Failure mode and effects analysis: A tool for identifying risk in community pharmacies

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CANADIAN HEALTH CARE LEADERS HAVE BEGUN TO LOOK AT SAFE practices in other industries to identify those with applicability to health care. A key characteristic of high-reliability industries, such as nuclear power, aviation, automobile manufacturing, and chemical processing, is acceptance of the fact 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. A tool that has been a cornerstone of safety efforts in these organizations is a proactive risk assessment process called failure mode and effects analysis (FMEA). Using FMEA, multidisciplinary teams first identify potential failures and their effects, and then develop strategies for improvement. FMEA focuses on how and when a system will fail, *not if* it will fail.

The US Veterans Affairs (VA) National Center for Patient Safety has developed an FMEA model for health care environments called Healthcare Failure Mode and Effect Analysis (HFMEA).[1] As part of its role in the Canadian Medication Incident Reporting and Prevention System, the Institute for Safe Medication Practices Canada (ISMP Canada) has adapted the VA model to develop a similar FMEA framework for use in Canada.[2,3]

TABLE 1 Steps in the FMEA process

Step 1	Select process and assemble the team.
Step 2	Diagram the process.
Step 3	Brainstorm potential failure modes and determine their effects.
Step 4	Identify the causes of failure modes.
Step 5	Prioritize failure modes.
Step 6	Redesign the process.
Step 7	Analyze and test the changes.
Step 8	Implement and monitor the redesigned process.

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. Such an analysis is undertaken with 3 goals in mind:

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

FMEA can be applied to processes in any health care setting; however, most of the published literature on FMEA in health care describes its application in hospitals. The requirement by the Canadian Council on Health Services Accreditation that hospitals undertake one prospective analysis annually has provided impetus for the use of FMEA in Canadian hospitals. As one example, the Calgary Health Region has published the results of its HFMEA on the process of ordering and administering potassium chloride and potassium phosphate.[4] Although FMEA is fundamentally an evaluation of processes specific to an individual organization, there is also value in learning from what other organizations have discovered in the analysis of their processes, so dissemination of FMEA findings provides important learning opportunities.

FMEA process

A failure mode and effects analysis follows a stepwise approach (described in Table 1) that begins with identifying a high-risk process and selecting a team to complete the analysis. Some characteristics of high-risk processes include complexity, lack of standardization, and heavy dependence on human intervention. An integral feature of FMEA is the involvement of a multidisciplinary team. An FMEA team for a community pharmacy project might include the owner/manager, staff pharmacist(s), pharmacy technician(s), and the pharmacy clerk. It is also helpful to include a "naïve" person on the team, i.e., someone who is not intimately familiar with the process being analyzed who can ask questions

FIGURE 1 Example of high-level process for prescription dispensing

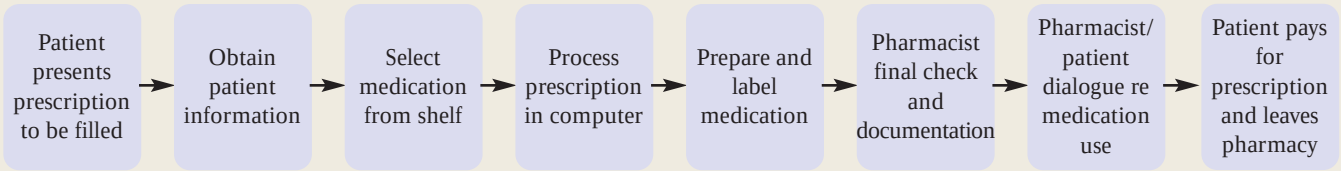
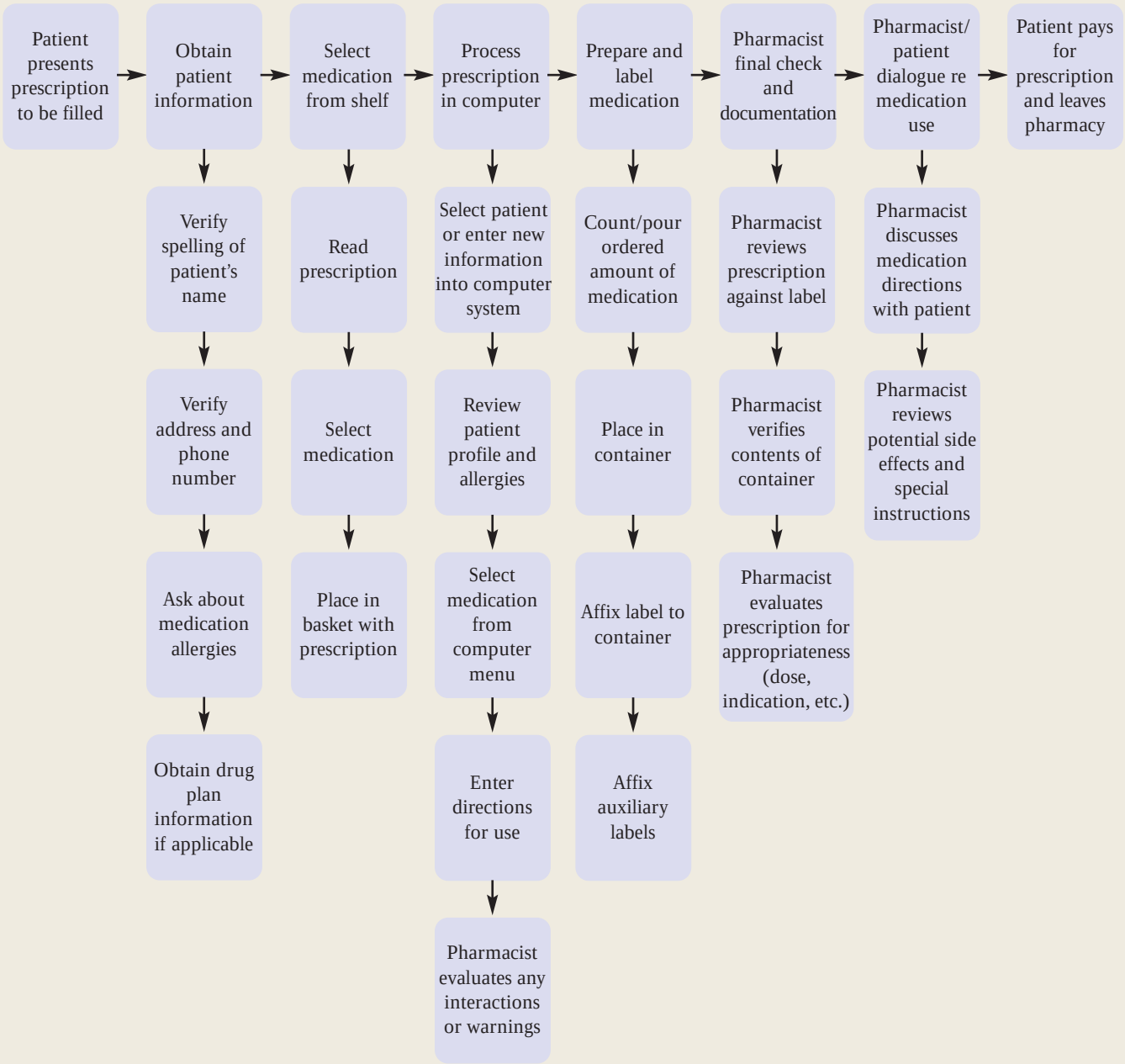


FIGURE 2 Example of sub-process breakdown for the dispensing process



about why the work is configured in a particular way.

The team's first task is to identify and diagram the high-level steps in the process under review in a flow chart format. An example of the high-level steps in a typical dispensing process is shown in Figure 1.

Once the high-level process steps have been identified, each one is then further broken down into "sub-process" steps. FMEA team members are often surprised by the complexity of processes they take for granted as part of their normal work environment. A sample sub-process breakdown is shown in Figure 2.

Once the process diagrams have been completed, the team may decide that the process selected for analysis is too large. It is often helpful to break large, complex processes into smaller, more manageable portions, to prevent overwhelming team members and increase the likelihood of successfully completing the project.

For additional information about the FMEA framework developed by ISMP Canada, or for information about FMEA training workshops, send an e-mail to fmea@ismp-canada.org.

The next stage in the FMEA is to work through each sub-process step to brainstorm potential "failure modes," which are the things that can go wrong. For example, under the "obtaining patient information step," some potential failure modes might include: incorrect spelling noted, patient information not verified, patient cannot remember allergies, drug plan information outdated. Failure modes are identified for each of the sub-process steps.

Once the failure modes have been identified, the team determines the causes and effects of the failures; in other words, the reasons why failures might occur, and the resulting consequences.

Most FMEAs identify a number of potential failure modes. As teams will often not be able to address all the potential failures, a prioritization process is used to assist the team to decide which items to work on first. This prioritization process assesses the *severity* of the outcome, the *frequency* of occurrence, and the likelihood of *detection* of the failure before the effect becomes evident.

Where possible, identified risks should be eliminated; if elimination is not possible, a control measure is needed. Successful strategies will focus on physical changes to processes rather than information and education. For example, solutions that are more likely to result in long-term positive outcomes are forcing functions and constraints (e.g., segregation of look-alike and sound-alike products), automation and computerization (e.g., barcode verification of medication dispensing), standardization of processes, and the use of reminders and checklists to ensure that work is carried out systematically.

When medication incidents have occurred in community pharmacy and other health care environments, corrective actions have often focused on educating and training the staff involved. While education and training are important and necessary, used alone they will not have lasting effects on safety, and do not address the underlying system deficiencies that contributed to the incident.

Experience with FMEA in community pharmacy

We were unable to find any published reports of the use of FMEA in community pharmacy practice; however, as part of a pharmacy residency project, an FMEA on the dispensing process is currently being conducted in an ambulatory pharmacy in Ontario. When complete, these will be shared to provide learning regarding application of this tool in the community setting and also to identify potential vulnerabilities that could exist at other practice sites.

Historically, the pharmacy profession has relied on the care and vigilance of individual practitioners to prevent medication errors. As our understanding of safety theory grows, we have come to realize that these characteristics are important but cannot be relied upon to ensure safe care of our patients in the complex environments that are the norm in community pharmacy and elsewhere in health care. FMEA is a useful tool for identifying areas of risk suitable for proactive correction, to reduce the likelihood of an adverse event due to a medication error.

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