The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national nonprofit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

The Healthcare Insurance Reciprocal of Canada (HIROC) is a member-owned expert provider of professional and general liability coverage and risk management support.

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Failure Mode and Effects Analysis (FMEA): Proactively Identifying Risk in Healthcare

Health care practitioners continue to implement initiatives to increase safety in the delivery of patient care. Leadership training, executive rounds, and non-punitive, responsive incident reporting programs are some of the initiatives adopted by health service organizations for the advancement of patient safety. ISMP Canada has, through collaborative efforts, previously developed tools such as the Medication Safety Self-Assessment® (MSSA) and the Canadian Root Cause Analysis Framework.[1] The MSSA provides insights into the characteristics of a safe medication use system.[2] Root cause analysis (RCA) assists health care organizations to identify and improve or correct system-based problems by exposing underlying factors that have contributed to a critical or sentinel event or a close call.[3] An important prospective safety tool that has been used in other industries for many years is failure mode and effects analysis (FMEA). FMEA is "F"orward-looking, in contrast to the "R"etrospective approach of RCA. Both approaches to system analysis are important for preventing adverse events.

FMEA proactively identifies potential failure modes and their effects and, based on these findings, guides the development of strategies to improve safety. The questions one asks in order to perform failure mode and effects analysis are: "What could fail and how?" and "Given the various possibilities for failure, what are the potential consequences of each?" FMEA can be applied to components (i.e., of equipment or systems) and to processes. Its aim is to develop system safeguards (e.g., redundancies and barriers) so that equipment or processes, and therefore overall systems, will be made safer. Industries already using FMEA include chemical, nuclear power, and other high-reliability organizations. As health care is a complex industry, it needs to also adopt the culture of a high-reliability organization, that is, accepting that error will occur, that the impact of errors can be devastating, and that efforts should be made to discover system weaknesses before harm occurs. Practitioners in health care have started using the FMEA technique to enhance patient safety. The Veterans Affairs (VA) National Center for Patient Safety developed the Healthcare Failure Mode and Effects Analysis (HFMEA).[4] The Canadian Council on Health Services Accreditation has included in its patient safety goals a requirement that organizations "Carry out one patient safety-related prospective analysis process per year"[5] and FMEA is cited as an example.

One of ISMP Canada's roles in the Canadian Medication Incident Reporting and Prevention System (CMIRPS) is to develop educational workshops on FMEA. ISMP Canada has developed an FMEA framework[6], adapted from the VA model, for use in Canada. The framework can be applied to all health care processes, such as medication use, patient identification, specimen labelling, operating room procedures, and emergency room triage, to list a few examples.

Although FMEA is only a tool, its adoption by the health care community can facilitate a culture shift towards an increased focus on patient safety. It will help health care organizations to think and behave like high-reliability organizations, in particular, to anticipate and forestall injury. FMEA demonstrates to practitioners that human error and component or system failures, each with the potential to lead to significant adverse events, are embedded within health care systems and processes. Using the FMEA framework, staff can design ways to make patient care safer before an adverse event occurs. FMEA can also be used to evaluate remedial actions identified in an RCA exercise.

ISMP Canada's FMEA framework includes the following key steps:

- Step 1: Select a high-risk process and form a team
- Step 2: Diagram the process and the sub-processes
- Step 3: Identify all failure modes and their effects
- Step 4: Identify potential causes
- Step 5: Prioritize failure modes by their effects
- Step 6: Redesign the process to prevent failures or to intercept adverse effects
- Step 7: Analyze and test the new process
- Step 8: Implement and monitor the redesigned processes

Human factors engineering (HFE) principles are fundamentally important to guide the FMEA. HFE recognizes inherent human characteristics, capabilities, and limitations when performing required functions in a process or when interfacing with systems, including computers, devices, and equipment. HFE principles are used to guide the recognition of failure modes. In addition, HFE principles are used to develop effective actions or redesigns aimed at 1) reducing the probability of errors, 2) making errors visible, and 3) mitigating harm from errors when they occur. A useful overview and discussion of HFE's applicability to medication use systems is provided in the American Society of Health-System Pharmacists' publication *Medication Safety: A Guide for Health Care Facilities*.[7]

A tenet of FMEA is the evaluation of processes specific to an organization. However, there is also value in learning from what other organizations have discovered in the assessment of their own processes.[8] In evaluating the failures reported by other organizations, you may improve the breadth of your own facility's analysis of new or planned situations or of those processes with which there is limited organizational experience. The comprehensive FMEA on the use of anticoagulants carried out by the Utah Patient Safety Steering Committee Adverse Drug Effects User Group is a good example of how much one can learn from the work of others. The executive summary, flowcharts, and an FMEA table are posted on the website of the Utah Hospitals and Health Systems Association.[9] The Utah

Hospitals' FMEA is a good example of how safety knowledge and experience can be shared. Another example comes from the FMEA for IV patient-controlled analgesia (PCA) conducted by ISMP (US).[10]

ISMP Canada is planning the development of an FMEA database specific to medication use systems. Canadian health service organizations are invited to share their FMEA results for inclusion in the shared database.

Acknowledgement

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For additional information about the FMEA framework developed by ISMP Canada, or for information about FMEA training workshops please contact ISMP Canada by e-mail: fmea@ismp-canada.org or by phone: 1-866-544-7672.

References

1. Canadian Patient Safety Institute; Institute for Safe Medication Practices Canada; Saskatchewan Health. Canadian root cause analysis framework. Edmonton (AB): Canadian Patient Safety Institute; 2005. Available from: http://www.patientsafetyinstitute.ca/uploadedFiles/Resources/March%202006%20RCA%20Workbook.pdf
2. Medication Safety Self-Assessment® for Hospitals Canadian Version II. Toronto ON: ISMP Canada; 2006. Available from ISMP Canada
3. Institute for Safe Medication Practices Canada. Root Cause Analysis of Medication Incidents. ISMP Saf Bull. 2005 [cited 2006 Dec 22];5(10):1-2. Available at: http://www.ismp-canada.org/download/ISMPCSB2005-10RCA.pdf
4. United States Department of Veterans Affairs, National Center for Patient Safety. Healthcare Failure Mode and Effect Analysis (HFMEA™). Accessed 2006 December 20 at http://www.va.gov/ncps/SafetyTopics.html#HFMEA
5. The Canadian Council on Health Services Accreditation. Patient safety: Frequently asked questions. Cited 2006 Dec 22. Available at: http://www.cchsa.ca/default.aspx?page=114
6. Failure Mode and Effects Analysis (FMEA): A framework for proactively identifying risk in healthcare. Version 1. Toronto ON: ISMP Canada; 2006.
7. Manasse HRJr, Thompson, KK. Medication Safety: A Guide for Health Care Facilities. Bethesda MD: American Society of Health-System Pharmacists; 2005.
8. Cohen M. One hospital's method of applying Failure Mode and Effects Analysis. In: Medication Errors. Cohen M, editor. Washington DC: American Pharmaceutical Association; 1999.
9. Utah Hospitals and Health Systems Association Adverse Drug Effects User Group. FMEA Project on High Risk Drugs - Inpatient Anticoagulant Agents — January 2005. Accessed on 2006 December 20 at http://www.uha-utah.org/ADEpublications.htm.
10. Example of a Health Care Failure Mode and Effects Analysis for IV Patient Controlled Analgesia (PCA). Accessed on 2006 December 21 at http://www.ismp.org/Tools/FMEAofPCA.pdf.

Medication Safety Self-Assessment® (MSSA)

The following medication safety self-assessment programs are available from ISMP Canada:

1. Medication Safety Self-Assessment® (MSSA) for Hospitals, Canadian Version II

2. Medication Safety Self-Assessment® for Community/Ambulatory Pharmacy, Canadian Version

Completion of the MSSA will assist health service organizations in:

- **Identifying priorities for improving medication use systems**
- **Measuring progress over time**
- **Meeting standards (e.g., CCHSA)**
- **Contributing to regional, provincial and national aggregate data**

The MSSAs were originally created by ISMP in the United States. The Canadian MSSAs were developed with the assistance of expert panels of health care professionals in Canada. Most of the characteristics for a safe medication use system identified within the MSSAs represent the learning from analysis of medication incidents. The Institute for Safe Medication Practices Canada (ISMP Canada) gratefully acknowledges the assistance provided by all individuals working in the Canadian health care community who share learning from medication incidents in order to inform development of safe medication practices. ISMP Canada also wishes to thank the Ontario Ministry of Health and Long-Term Care, the Canadian Patient Safety Institute, Greenshield and Health Canada for support for the MSSA programs.

Additional information about the MSSA programs is available by email: mssa@ismp-canada.org.

ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.

Medication Incidents (including near misses) can be reported to ISMP Canada:

(i) through the website http://www.ismp-canada.org/err_report.htm or

(ii) by phone: 416-733-3131 or toll free: 1-866-544-7672.

ISMP Canada can also be contacted by e-mail: cmirps@ismp-canada.org. ISMP Canada guarantees confidentiality and security of information received, and respects the wishes of the reporter as to the level of detail to be included in publications.

A Key Partner in the Canadian Medication Incident Reporting and Prevention System