

Improving Patient Safety through Incident Reporting and Learning in Health Care

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HumanEra  UHN

Rationale

- Health care incident learning processes have the potential to minimize preventable errors and patient deaths
- Currently experiencing mixed success
- Little guidance exists for decision makers on how to successfully learn from incidents

Objectives

1. Describe areas for improvement in health care incident learning processes
2. Explore existing barriers and end-user needs
3. Identify strategies that aviation and nuclear power have implemented to achieve their successes
4. Evaluate preliminary strategies based on health care stakeholder feedback
5. Propose strategies for the development of successful incident learning systems in health care

WHO Recommendations

Quality	Description
Non-Punitive	Reporters are free from fear of retaliation against themselves or others as a result of reporting
Confidential	Patient, reporter, and institution identities are never revealed
Independent	Reporting system is independent of any authority with the power to punish the reporter or organization
Expert Analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems causes
Timely	Reports are analyzed promptly and recommendations are rapidly disseminated to those who need to know
Systems-Oriented	Recommendations focus on changes in systems, processes, or products, rather than on individuals
Responsive	The agency that receives reports is capable of disseminating recommendations and the participating organizations consent to implementing recommendations when possible

The World Health Organization, "WHO Draft Guidelines for Adverse Event Reporting and Learning Systems," WHO Document Production Services, Geneva, 2005.

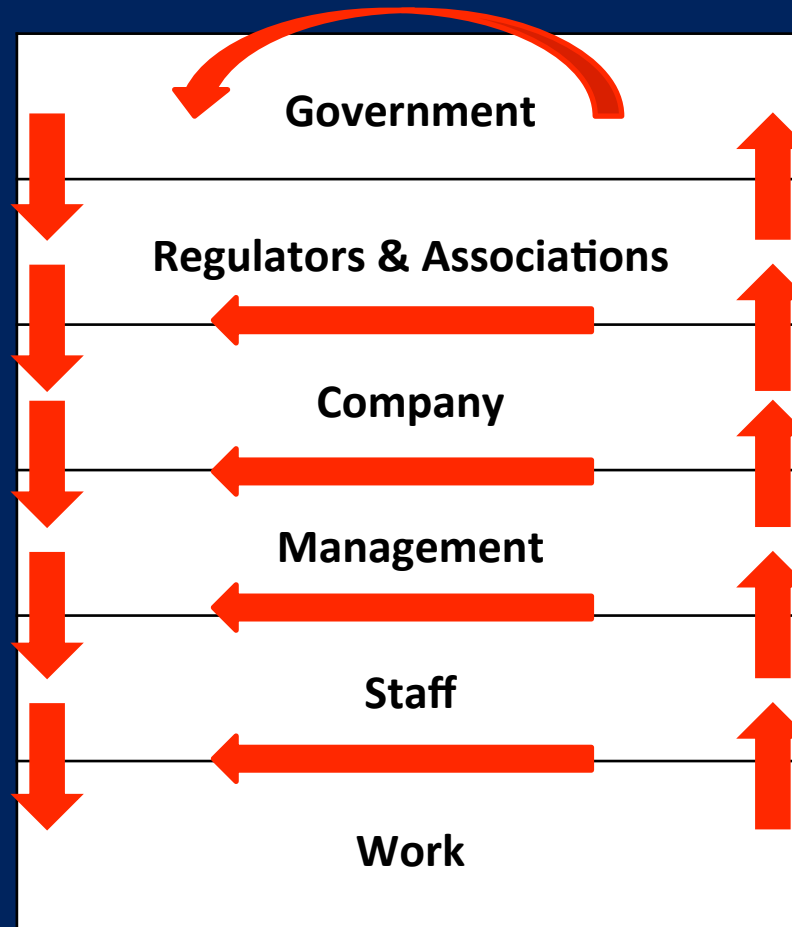
WHO Recommendations

Quality	Health Care*	Aviation (ASRS)	Nuclear Power (IAEA/NEA)
Non-Punitive	X	✓	✓
Confidential	Varies	✓	X
Independent	Varies	✓	X
Expert Analysis	X	✓	✓
Timely	X	✓	✓
Systems-Oriented	Varies	✓	✓
Responsive	X	✓	✓

**general trends*

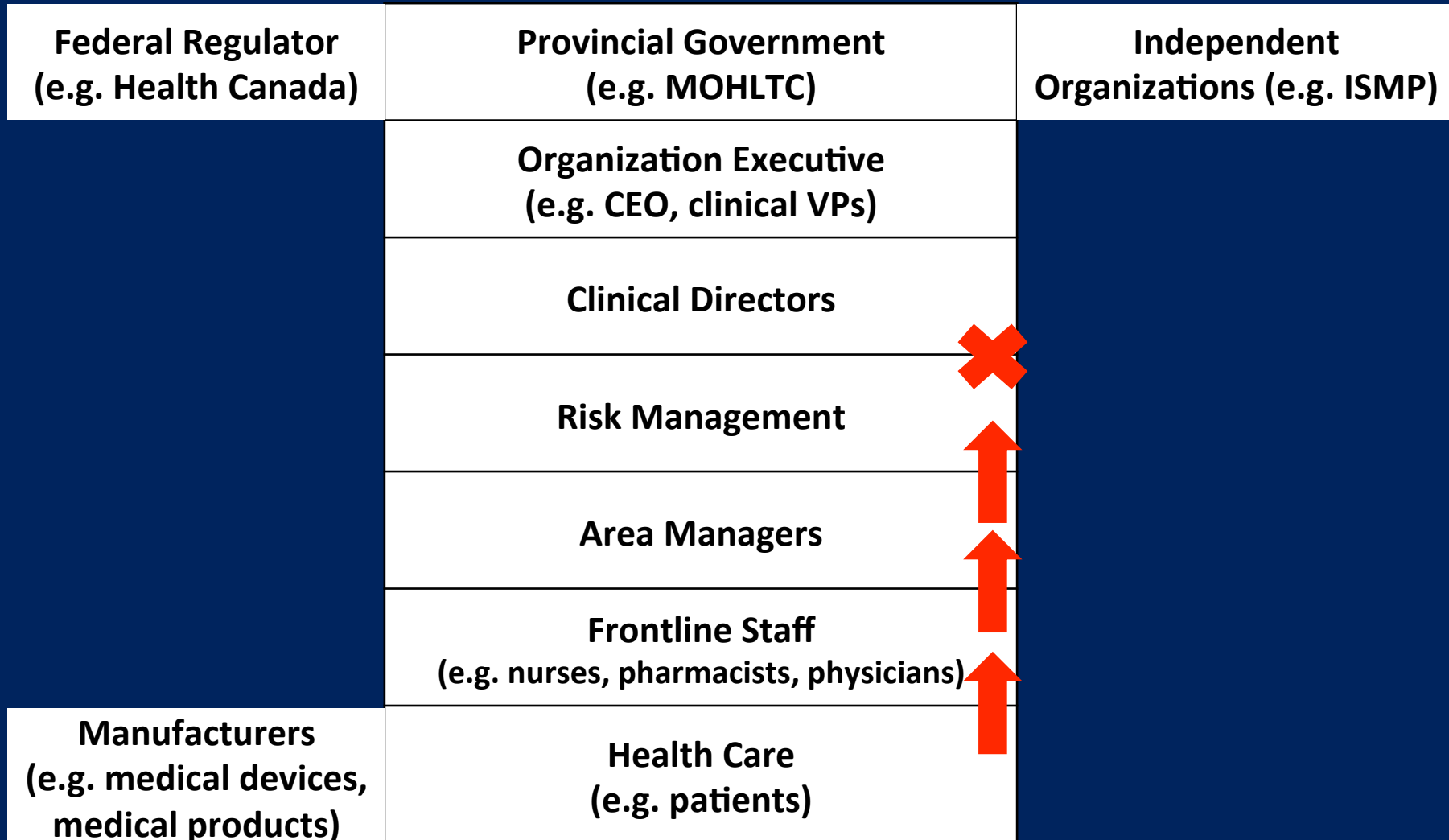
January 10, 2014

Rasmussen's Risk Management Framework



J. Rasmussen, "Risk Management in a Dynamic Society: A Modelling Problem," *Safety Science*, pp. 183-213, 1997.

Rasmussen's Risk Management Framework



Phase 1 – Explore and Compare Incident Learning Systems

- Examine aviation, nuclear power, and health care (reported trends, 8 diverse systems, and 3 case studies)
- Research focused on areas identified for improvement:
 - Reporting culture
 - Reporting process and analysis techniques
 - Information dissemination and implementation of improvements

Phase 1 – Data Collection and Analysis

- For each area for improvement:
 - Health care ideals (WHO, Rasmussen)
 - Description of aviation, nuclear power, health care

	Reporting Culture	Reporting Process and Analysis	Dissemination and Implementation
Ideal			
Aviation			
Nuclear Power			
Health Care 1			
Health Care 2			
...			

Phase 1 – Data Collection and Analysis

- For each area for improvement:
 - Health care ideals (WHO, Rasmussen)
 - Description of aviation, nuclear power, health care

	Reporting Culture	Reporting Process and Analysis	Dissemination and Implementation
Ideal	System details	System details	System details
Aviation	System details	System details	System details
Nuclear Power	System details	System details	System details
Health Care 1	System details	System details	System details
Health Care 2	System details	System details	System details
...	System details	System details	System details

Phase 1 – Data Collection and Analysis

- For each area for improvement:
 - Comparative trends across all systems

	Reporting Culture	Reporting Process and Analysis	Dissemination and Implementation
Ideal	System details	System details	System details
Aviation	System details	System details	System details
Nuclear Power	System details	System details	System details
Health Care 1	System details	System details	System details
Health Care 2	System details	System details	System details
...	System details	System details	System details
TRENDS	TRENDS	TRENDS	TRENDS

Phase 1 – Potential Strategies

- For each area for improvement:
 - Identified potential strategies

	Reporting Culture	Reporting Process and Analysis	Dissemination and Implementation
Ideal	System details	System details	System details
Aviation	System details	System details	System details
Nuclear Power	System details	System details	System details
Health Care 1	System details	System details	System details
Health Care 2	System details	System details	System details
...	System details	System details	System details
TRENDS	TRENDS	TRENDS	TRENDS
POTENTIAL STRATEGIES	STRATEGIES	STRATEGIES	STRATEGIES

Phase 1 – Explore and Compare Incident Learning Systems

- Strengths
 - Comparing systems objectively across same characteristics
 - Information directly from systems
- Limitations
 - Number of systems examined
 - Could not capture intangible, contextual elements

Phase 2 – Refine Potential Strategies for Health Care

- Focus groups and in-depth interviews with stakeholders at all Rasmussen levels
- Questions to:
 - Understand current processes in health care
 - Evaluate end-user needs
 - General discussion about areas for improvement
 - Evaluate potential strategies
 - Brainstorm alternative strategies

Phase 2 – Refine Potential Strategies for Health Care

Rasmussen Level	Participants	Focus Group/Interview Topic
Frontline Staff & Management (Clinical, Risk)	1 risk manager, 1 physician, 2 pharmacists, 1 nurse	Topic 1 – Reporting Culture
Frontline Staff & Management (Clinical, Risk)	1 risk manager, 1 physician, 1 pharmacist	Topic 2 – Reporting Process and Analysis Techniques
Frontline Staff & Management (Clinical, Risk)	1 risk manager, 1 physician, 1 pharmacist, 2 nurses	Topic 3 – Information Dissemination and Implementation of Improvements
Frontline Staff & Management (Clinical, Risk)	1 risk manager, 3 pharmacists, 1 nurse	Topic 1, 2, 3
Hospital Executive	UHN CEO	Topic 1, 2, 3
Regulators	Health Canada	Topic 1, 2, 3
Government	2 MOHLTC	Topic 1, 2, 3

**Participation based on availability*

Phase 2 – Analysis

- Transcription
- Coding
 - Sentiment behind comments
 - Two coders
- Thematic analysis
 - Discussed with second coder
- Relate themes to WHO qualities and Rasmussen levels

Phase 2 – Refine Potential Strategies for Health Care

- Strengths
 - Discussion between Rasmussen levels
 - Co-coding
 - Theoretical saturation of ideas
- Limitations
 - Participants from 1 organization, 1 province
 - Recruitment and scheduling challenges
 - Participant bias due to self-selection

Phase 2 – Themes

1. Current underuse of incident reporting systems
2. Need for incident learning education
3. Promote safe culture and actively encourage reporting
4. Improve reporting process
5. Improve analysis process
6. Need for effective dissemination of incident information and review outcomes
7. Learn from non- critical/severe incidents and near-misses
8. Increase systems improvements resulting from incident reporting and review
9. Dedicate additional resources to support incident learning
10. Balance commitment to public transparency with protection for health care professionals and institutions

Phase 2 – Suggested Approaches and Strategies

Approaches	Suggested Strategies
<u>Theme 1 (Need)</u>	
Approach 1	Strategy 1
	Strategy 2
Approach 2	Strategy 3
<u>Theme 2 (Need)</u>	
Approach 3	Strategy 4
	Strategy 5
	Strategy 6
Approach 4	Strategy 7

Proposed Strategies to Improve Health Care Incident Reporting and Learning

Stakeholder Feedback & Suggestions

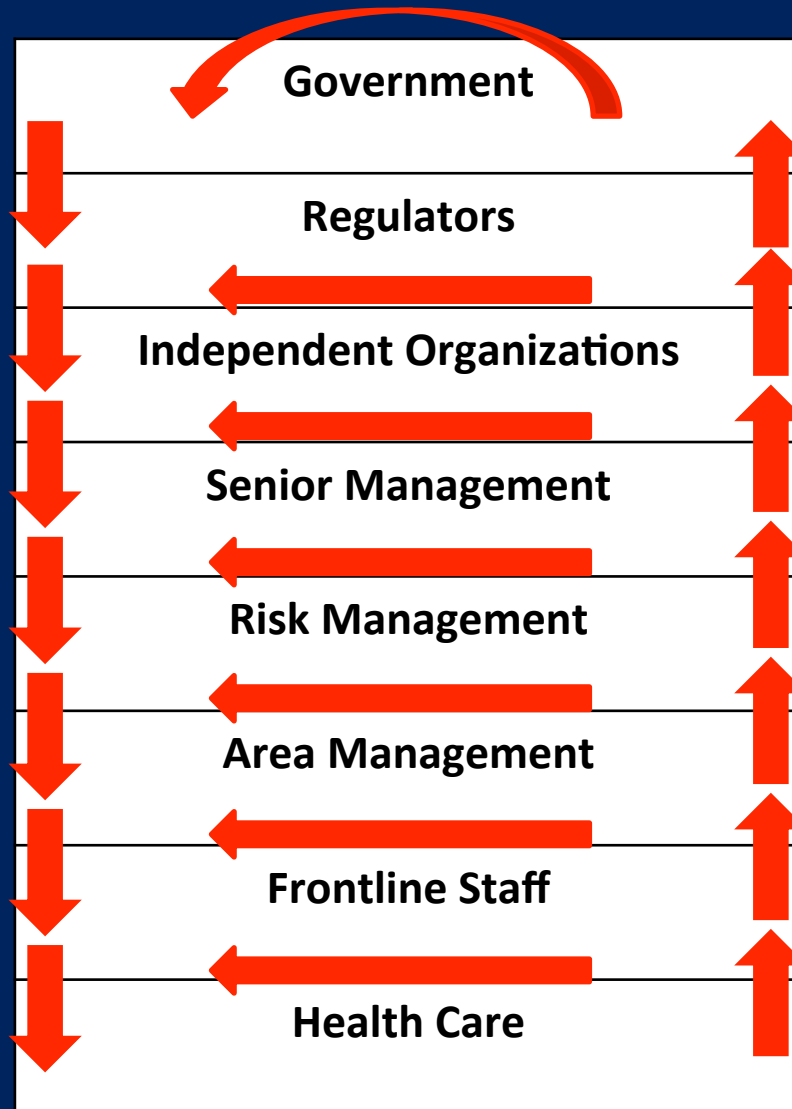
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Proven Strategies from Aviation & Nuclear Power

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PROPOSED STRATEGIES

Proposed Strategies to Improve Health Care Incident Reporting and Learning



Proposed Strategies to Improve Health Care Incident Reporting and Learning

WHO Quality	Proposed Strategies
Non-punitive	<ol style="list-style-type: none">1. Education and training for the frontline staff about the complete process:<ol style="list-style-type: none">a. Presentations at new employee orientations.b. Recurring hands-on workshops on units.c. eLearning modules.2. Incorporate incident learning outreach into November Patient Safety Month.3. Appoint more Patient Safety Officers in upper management.4. Give employees positive evaluations based on increased reporting.5. Modify terminology around incident reporting and learning.

Proposed Strategies to Improve Health Care Incident Reporting and Learning

WHO Quality	Proposed Strategies
Confidential	Although health care incident reporting systems all protect patient, reporter, and institution identities, there is still a need to identify strategies to assure reporters of this confidentiality.

Proposed Strategies to Improve Health Care Incident Reporting and Learning

WHO Quality	Proposed Strategies
Independent	1. Develop a unified incident reporting and learning system established by an external organization.

Proposed Strategies to Improve Health Care Incident Reporting and Learning

WHO Quality	Proposed Strategies
Expert Analysis	<ol style="list-style-type: none"><li data-bbox="369 611 1837 711">1. Provide report initiators with a field to identify contributing factors and prevention recommendations.<li data-bbox="369 725 1591 768">2. Include a process improvement expert in all investigations.<li data-bbox="369 782 1321 825">3. Train managers on how to facilitate debriefs.<li data-bbox="369 839 1083 882">4. Make debriefs multi-disciplinary.

Proposed Strategies to Improve Health Care Incident Reporting and Learning

WHO Quality	Proposed Strategies
Timely	<ol style="list-style-type: none"><li data-bbox="413 668 1818 768">1. Prioritize incidents for investigation based on the significance of the hazards revealed.<li data-bbox="413 782 1599 826">2. Model processes after those in place in operating rooms.

Proposed Strategies to Improve Health Care Incident Reporting and Learning

WHO Quality	Proposed Strategies
Systems-oriented	1. Emphasize the main objective of incident reporting as quality improvement.

Proposed Strategies to Improve Health Care Incident Reporting and Learning

WHO Quality	Proposed Strategies
Responsive	<ol style="list-style-type: none"><li data-bbox="407 434 1889 491">1. Formalize standard processes for all incidents and near-misses.<li data-bbox="407 495 1889 715">2. Disseminate incident information and lessons learned using a combination of regulations, standards, policies, alerts, newsletters, bulletins, digests, research exchanges, meetings, and eLearning education modules, depending on the organization.<li data-bbox="407 719 1889 829">3. Facilitate frontline generation of aggregate incident reports by event type.<li data-bbox="407 833 1889 943">4. Combine existing mandatory morbidity and mortality rounds with incident reporting and learning processes.<li data-bbox="407 948 1889 1053">5. Create a shared central database for participating organizations to submit and view incidents.

Proposed Strategies to Improve Health Care Incident Reporting and Learning

WHO Quality	Proposed Strategies
Convenience and ease of reporting	<ol style="list-style-type: none"><li data-bbox="407 629 1116 682">1. Improve the reporting platform.<li data-bbox="407 686 1039 739">2. Improve the reporting form.<li data-bbox="407 743 1696 855">3. Tailor reporting forms to be appropriate for each profession's structures and workflows.

Contributions and Significance

- Proposed strategies to address shortcomings and achieve best incident learning practices
 - Effective and efficient system design
 - Decrease preventable errors and deaths
- Examined entire incident learning process and interactions, not components in isolation
- Proactive application of Rasmussen's risk management framework

Future Directions

- Validate findings across institutions and regions
- Further specification on approaches and strategies
 - Explore intangible qualities in aviation and nuclear power
 - User-centred design to detail each strategy
- Implement strategies

Thank you.

Questions?

Risk Management Frameworks

- Failure Modes and Effects Analysis
- Fault Tree Analysis
- Probabilistic Risk Assessment
- Many more...

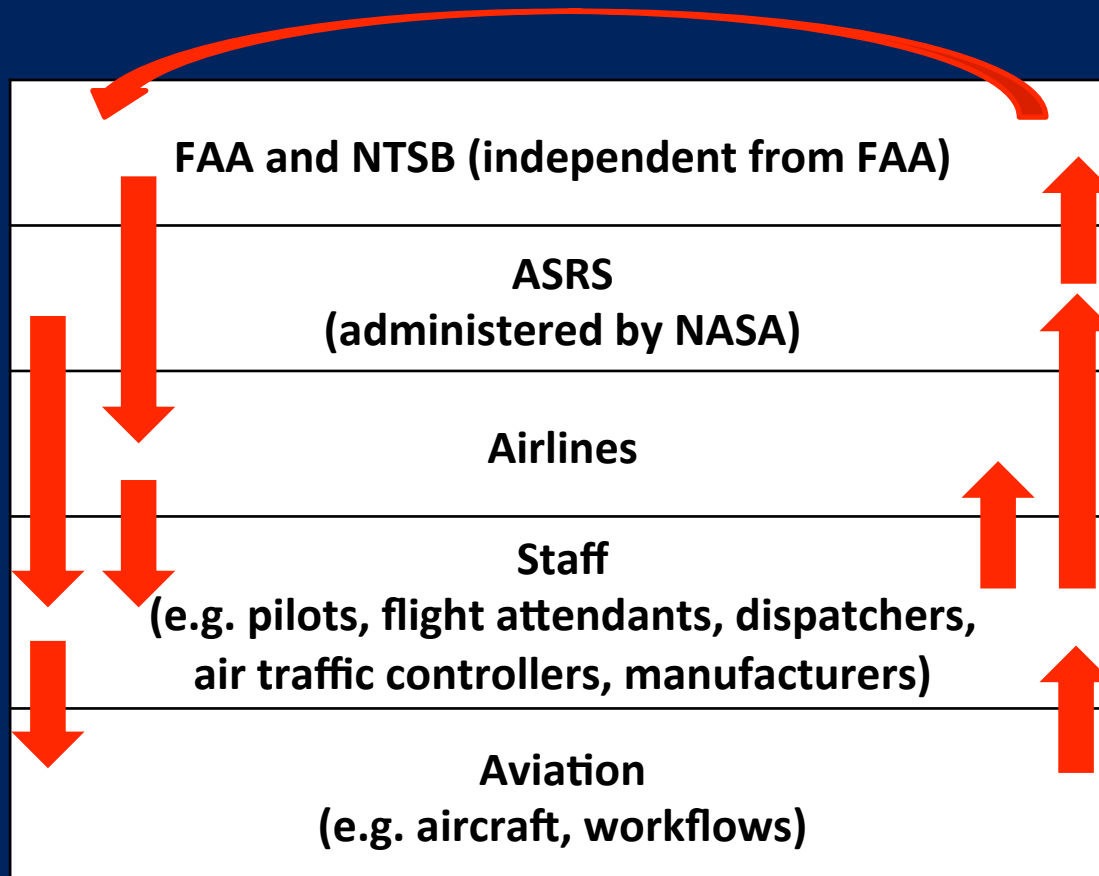


Office of the Auditor General of Canada, "October Report of the Auditor General of Canada: Chapter 5 - Keeping the Border Open and Secure - Canada Border Services Agency," 2007.

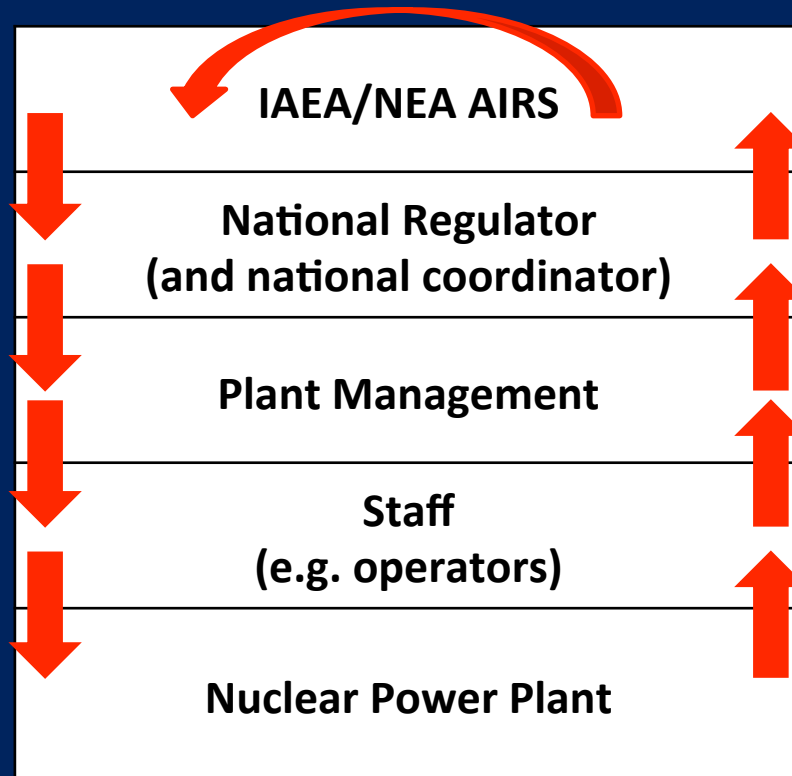
Rasmussen's Risk Management Framework

- Strengths
 - Models information flow through a system
 - Illustrates how organization levels support each other
 - Accounts for interconnectivity of all system components
- Weaknesses
 - Does not include more “abstract”, non-structural qualities associated with successful systems

Aviation Mapped to Rasmussen's Framework



Nuclear Power Mapped to Rasmussen's Framework



Phase 1 – Literature Review

Systems Studied

Incident Reporting System	Administering Organization	Location
-----	University Health Network (UHN)	Toronto, Ontario
Canadian Medication Incident Reporting and Prevention System (CMIRPS) & Analyze-ERR (a standardized tool provided for use in institutions)	Institute for Safe Medication Practices (ISMP)	Canada
Manufacturer and User Facility Device Experience (MAUDE) (mandatory reports from manufacturers) & MedWatch (voluntary reports from practitioners)	Food and Drug Administration (FDA)	United States
MedMARx	United States Pharmacopeial	United States
National Centre for Patient Safety (NCPS)	Veterans Health Administration (VA)	United States
Australian Incident Monitoring System (AIMS)	Australian Patient Safety Foundation (APSF)	Australia
National Reporting and Learning System (NRLS)	National Health Service (NHS) National Patient Safety Agency (NPSA)	Great Britain
-----	Boots Pharmacies	Great Britain
Case study	Massachusetts General Hospital, Department of Anesthesia, Critical Care, and Pain Medicine	Boston, Massachusetts
Case study of C. difficile	-----	Ontario, Canada
Case study	Department of Anesthesia	Geelong, Australia

Details of Interest

Area for Improvement	Questions
Reporting culture	<p>What are the system's objectives?</p> <p>What is the reporting culture? How is it encouraged, created, and maintained?</p> <p>Is the system punitive or non-punitive?</p> <p>Is the system identifying, confidential, or anonymous?</p> <p>Who are reports submitted to?</p> <p>Who are reports analyzed by?</p> <p>Does the system adopt a systems approach to error analysis or human?</p> <p>Who has access to the system?</p>
Reporting process and analysis techniques	<p>Is the system mandatory or voluntary?</p> <p>Who reports?</p> <p>What is reported?</p> <p>How long after an incident are reports filled out?</p> <p>How are reports entered?</p> <p>How long does it take to fill out a report?</p> <p>Are events classified and coded? If so, how?</p> <p>How is data analyzed and used?</p>
Dissemination of information and implementation of improvements	<p>Who disseminates the results of an analysis?</p> <p>What information is disseminated?</p> <p>How is information fed back to reporters and the community?</p> <p>Who does feedback reach?</p> <p>Is anyone accountable for acting on information disseminated? If so, who?</p> <p>What is the timing of dissemination?</p> <p>How is the system searched?</p> <p>How standardized is the system (e.g. across a region or discipline)? How is this level of standardization achieved?</p>

Potential Strategies for Reporting Culture

Potential Strategy	System Identified From
Provide legislative immunity to reporters.	Aviation
Report to an organization with no punitive powers.	Aviation, ISMP, AIMS
Truly blameless, systems approach to error analysis.	Aviation, nuclear power
Emphasize trust, openness, and honesty through policies and examples.	Nuclear power
Change industry connotations around standard procedures (e.g. checklists, instrumentation, reporting) from detracting from professionals' art to disciplined practice to be encouraged.	Aviation
Unions for frontline staff.	Aviation, nuclear power, nursing
Enforce disciplinary actions if an event is NOT reported.	Boots Pharmacies
Remove section with all identifying information from the report before entry into the permanent database and return it to reporter to ensure confidentiality.	Aviation
Introduce legislation to prevent incident information disclosure to the public.	Ontario health care

Potential Strategies for Reporting Process and Analysis Techniques

Potential Strategy	System Identified From
Voluntary to report near-misses and mandatory to report incidents within an organization, but voluntary to report anything on a national or international level.	Aviation, nuclear power
Hazards, near-misses, and all incidents reported to the same system.	Aviation, nuclear power
Paper and electronic reporting.	Aviation
Reporting completed through existing medical record.	Department of Anesthesia, Massachusetts General Hospital
Mobile reporting.	Department of Anesthesia in Geelong, Australia
Reporting form approximately three pages in length.	Aviation
Combination of structured fields with areas for free-text descriptions.	Aviation, some health care
Unique reporting forms based on profession of reporter.	Aviation, NHS
Require basic event information with event description, preliminary analysis, and recommendations.	Aviation, nuclear power
Reports are analyzed and/or disseminated by an influential organization to ensure the resulting recommendations are the strongest possible and are not limited by feasibility concerns.	Aviation, nuclear power
Involve the reporter throughout the analysis and recommendation development to promote effective recommendations and prompt implementation of improvements.	Nuclear power
Events are coded and classified according to some criteria.	Aviation, nuclear power
Root cause analysis, beyond the most proximal cause to the system failure.	Aviation, nuclear power
Extent of condition and cause evaluations.	Nuclear power
Generate and release performance metrics.	AIMS, Department of Anesthesia in Geelong, Australia

Potential Strategies for Dissemination of Information and Implementation of Improvements

Potential Strategy	System Identified From
Organizational structure and escalation hierarchy within industry is simplified, clearly defined, and standardized.	Aviation, nuclear power
Information is disseminated by the organization that analyzes reports.	Aviation, most health care
Information is disseminated up and down Rasmussen's hierarchy without skipping any levels.	Nuclear power
Communication should be tailored and unique for audience (i.e. management, frontline staff, media, public).	Aviation and nuclear power
Methods of information dissemination include regulations, standards, alerts, bulletins, newsletters, studies, and meetings.	Aviation, nuclear power, and health care
Relay excerpts from de-identified reports along with the lessons learned.	Aviation
Information is aggregated and available to look through by topic.	MAUDE, NHS
Incident database is accessible through a search engine.	Aviation, nuclear power
Management is held accountable for making and monitoring improvements and is responsible for communicating back to the centralized body.	Nuclear power

Phase 2 – Focus Groups and Interviews

Transcription and Coding

Question	Strategy	Comment	Code

Thematic Analysis

Code	Quotation
<u>Theme 1</u>	
Subtheme 1	
Code 1	P4: Comment
	P15: Comment
Code 2	P3: Comment
Subtheme 2	
Code 3	P8: Comment
	P22: Comment
	P15: Comment
Code 4	P11: Comment
	P19: Comment

Approaches and Strategies to Address Need for Incident Learning Education

Approaches	Suggested Strategies
Define and communicate the objectives of incident reporting.	Objective: to provide aggregate quality data. Objective: to drive systems and process improvements.
Define and communicate what events should be reported and by who.	Report anything not done according to policy. Report anything that can be improved.
Provide transparency to frontline staff on the analysis and quality improvement aspects of the process beyond report submission.	Educational outreach to frontline.
Educate frontline about QCIPA.	Educational outreach to frontline.
Engage physicians in incident reporting and learning.	Connect existing mandatory physician quality improvement processes (e.g. morbidity and mortality rounds, quality review committees) with the rest of the organization and central incident learning systems. Emphasize the value that incident reporting and learning add beyond existing processes. Involve physicians early in their training.
Standardize incident investigation processes.	Train managers on how to facilitate incident reviews.
Educational outreach to all stakeholders (e.g. frontline staff, managers).	Presentation at new employee orientation. Frequent hands-on workshops and educational sessions on units. Mandatory continuing education eLearning modules.

Approaches and Strategies to Promote Safe Culture and Actively Encourage Reporting

Approaches	Suggested Strategies
Enable follow-up with report initiator during investigation, while easing reporter trepidations about being linked to a report.	-----
Encourage culture of sharing and support among colleagues.	<p>Initiate culture shift within leadership.</p> <p>Emphasize main objective as quality improvement.</p> <p>Investigate reports and actually use to inform quality improvement.</p>
Emphasize reporting of positive events.	<p>Educational outreach to all stakeholders.</p> <p>Redesign terminology used around incident reporting.</p>
Increase visibility of incident reporting.	<p>Tie incident reporting and learning in with other safety initiatives (e.g. November “Patient Safety Month”).</p> <p>Increase number of Patient Safety Officers.</p> <p>Evaluate employees, units, and sites on reporting levels (increased reporting results in a positive evaluation).</p>

Approaches and Strategies to Improve Reporting Process

Approaches	Suggested Strategies
<p>Make the incident reporting platform more accessible and user-friendly.</p>	<ul style="list-style-type: none"> Allow access to incident reporting systems from non-hospital-based computers. Use consistent login information across organization computer systems. Enable reporting on mobile technologies. Provide the ability to save an incomplete report and return to submit later. Offer spell-check in system. Eliminate character limits on fields. Provide the functionality to upload videos and pictures pertaining to an incident.
<p>Redesign incident reporting forms.</p>	<ul style="list-style-type: none"> Length of reporting form: 5 minutes to complete. Use combination of structured and free-text fields. Patient information should be an optional field so conditions with no patient harm can be reported. Provide field for frontline reporter to identify incident causes and preventative strategies. Classify incidents by patient harm and extent of problem separately. Add “unable to assess” option for classification.
<p>Increase the applicability of the reporting process to a variety of professional workflows and organization structures.</p>	<ul style="list-style-type: none"> Have different reporting forms for each profession. Modify reporting workflow to allow for multi-disciplinary input.
<p>-----</p>	<p>Structure the reporting form to reflect and guide the analysis process.</p>
<p>Determine the ideal timing for report initiation.</p>	<p>-----</p>

Approaches and Strategies to Improve Analysis Process

Approaches	Suggested Strategies
Formalize the incident investigation process.	Step- by-step instructions for investigators to follow that leads team through equal consideration of all possible contributing factors (e.g. systems, environment, workflow, human).
Ensure the investigation team is made up of people who together can produce the most valuable outcomes.	Multi-disciplinary debriefs. Involve a process improvement expert in all debriefs.
Determine if people involved in an incident should be included in the debriefing process.	-----
Determine how close to units debriefings should be held.	-----
Determine the ideal timing for incident analysis.	-----

Approaches and Strategies to Address Need for Effective Dissemination of Incident Information and Review Outcomes

Approaches	Suggested Strategies
Maintain, but connect de-centralized incident learning and quality improvement efforts.	<p>Arrange for representatives from each de-centralized committee to meet periodically.</p> <p>Have individual committees submit to and access a centralized database with all incidents, near-misses, and hazards.</p>
Create mechanisms and channels for organizations to share with and learn from each other.	<p>Adopt standards across health care institutions in terms of terminology, reference points, and procedures.</p> <p>Establish central, independent health care organizations across regions and disciplines to facilitate sharing and learning across organizations.</p> <p>Offer free participation in centralized program.</p> <p>Structure information flow according to Rasmussen’s hierarchy (i.e. each level receives reports from the one below and lead reporters report relevant incidents to the one above).</p>
Ensure incident information and review outcomes are communicated back to frontline.	<p>Disseminate aggregate incident information by event type with select de-identified incident narratives, lessons learned, and recommendations.</p> <p>Feed information back to managers and require them to determine what is appropriate for their units and communicate it to their staff.</p> <p>Release incident summary bulletins.</p> <p>Publish monthly incident newsletters.</p> <p>Participate in quality improvement research exchanges.</p> <p>Provide online incident digests.</p> <p>Develop eLearning continuing education modules based on incident review outcomes.</p> <p>Create new policies informed by incident investigations.</p> <p>Create a searchable database to enable frontline staff to self-generate summary incident reports.</p> <p>Store aggregate incident information in an archive available to frontline retrospectively.</p>
Keep report initiator informed as his/her report is processed.	<p>Issue a “thank you for submitting an incident report” message from a prominent person in the organization.</p> <p>Provide notifications when a report has been added to and/or signed-off on</p> <p>Directly communicate the outcomes of the incident review to the report initiator.</p> <p>Providing the report initiator with research and information related to their incident.</p>

Approaches and Strategies to Learn from Non – Critical/Severe Incidents and Near-Misses

Approaches	Suggested Strategies
Emphasize proactive incident reporting and learning.	Instate formal review procedures for moderate/ minor incidents, near-misses, and hazards.

Approaches and Strategies to Increase Systems Improvements Resulting from Incident Reporting and Review

Approaches	Suggested Strategies
Ensure capturing complex inherent systems issues.	-----
Formalize a mandatory incident investigation process.	Incident review recommendations should consider using technology to reduce load on humans.
Decrease the response time in addressing incident reports.	Use operating room incident review processes as a model for other health care areas.
Initiate systems improvements at senior management level.	-----

Approaches and Strategies to Dedicate Additional Resources to Support Incident Learning

Approaches	Suggested Strategies
<p>Prioritize incident reports for in-depth investigation.</p>	<p>Leave decision about whether an incident merits a full investigation to manager's judgement.</p>
<p>-----</p>	<p>Annually identify the top five systemic problems to be addressed.</p>
<p>-----</p>	<p>Increase size of and resources available to risk management departments.</p>
<p>-----</p>	<p>Keep organization computer systems up-to-date.</p>

Approaches and Strategies to Balance Commitment to Public Transparency with Protection for Health Care Professionals and Institutions

Approaches	Suggested Strategies
Be transparent to the public, but enable health care professionals to discuss incidents safely.	Pass legislation similar to QCIPA.
Release enough incident detail to be meaningfully interpreted without implicating individuals or institutions.	Release aggregate information about pools of hospitals, grouped together by size, location, complexity of cases seen.