

# Failure Mode and Effects Analysis: Proactively identifying risk in health care

By David U and Donna Walsh

In Canada, we have begun to see a shift toward a culture of patient safety. Health-care organizations and practitioners are participating in local and national initiatives to enhance safety in the delivery of patient care. An important safety tool that has been used in other industries for many years and is now being used in health care is Failure Mode and Effects Analysis (FMEA). FMEA is a proactive risk assessment tool used to identify potential failures and their effects and guides the development of strategies for improvement. Using FMEA, one asks the questions: "What could fail and how?" and "Given the various possibilities for failure, what are the potential consequences of each?"

FMEA can be applied to processes, equipment, and systems. It has been a cornerstone of safety practice in high-reliability industries such as nuclear power, automobile manufacturing and chemical processing for many years. Leaders in health care have begun to adopt the attitude of high-reliability organizations, that is, accepting that errors will occur; that the impact of errors can be devastating, and that efforts should be made to discover system weaknesses before harm occurs.

The Veteran Affairs (VA) National Center for Patient Safety has developed a FMEA model for health-care environments, called Healthcare Failure Mode and Effects Analysis (HFMEA). As part of its role in the Canadian Medication Incident Reporting and Prevention System (CMIRPS), ISMP Canada has adapted the VA model to develop a similar FMEA framework 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.

The ISMP Canada FMEA framework highlights the fact that component or system failures are embedded within health-care processes. Once potential failures have been identified, improvements can be made. FMEA is undertaken with three goals in mind:

- Eliminate failures before they occur;
- Make failures visible, thereby, preventing them from reaching the patient; and
- Reduce the impact of a failure if it does reach the patient.

While use of FMEA originated with the objective of enhancing safety, the quest for quality improvement and cost control has also increased its utility. FMEA can reduce costs by identifying product and process improvements early in the

development stage of a new process when relatively inexpensive changes can be made. FMEA also makes systems more robust, thereby enhancing system performance. Finally, FMEA can make systems more "fault tolerant" by ensuring that systems are designed to continue to perform even if there is a fault or failure in one part of the system.

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. Canadian hospitals have begun to conduct FMEA to enhance patient safety efforts. The Calgary Health Region published their HFMEA on the process of ordering and

administering potassium chloride and potassium phosphate in *Healthcare Quarterly* (Vol. 8, Special Issue 2005). This FMEAs is a good example of how local knowledge and experience can be shared with others.

ISMP Canada is planning the development of a FMEA database specific to medication use systems. Canadian health-care

organizations are invited to share their FMEA results for inclusion in the shared database.

For additional information please contact ISMP Canada by e-mail: [fmea@ismpcanada.org](mailto:fmea@ismpcanada.org) or by phone: 1-866-544-7672.

*Donna Walsh, RN is Educator and David U is President of the Institute for Safe Medication Practices.*