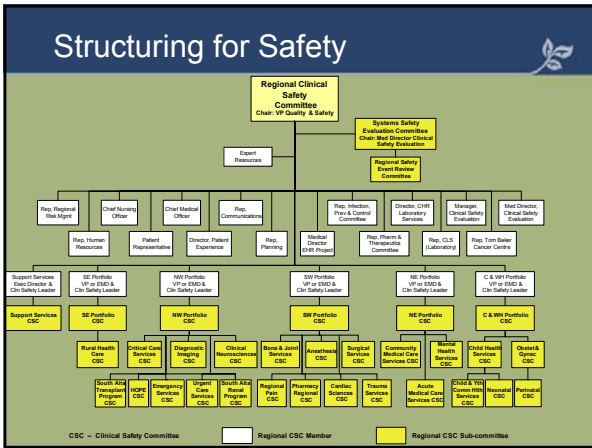


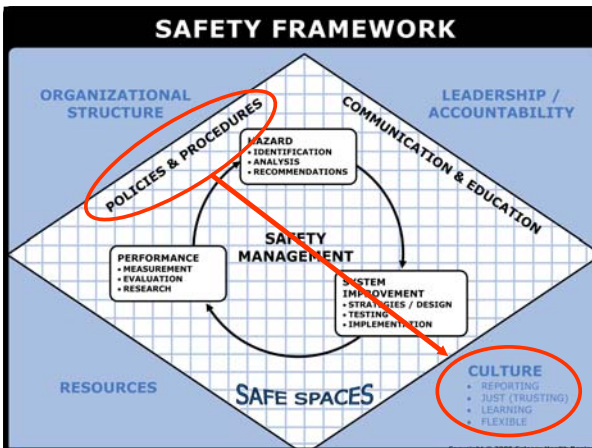
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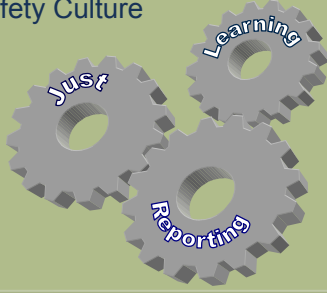






Making Healthcare Systems Safer

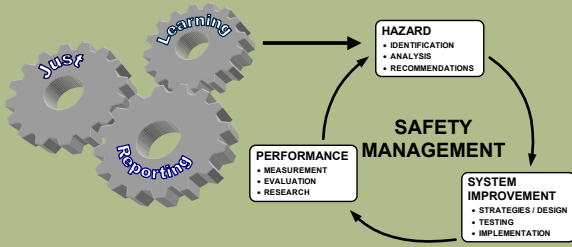
Organizational Safety Culture



J Reason & A Hobbs. *Managing Maintenance Error*. 2003

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Making Healthcare Systems Safer



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Safety Policies – a Social & Ethical Contract

Between the Region / Providers AND Patients

- **DISCLOSURE** (Harm)

Between Providers AND the Region

- **REPORTING** (Hazards / Close Calls / Harm)

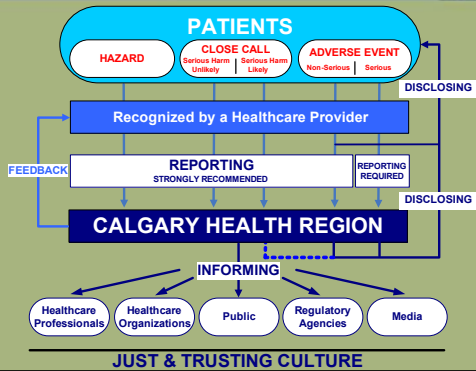
Between the Region AND its Providers

- **JUST & TRUSTING**

Between the Region AND its Principal Healthcare Partners / Stakeholders

- **INFORMING**

Safety Policies



Disclosure Policy

The Disclosure Process includes:

1. Acknowledging the harm to the patient
2. Providing an apology for the harm
3. Disclosing factual information about how the harm occurred

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Disclosure Policy

Level of harm

- Determines who will be involved in disclosure
- Coordination / communication vital

Discretion

- For close calls (nearly harmed)

Support for Health Partners

- For patients and their families
- For staff, physicians, health professionals involved

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Disclosure – a risky business?



"I'm required to make it clear that the hospital is in no way bound by this get-well card for your husband."

Just & Trusting Culture



Two types of Evaluations (Separate)

- **Safety Analysis**
 - Focus on systems
 - Structured analytical approach ('RCA like')
- **Administrative Review**
 - Evaluates the actions of healthcare providers
 - Roles, responsibilities, competencies
 - In the context of the safety evaluation

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Just & Trusting Culture

Region's Response to Provider's Actions



Errors

- The failure of a planned action to be completed as intended

The Region will not discipline

Non-compliance

- Deviations from established policies / standards

The Region will evaluate – the appropriateness of i) the policies & standards and ii) the circumstances leading to the non-compliance

Willful Intent to Harm

The Region will not tolerate – disciplinary action will be taken & criminal investigations may result

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Reporting – where is the focus?



} Adverse Events
} Close Calls
} Hazards
No Adverse Events or
Close Calls . . . yet!

Making Patient's Safer

Learning from Direct Care Providers



Commit to Listening

Reporting System

- Easy to use
- Right Focus
- Deal with the fear of retribution
- Show people it makes a difference
 - Feedback
 - Demonstrate positive change

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Reporting - Key Concepts



Focus is on LEARNING

Safety Hazards **not** Incidents

Safety Learning Reports **not** Incident Reports

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Confidentiality



Confidentiality of Reporter

Reporter is Identified (i.e., not Anonymous)

- Contact if further info is required
- Enables feedback to reporter

- The Region commits to ensuring the confidentiality of the reporter when requested.

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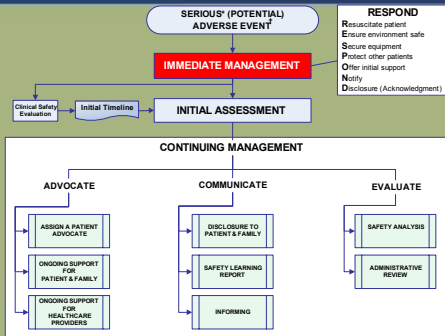
Managing Serious (Potential) Adverse Events*



Steps to follow when the inevitable happens

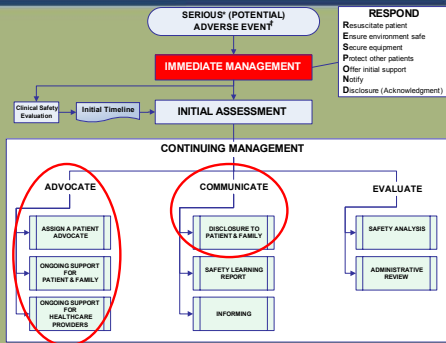
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Managing Serious* (Potential) Adverse Events†



* Serious – Fatal or Severe (loss of limb or organ function or resuscitation required to sustain life)
† or substantial risk thereof (close call)

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Communicate

Disclosure

- Disclosure Team
 - Admin (Medical) Lead
 - Attending Physician
 - ± Non-physician
 - Patient Advocate

4 phases

- Acknowledgement
- Initial
- Follow up
- Final

Apology – type depends on whether standard of care was met or not met (in whose opinion?)

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Disclosure Team

Key Functions

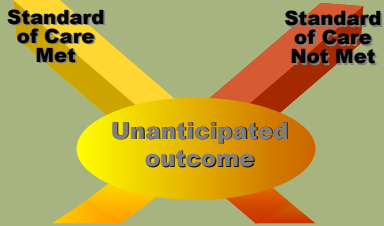
- convey concern and regret
- can answer clinical questions
- can answer administrative questions
- can answer financial questions

Team composition has to reflect the key functions

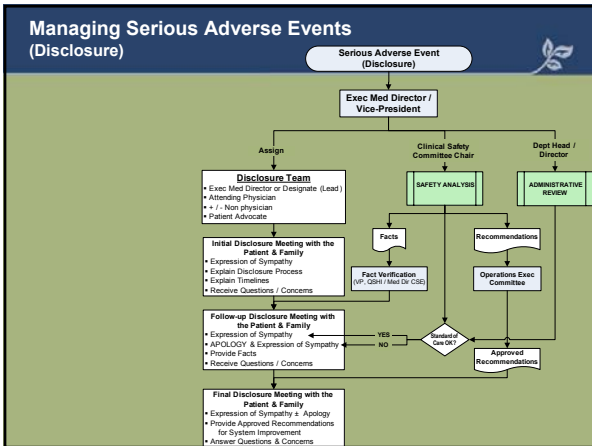
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Unanticipated outcomes Important distinction

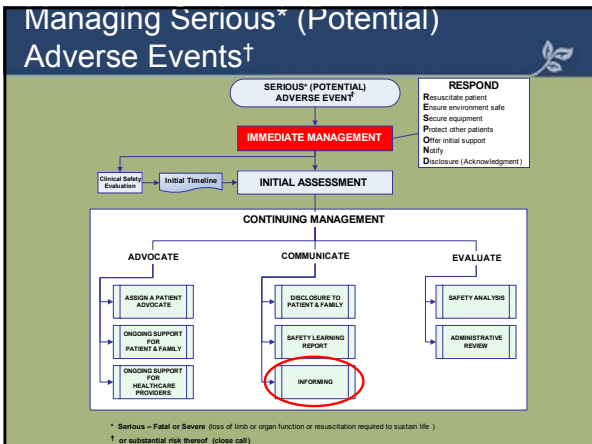
PREMISE 5



Managing Serious Adverse Events (Disclosure)



Managing Serious* (Potential) Adverse Events†



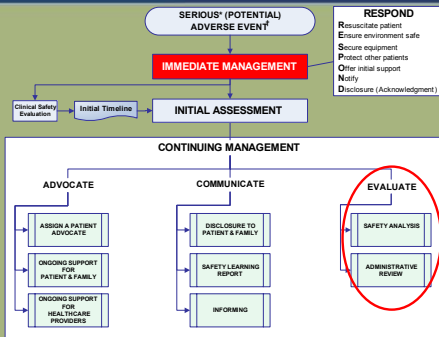
Communicate

Informing

- 3 reasons to inform
 - Protect the health / welfare of others when the risk of harm substantially changes
 - To help the Region and other healthcare organizations learn
 - To maintain public trust through transparency (avoid the perception the Region is hiding something)
- Who is informed depends on which of the three objectives are being addressed
- VP /EMD + CMO/CNO/CCO should decide

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Managing Serious* (Potential) Adverse Events†



* Serious – Fatal or Severe (loss of limb or organ function or resuscitation required to sustain life)
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Safety Analysis

What are they & what do you do with the outputs?

What is it?

- Structured systematic review of system contributing factors
 - Health system safety analysis
 - Root cause analysis

What are the outputs?

- Facts about what happened
 - Used for
 - Disclosure
 - Informing (Learning)
 - Admin Reviews (in some cases)
- Recommendations for System Improvement
 - Must be approved by an appropriate Admin Committee / Person
 - Approved → the Region will implement
 - Will be part of disclosure / informing

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Administrative Reviews



Evaluate the Actions / Behaviours of individuals

Avoid the use of retrospection

- Evaluating the severity of the actions / behaviours based on the severity of the outcome
- Impart expectations of individual actions based on knowing what the outcome was
- Foresight test
- Substitution Test

Errors / Non-compliance / Wilful intent to harm

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Evidence Acts & Health Information Acts



Safety Analyses

- Conducted by a quality assurance (clinical safety) committee
- Protected from discovery in the setting of an action (Alberta)
- ? Sharing of facts outside of a quality assurance committee

Administrative Reviews

- Conducted by administrators
- Not protected from discovery
- Information about individuals can not be shared
- Health Information Act

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Understanding privacy laws



Summary



- **Swiss cheese** → systems approach
- **Everybody makes errors** → design processes with this in mind (high reliability)
- **Safety Management**
 - Focus on Hazards & Close Calls
 - Require a robust reporting system & philosophy
 - Just & Trusting Culture
- **When adverse events occur:**
 - **RESPOND**
 - **ACE**

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