

The Systems Approach to Quality Assurance  
for Pharmacy Practice:

## A Framework for Mitigating Risk



# Acknowledgements

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<sup>1</sup> Institute for Safe Medication Practices Canada. *Canadian Failure Mode and Effects Analysis Framework: Proactively Assessing Risk in Healthcare*. Toronto: CJ Graphics, 2007. Print.

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# Introduction

Pharmacists take great pride in the consistently high ratings they receive in public surveys of trust;<sup>2</sup> however, we know that errors can and do happen, sometimes leading to patient harm. As a profession, we are not alone in trying to understand how errors happen and how to work to prevent future errors. In the last few years, patient safety has become a central theme for the healthcare industry. Lessons learned in “high reliability” industries such as aviation and nuclear power are being applied in the healthcare setting. While providing healthcare to individual patients adds complexity that is not present in these industries, we can learn a great deal from them about reducing risk in systems. One such opportunity is to prospectively evaluate systems and processes to identify and correct vulnerabilities before a harmful incident occurs. This is the focus of this module of the *Systems Approach to Quality Assurance*, which complements the first module on retrospective incident analysis. There are several tools available with which to conduct prospective analysis. This module will describe the use of Failure Mode and Effects Analysis (FMEA) in pharmacy practice.

## What is FMEA?

Failure Mode and Effects Analysis (FMEA) is a technique used to identify process and product problems before they occur. FMEA is forward-looking, in contrast to the retrospective approach of incident analysis and techniques such as root cause analysis. FMEA is based on the premise that all systems and processes contain embedded system failures.

The goals of FMEA are to:

1. Reduce the likelihood of and, where possible, eliminate failures before they occur;
2. Make failures visible (e.g., to prevent them from reaching a patient); and
3. Reduce the impact of a failure if it does occur.

FMEA is a team-based, structured process that includes diagramming or “mapping” the steps in a process, identifying the potential failure points and consequences of each, and ultimately determining what steps to take in order to reduce the potential for the identified failures to occur.

**F – Failure:** The breaking of a process, lack of success, non-performance, or non-occurrence.

**M – Mode:** The way in which something is operated or performs. A “failure mode” is the manner in which something might fail, the specific type of failure, or the degree of failure.

**E – Effects:** The results or consequences of an action. In the context of FMEA, effects are the direct, indirect, short-term, or long-term effects of a failure on the operation, function, status, or outcome of a process step.

**A – Analysis:** The detailed examination of a process, substance, or situation. FMEA teams analyze a system to find the potential failure modes, their effects, and the severity of those effects. The teams consider ways to eliminate or reduce failure and its associated risks, with a focus on preventing or minimizing harm.

FMEA is not a new concept.<sup>3</sup> In 1949, the US military developed FMEA as a reliability evaluation technique to determine the effect of system and equipment failures. The National Aeronautics and Space Administration (NASA) adopted FMEA in the 1960s, and in the 1960s and 1970s, reliability engineers in U.S. manufacturing plants became aware of the tool and began to test it in their own settings. The FMEA process is now used widely in industries such as aviation, aerospace, nuclear power, and in the automotive industry. These industries rely on FMEA as an integral aspect of improving quality and safety. An Accreditation Canada requirement for healthcare organizations to conduct at least one prospective risk assessment annually has increased awareness and use of FMEA in hospitals and long-term care homes over the last few years.

## Why is FMEA a good technique for healthcare, including pharmacy?

FMEA is a proactive approach for identifying and reducing gaps in quality and safety. With FMEA, we can identify and fix system problems before patient harm occurs.

With this in mind, FMEA is a useful tool to help pharmacy teams meet the quality assurance objectives of the Alberta College of Pharmacy’s *Standards for the Operation of Licensed Pharmacies* (SOLP). All pharmacy staff have a duty to minimize the risk of drug incidents. Using FMEA helps teams identify potential vulnerabilities in the pharmacy before an incident occurs. Using the FMEA process helps teams to minimize the risk of incidents occurring.

The premise that individual practitioners will act with positive intent and not knowingly work to cause harm to patients is fundamental to the FMEA process. The following sections describe work by James Reason on the “systems approach,”<sup>4</sup> David Marx’s

2 Dabu Nonato, Sheila. “Trust greatest for pharmacists, doctors, soldiers, poll says.” *Canada.com*. Postmedia News: 3 Jan. 2012. Web. <<http://www.canada.com/news/Trust+greatest+pharmacists+doctors+soldiers+poll+says/5941671/story.html>>

3 McDermott, R.E., R.J. Mikaluk, and M.R. Beauregard. *The Basics of FMEA*. New York: Productivity Press, 1996. Print.

4 Reason, J. “Human Error: Models and Management.” *BMJ* 320.7237 (2000): 768–770.

work on “just culture,”<sup>5</sup> and application of human factors engineering principles, which support this premise.

## Systems approach

In healthcare environments, we have historically expected practitioners to maintain professional competence and exercise due care in day-to-day practice. When errors happened, we had a tendency to focus on the actions of the individual(s) involved, rather than taking a broader system perspective. The systems approach recognizes that, as humans, we are not capable of performing perfectly. This approach supports the principle that flaws in the working environment (or system) cause accidents, and that human error should be an expected part of any working environment. To prevent accidents, we need to identify the potential human errors that can occur in a particular system and rebuild the system to make it resilient to these expected errors.

## Just culture

David Marx’s work on “just culture” differentiates between aspects of daily practice that are within and outside the control of individual practitioners. As individuals we choose how we practice within an environment, but have less control over the environment itself. For example, in both community and hospital pharmacy environments, it is common for all staff to multi-task—for example, entering prescriptions into the computer system or checking prescriptions while talking on the phone or waiting on hold, or while chatting with other staff. Marx would consider these to be “at risk” behaviours—and we should recognize that they

increase the risk of error. However, the pharmacy environment is highly distracting—phones and fax machines are ringing, interruptions are frequent, and workload is not predictable—and these things are not within the control of the staff in the pharmacy. The concept of a just culture recognizes that in designing systems and processes, the individual and system factors must achieve a balance. There are things that licensees and individual practitioners can do from a system design perspective to reduce the likelihood of error, but we all need to take responsibility for safe behavioural choices within the system.

## Impact of human factors engineering principles

Human factors engineering is a branch of engineering science that deals with how we, as humans, interact with the world around us. This discipline combines biomechanics, kinesiology, physiology, and cognitive science to design processes that improve efficiency, reliability, and safety through an understanding of human capabilities and limitations. A basic understanding of human factors is key to the FMEA process, as these principles impact both the potential for errors to happen and the development of strategies for improvement that are likely to result in sustained change.

As pharmacists or pharmacy technicians must perform a final check on each and every prescription, pharmacy culture has supported the focus on individual care and vigilance to prevent errors. As a result, approaches to error prevention have commonly relied on education, training, and policy development. While these are important supports, human factors principles tell us that when used alone, they are unlikely to be effective

over the long term. The following *hierarchy of effectiveness*<sup>6</sup> illustrates the types of strategies that are likely to be more effective.

### The Hierarchy of Effectiveness



- Forcing functions and constraints
- Technology and automation
- Standardization and simplification
- Reminders, checklists and double-checks
- Policies and procedures
- Education, training and communication

The first two items on the list involve physical process changes, which help, and in some cases *force*, practitioners to work in a particular way. For example, if the pharmacy computer system will not process a prescription unless the user also enters allergy information, this is a forcing function. If correctly designed, process changes based on these *higher leverage* strategies are more likely to result in sustained positive system impact than those that rely on individual care and vigilance.

Reminders, checklists, and double-checks as well as standardization and simplification reduce reliance on memory and individual vigilance to prevent errors.

The last two items on this hierarchy are policy development and education. While necessary, they are *low leverage* strategies because they rely on individual practitioners to remember and follow them consistently to be effective. In terms of FMEA, this hierarchy can be very useful in identifying why vulnerabilities are present and in planning for system changes identified through the analysis.

<sup>5</sup> Marx, D. *Patient Safety and the “Just Culture”: A Primer for Health Care Executives*. Prepared for Columbia University under a grant provided by the National Heart, Lung, and Blood Institute, 17 Apr. 2001. Available at: [http://www.unmc.edu/rural/patient-safety/tools/Marx Patient Safety and Just Culture.pdf](http://www.unmc.edu/rural/patient-safety/tools/Marx%20Patient%20Safety%20and%20Just%20Culture.pdf).

<sup>6</sup> Institute for Safe Medication Practices. “Medication Error Prevention “Toolbox.”” *ISMP Medication Safety Alert*. 2 Jun. 1999: 11. Print.

#### Process tip:

When assessing risk in systems, look beyond the provider-patient interface, to system-based factors that contribute to the potential for errors further down the line.

Incorrect actions on the part of a provider can cause direct and immediate harm to a patient; however, from analysis of many incidents, we have learned that many of the factors that lead to incidents are beyond the control of an individual practitioner and result from decisions made far from the patient-provider interface. The purpose of an FMEA is to look for the underlying factors that may contribute to a future incident. These factors may include things like management and regulatory factors, physical environment issues, and organizational culture.

In a pharmacy setting, factors commonly identified as potential risks include failure to identify an incorrect product dispensed, or misinterpretation of a handwritten prescription. These factors would appear to rest with the practice or competence of the individual practitioner until we identify contributing factors, such as sub-optimal lighting, look-alike packaging and labelling, reliance on handwritten prescriptions (rather than computer-generated), and staffing ratios that do not reflect workplace needs. All of these things are beyond the control of individual pharmacists, pharmacy technicians and other pharmacy staff.

### When should you consider an FMEA?

Organizations can use FMEA to assess existing systems and processes and also to determine the potential for negative consequences in new systems. The overall concepts for FMEA can be applied to any process or system. While various types of FMEAs can

be conducted, this document will describe a *process* FMEA. A process FMEA involves assessment of the steps, or components, of a process and includes examination of the activities of individuals, equipment, methods and materials, and environmental considerations. Each component of a process has its own sub-processes, which may react individually, in tandem, or interactively to create a failure. Depending on the complexity of these factors, a process FMEA can be complicated and time-consuming. Nonetheless, FMEA is well-suited for analyzing many healthcare processes. Some examples of pharmacy processes that could be targeted for FMEA review include:

- Implementing a new computer system
- Communicating patients' allergy information
- Developing unit-dose packaging processes
- Using patient-controlled analgesia pumps
- Renovating or designing a pharmacy dispensary
- Developing processes for compounding extemporaneous or sterile products
- Identifying drug therapy problems
- Documenting patient care activities

The ultimate goal of FMEA is to prevent harm from reaching a patient. Reducing the frequency of errors, making errors more obvious, and reducing the severity of the impact of an error can make systems safer. Many safety systems that we all encounter in everyday life, such as seat belts, baby safety devices, and traffic safety interventions, were developed using FMEA concepts.

FMEA is useful for identifying system vulnerabilities so that organizations can implement proactive process and workflow changes. In a pharmacy setting, FMEA can be used to assess both operational and clinical processes.

You can use FMEA to meet requirements (b) and (c) of SOLP 6.3, which states that a licensee must ensure that a quality assurance process is implemented and maintained in a licensed pharmacy and that the quality assurance process should:

- a. provide for reporting, investigating, documenting and evaluating drug incidents that occur in the pharmacy;
- b. include regular review and feedback mechanisms to prevent drug incidents; and
- c. include a process or procedure for responding to complaints or concerns.



# Conducting an FMEA

When conducted in a systematic,<sup>7,8</sup> step-wise manner, the FMEA process is easy to follow. A typical FMEA includes eight steps as shown below in Table 1.

**Table 1: Steps in a failure mode and effects analysis**

Step	Description
1	Select a process to analyze and assemble a team
2	Diagram the process and sub-processes
3	Brainstorm potential failure modes within the process
4	Identify the effect(s) and cause(s) of the potential failure modes
5	Prioritize the potential failure modes
6	Redesign the process(es) to address the potential failure modes
7	Analyze and test the changes
8	Implement and monitor the redesigned process(es)

## Step 1: Select a process to analyze and assemble a team

### 1a) Select a high-risk process to analyze

Select a topic for analysis that relates to an area of substantial risk for patients—FMEA can be resource-intensive, and carefully selecting topics for analysis will help to optimize use of resources. It is important to keep the scope manageable—if the topic is too broad, the task will be overwhelming; conversely, if the topic is too narrow, the project may fall short of achieving the desired improvement.

Teams new to FMEA should start with a small project and complete it before moving on to larger or more complex projects.

Clearly define the topic and specific process(es) for analysis at the outset. In one method for topic selection, the pharmacy or organizational leadership (e.g., corporate management/licensee) selects the general topic area and the team then selects a more specific area for analysis within the general topic. Another approach is to select a “mega”-topic, and then have small groups work on various components of the mega-topic, or work on the components sequentially.

**Table 2: Selection of a high-risk process**

Examples of “mega”-topics	Possible subtopics
Diabetes care	<p>Process for identifying new diabetic patients</p> <p>Training process for blood glucose meters</p> <p>Medication reconciliation process for diabetic patients</p> <p>Patient assessment process for diabetic patients</p>
Patient identification	<p>Process for identifying patients picking up prescriptions</p> <p>Process for ensuring correct patient selection in the pharmacy computer system when entering new prescriptions</p>

One benefit of using the mega-topic approach is that everyone can benefit from the smaller learning experiences of the individual projects. It is important for team members to review the topic definition frequently throughout the FMEA process to avoid drifting off course and also to avoid trying to solve all of the organization’s problems at once.

When selecting the topic, consider the following questions:

- What processes within the organization represent high risks to the patients we serve?
- Where can we obtain information about high-risk processes? Does organizational data exist from which we can draw useful information?
- What is the scope of the FMEA for the selected high-risk process?

### 1b) Assemble a multidisciplinary team

FMEA is intended to be conducted by a team that includes both front-line practitioners and management. This ensures that there is a clear understanding of the details and challenges of the day-to-day work as well as a perspective on resource management.

The FMEA team should consist of three to eight people with appropriate involvement in the process under review. Including members with different perspectives and expertise can add value to the team and the analysis process.

Select the team members to provide a multidisciplinary approach and fulfill required roles:

- *Leader:* Someone with a vested interest in the anticipated improvements
- *Subject matter expert(s):* Staff member(s) with knowledge of the process under analysis
- *Advisor:* Someone who can coach the team and keep the FMEA

<sup>7</sup> Joint Commission on Accreditation of Healthcare Organizations. *Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction*. Oakbrook Terrace, IL: Joint Commission Resources, 2002. Print.

<sup>8</sup> Stamatis, D.H. *Failure Mode and Effect Analysis: FMEA From Theory to Execution*. 2nd ed. Milwaukee, WI: American Society for Quality, 2003. Print.

- process going
- *Recorder*: Ideally someone with computer skills

*Subject matter experts* are invaluable to the FMEA team. They can bring process-specific knowledge, information about stakeholder interests, knowledge about how actual practice measures up to policy, and follow-up and measurement skills. Including these people on FMEA teams can improve the safety culture and teamwork of an organization. Examples of subject-matter experts include:

- Front-line staff (e.g., pharmacists, pharmacy technicians, pharmacy clerks);
- Pharmacy buyers/procurement technicians;
- Members of other disciplines who may be involved in the process (e.g., nurses, physicians); and
- Physical facilities staff (e.g., security, housekeepers).

The *Standards of Practice for Pharmacists and Pharmacy Technicians* Standard 1.9 states that, “Each pharmacist and pharmacy technician must participate in the quality assurance processes required by the *Standards for the Operation of Licensed Pharmacies* or another workplace quality assurance program applicable to the pharmacists’ or the pharmacy technicians’ practice.”

As pharmacy licensees and corporate managers have a key responsibility for the overall management of the pharmacy, their involvement in an FMEA helps to demonstrate a

commitment to a system-based approach to providing care. Additionally, they are responsible for overseeing the implementation of recommendations for system change; thus, they need to fully understand the rationale and level of urgency for recommendations made by the team.

#### As described in SOLP 6.1:

A licensee must ensure that:

- the licensed pharmacy has appropriate systems, policies and procedures in place to minimize the risk of a drug incident or an adverse drug event
- regulated members and employees of the licensed pharmacy:
  - are trained, and
  - are required as a term of their employment to comply with those systems, policies and procedures.

Further, in SOLP 6.7, the licensee has a duty “...to make changes or take preventative measures promptly in response to a drug error if the protection of the public requires it”; preventive processes undertaken with the goal of preventing errors require a similar level of involvement by the licensee.

Outside experts with related experience can complement the FMEA team. Individuals who are naïve to the process chosen for analysis will ask questions about things that those involved with the process take for granted. In large organizations, there

may be staff available with expertise in flow diagramming, system design and measurement, and performance improvement, such as information system staff, engineers, and quality improvement personnel. If they are available, consider adding these individuals to an FMEA team—they can add objectivity and system thinking. Sometimes teams invite external experts/consultants with specialized knowledge to assist with specific aspects of the analysis or development of recommended actions. For example, a pharmacy FMEA team might ask a representative from their computer software company to come to the pharmacy to discuss potential enhancements to the computer system screen display that the team has identified as problematic. Pharmacy teams should also consider including patient/family representatives on FMEA teams. This is a relatively new concept that has been used with some success in retrospective incident analysis and is worthy of consideration for prospective analysis.<sup>9,10,11</sup>

In a small community pharmacy, it is likely that the full dispensary staff will be involved in an FMEA, while in a pharmacy with a larger team, such as a corporate store or a hospital pharmacy, only selected staff members may be asked to participate. Regardless of the size of the team, it is important that as many perspectives as possible are represented (e.g., licensee/pharmacy leadership, staff pharmacist, pharmacy technician, pharmacy student). In a hospital pharmacy setting, a senior leadership representative may also be involved. It can be helpful to invite people to participate who are not involved in the day-to-day dispensing processes; for example, staff or management from a community pharmacy front shop. In a community pharmacy, front shop staff will have observed dispensary processes without being directly involved; as well, they may have received or overheard patient comments. In a chain pharmacy organization, consider including staff

<sup>9</sup> Institute for Safe Medication Practices. “Benefits and Risks of Including Patients on RCA Teams.” *ISMP Medication Safety Alert*. ISMP: 5 Jun. 2008. Web. <[http://www.ismp.org/newsletters/acutecare/articles/20080605\\_2.asp](http://www.ismp.org/newsletters/acutecare/articles/20080605_2.asp)>

<sup>10</sup> Munch, D. “Patients and Families Can Offer Key Insights in Root Cause Analysis.” *Focus on Patient Safety*. 7.4 (2004): 6-7. Print.

<sup>11</sup> Zimmerman, Theresa M. and Geraldine Amori. “Including Patients in Root Cause and System Failure Analysis: Legal and Psychological Implications.” *Journal of Healthcare Risk Management*. 27.2 (2004): 27-34. Print.



from a different store; these individuals will understand the corporate policies and procedures, but each store will put corporate policies into operation in a slightly different way, and may have experienced different failures and successes.

Depending on the process selected for analysis, consider inviting other practitioners from the community (e.g., family physicians, community nurses). In a hospital setting, it will be helpful to include individuals from other departments and professional backgrounds relevant to the topic for analysis. See below for two examples of FMEA teams for community pharmacy projects.

**Team composition: Patient identification during the dispensing process**

- Dispensary manager
- Staff pharmacist(s)
- Pharmacy technician(s)
- Pharmacy clerk/cashier/student
- Patient representative

**Team composition: New program for influenza vaccine administration by a pharmacist with injection authorization**

- Licensee
- Dispensary manager
- Staff pharmacist(s)
- Pharmacy technician responsible for inventory procurement
- Pharmacy clerk
- Registered nurse
- Family physician
- Patient representative

It is important to orient the team to the FMEA process before beginning the FMEA. Orientation should include:

- An overview of the FMEA process;
- The topic for analysis;
- Desired outcomes of the project; and

- Expectations related to assigned team roles as appropriate (e.g., team leader, recorder).

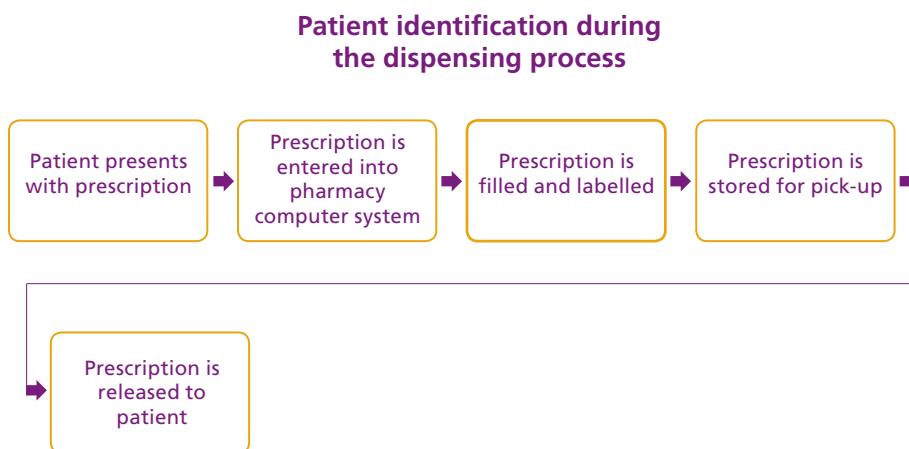
A team charter (Appendix 2) can be a helpful tool to articulate the goals of the FMEA, roles of team members, anticipated timelines, etc. See Appendix 3 for an example of an “everyday” FMEA that may be useful for training purposes, along with additional pharmacy-specific examples.

## Step 2: Diagram the process and sub-processes chosen for analysis

Steps 2-8 are illustrated using the patient identification process for a community pharmacy as an example.

### 2a) Start with the basic components of the process

Using the team’s collective knowledge, sketch a block diagram or flow chart of the high level components of the process chosen for analysis. At this stage, take a broad view of the process, focusing on the key components and avoiding excessive detail. Usually five to eight components will be sufficient for this high level view of the process, as shown in Figure 1.



**Figure 1: High level process block diagram**

Diagramming helps to clarify understanding among team members. Other types of diagrams might also be useful (e.g., schematics and blueprints), but process diagrams or “maps” are the most common.

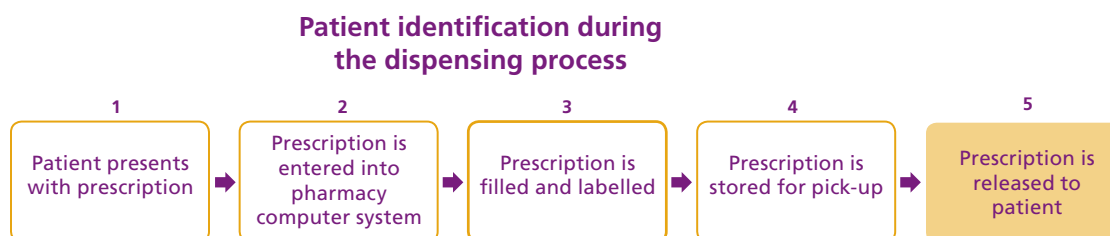
### Process tips:

- Write each process component on a separate sticky note.
- Ensure everyone on the team can read the writing from a distance.
- Post the sticky notes so that the team can re-arrange them as they work out the diagram.

If computer equipment is available and staff is comfortable with its use, you can create the diagram electronically and project the information on a screen or wall space. This has the added benefit of recording the information at the same time.

## 2b) Number the components of the process

Identify all of the high level components in the process and number each component (Figure 2). Because the processes themselves are usually complex, the resulting diagrams can also be complex, and numbering will help your team stay organized.



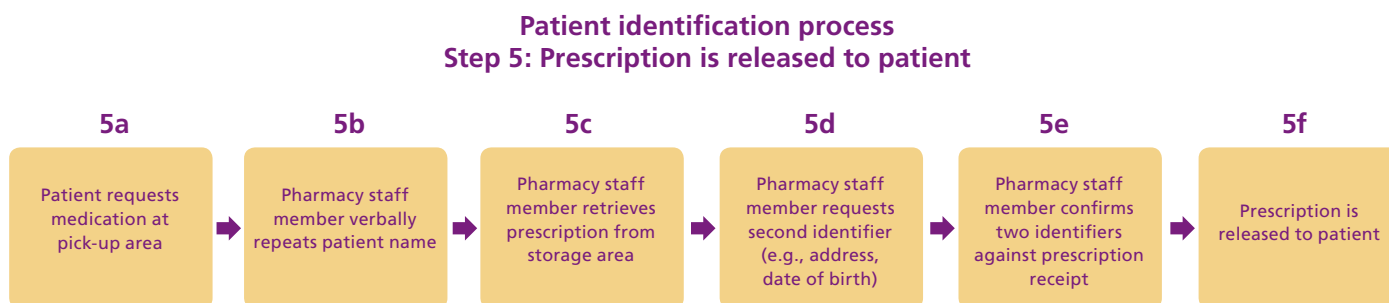
**Figure 2: Block diagram of the high level components, labelled with numbers (Step 5 is selected to diagram in more detail)**

## 2c) Select a component of the process to diagram in more detail

As a team, select one component of the process at a time to diagram in more detail (Figure 2). If the original topic selected is too big, the team may be able to complete the FMEA on only one of the process components, because that component is complex enough that it warrants its own FMEA. In our example, the team recently had a near miss where a prescription was almost given to the wrong patient so they decided to focus on Step 5: *Prescription is released to patient*.

## 2d) Diagram the components of the sub-process

Break down the selected component of the process and diagram the sub-process (Figure 3). Label each sub-process component with the step number and an alphabetical identifier; e.g., 5a, 5b, 5c.



**Figure 3: Block diagram of the sub-process components, labelled with the step number and an alphabetic identifier**

These beginning steps are often very eye-opening for first-time team members, as they start to see just how complex their processes are. Once they complete the diagramming, the team may realize that the topic is too large. If this appears to be the case, consider redefining the selected topic to something more manageable—the larger diagram will still be useful for seeing the interrelationships between different parts of the process. Note that it is not uncommon for process diagrams to be more complex than illustrated in this example, possibly including branching in addition to the main linear flow (i.e., sub-processes of sub-processes).

#### Process tips:

- Label and number all process and sub-process components as you go through the mapping and analysis process to keep the team organized.
- Use different coloured sticky notes as you move through the analysis steps; e.g., yellow for the high level process, green for the sub-process.

#### Policies and procedures

When developing process maps, teams should document the way they usually complete the process, rather than copy what exists in the policy and procedure manuals. Conducting an FMEA provides an opportunity to assess how well policies and procedures reflect usual work practices, as well as whether or not they are up-to-date and aligned with current evidence and standards of practice.

#### Using cognitive walkthrough

*Cognitive walkthrough* is a human factors engineering tool that is very helpful in process mapping.

"A cognitive walkthrough involves physically walking through the process or task of interest, examining the mental activities required at each step and the challenges encountered. This method goes beyond the current practice in healthcare of relying on incident data, individual opinion, or collective 'brainstorming' by a team to identify potential risks, errors, or failure modes. . . . A participant (i.e., a representative user, such as a front-line practitioner) is asked to simulate all or part of a task and to "think out loud" while performing the simulation. The intent of thinking out loud is to allow observers to comprehend the task from the participant's viewpoint as it is being carried out. The participant expresses the reasons for any decisions made or actions taken during the simulated task, as well as any frustrations, confusion, or doubts. The cognitive walkthrough can help to identify specific parts of the process or task that may not match the participant's goals, understanding, or abilities, along with aspects that may be inefficient or that pose an excessive cognitive or physical burden. A cognitive walkthrough helps the FMEA team to better understand, from the perspective of the practitioner, the process or task under review. Its approach to identifying failure modes (potential risks) is more structured than that of brainstorming, and can be complementary to brainstorming. Interestingly, it can also help to identify potential failure modes not recognized through incident reports or reviews."<sup>12</sup>

A cognitive walkthrough can help team members gain a thorough understanding of the processes and related sub-processes, as well as how and why decisions are made at various points in the process and where difficulties or challenges occur. Photographs of key process components or equipment used in the process can support the findings of a cognitive walkthrough.

## Step 3: Brainstorm potential failure modes

### 3a) Create a failure mode diagram

Transfer the sub-process components to a failure mode diagram (Figure 4).

### 3b) Brainstorm potential failure modes

As a team, brainstorm potential failure modes for each sub-process component. Potential failure modes (or error modes) can relate to people, materials, equipment, methods, and the environment. Examples of failure mode categories include:

- Quantity – too little, too much, partial;
- Availability – missing or none;
- Timing – too early, too late;
- Quality – wrong element (e.g., patient, drug); and
- Effectiveness – desired outcome not achieved (e.g., therapy does not work as well as intended).

Note that the team may identify several potential failure modes for some sub-process components while others will have just one or two. See Figure 4 for an example of a completed failure mode diagram.

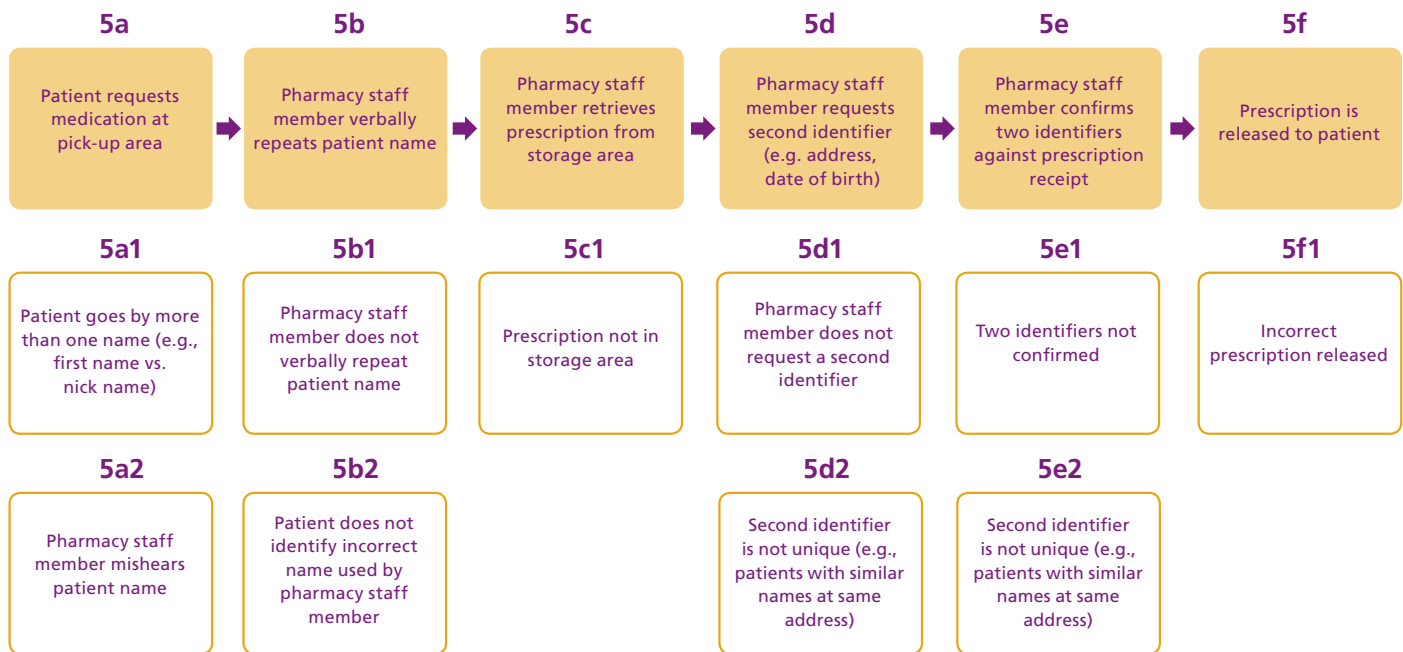
#### Notes about brainstorming

Brainstorming is a structured, creative process where a group of people generate as many ideas as possible in a minimum amount of time without judgement of the value of each idea. Brainstorming stimulates ingenuity and encourages many perspectives on an issue, and should encourage "out of the box" thinking. It is important that team members feel they can express their ideas freely. Effective brainstorming has the added benefit of enhancing team cohesiveness.

When brainstorming potential failure modes, consider what could go wrong at each step of the selected sub-process,

<sup>12</sup> Institute for Safe Medication Practices Canada. "Include Cognitive Walkthrough in Proactive Risk Assessments." *ISMP Canada Safety Bulletin*. 23 Jan. 2012. Web. <[http://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-01-Cognitive\\_Walkthrough.pdf](http://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-01-Cognitive_Walkthrough.pdf)>. Also provided in Appendix 6.

### Patient identification process Step 5: Prescription is released to patient



**Figure 4: Diagram showing sub-process components and failure modes (numbered)**

identifying "plausible worst-case" scenarios. During this phase of FMEA, the value of the expertise of team members cannot be overstated. Front-line team members bring invaluable insight to the identification of potential failure modes. Other resources available to the team as they consider potential failure modes include the healthcare literature and reports (either published or informal) of failures in similar settings. ISMP Canada Safety Bulletins (available at <http://www.ismp-canada.org/ISMPCSafetyBulletins.htm>) and ISMP [US] newsletters (available at <http://www.ismp.org/Newsletters/default.asp>) are examples of publications describing failures associated with the medication use system.

#### Process tip:

- Assign one or two individuals to look for and review relevant literature before brainstorming potential failure modes.

#### 3c) Number the potential failure modes

It is important to number the potential failure modes to help keep the FMEA organized; however, the sequence of numbering potential failure modes is not important (Figure 4).

#### 3d) Transfer failure modes to FMEA spreadsheets

At this point, transfer the sub-process components with their accompanying potential failure modes to FMEA spreadsheets (Figure 5, next page). Use one spreadsheet for each sub-process; some sub-processes may require more than one spreadsheet. In order to complete a full FMEA on a complex process, you will need

to use many spreadsheets—some complex processes have required more than 50 spreadsheets.

Our example illustrates the completion of the spreadsheet for one sub-process component, 5c: *Pharmacy staff member requests second identifier (e.g., address, date of birth)*. See Appendix 3 for more examples of completed spreadsheets for pharmacy processes.

#### Process tips:

- Spreadsheets can be in the form of a paper printout, or a computer program projecting the spreadsheet on a screen or wall.
- Label each spreadsheet with the project description and process and sub-process numbers.

FMEA subject: Patient identification in the dispensing process							Process: #5: Prescription is released to patient		
Sub-process component: 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)									
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame
5d1	Pharmacy staff member does not request second identifier								
5d2	Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building								

Figure 5: FMEA spreadsheet with “failure modes” section completed

## Step 4: Identify the effects and causes of the potential failure modes

### 4a) Identify the potential effect(s) of the failure modes

Once the team has transferred the failure modes to the spreadsheet, they must answer the question “*What would happen if this particular failure occurred?*” Repeat the questioning process for each identified failure mode and enter the results into the spreadsheet (Figure 6). Use the team’s knowledge of the subject and personal experience, supported by information from the literature to identify the anticipated effects of the failure mode. Remember that the goal is to improve patient safety; view the identified effects from this perspective. Note that it is not uncommon for different failure modes to result in the same effect(s).

For each potential failure mode listed, the team should be able to identify one or more causes of the failure and answer the question, “*Why might the failure occur?*” Enter this information in the next highlighted section as shown in Figure 7.

**Failure modes are the WHATs that could go wrong.**

**Failure mode causes are the WHYs.**

**Process tips:**

- Focus on processes and systems, not on individuals.
- Ask “why?” not “who?”
- Try to identify all possible causes.

In this part of the analysis, the focus is on recognizing the system and human factors issues that could contribute to a preventable adverse event.

This is sometimes referred to as prospective root cause analysis—thinking about how particular adverse events might occur. It is important to consider human factors principles when identifying causes. This will help teams to identify design problems and/or design features that conflict with known human factors principles and therefore can lead to the failure modes. While it is human nature to focus on the actions of practitioners at the point

where they are providing direct care to patients, the goal of FMEA is to push the team to move towards underlying system factors that could contribute to an incident but are not under the direct control of the practitioner(s) caring for the patient.

During this phase of the analysis, the team will need to ask questions such as:

- Why/how would this happen?
- What could cause this?
- How often could this happen?

Using knowledge of usual work practices, consider other information such as environmental factors (e.g., lighting, staffing levels, noise level, and interruptions in the workplace) to answer these questions. Analysis teams are generally highly successful at identifying failure mode causes close to the provider/patient interface, but often find it difficult to identify the deeper issues.

A key aspect of the FMEA process is working to understand how the various failure modes relate to each other and ensuring that the analysis



FMEA subject: Patient identification in the dispensing process							Process: #5: Prescription is released to patient		
Sub-process component: 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)									
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame
5d1	Pharmacy staff member does not request second identifier	Incorrect prescription released leading to risk of harm for patient receiving incorrect medication and loss of confidentiality for other patient re: medication prescribed							
5d2	Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building	Same as 5d1							

Figure 6: FMEA spreadsheet with “Effects” section completed

FMEA subject: Patient identification in the dispensing process							Process: #5: Prescription is released to patient		
Sub-process component: 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)									
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame
5d1	Pharmacy staff member does not request second identifier	Incorrect prescription released leading to risk of harm for patient receiving incorrect medication and loss of confidentiality for other patient re: medication prescribed	Incomplete identification.						
5d2	Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building	Same as 5d1	Second identifier is not unique						

Figure 7: FMEA spreadsheet with “Causes” section completed

has progressed deeply enough into the system.

Note that while our example presents this as a stepwise process, it is quite fluid and not always as linear.

Recognizing and understanding the causes of the potential failure modes is vital to developing effective recommended actions to improve patient safety.

## Step 5: Prioritize the potential failure modes

### 5a) Score the potential failure modes and determine their overall impact

Once the team determines the failure modes, effects, and causes, use a prioritization step to help determine which failure modes are most critical. As a team, assess the severity of the effect, the estimated frequency of occurrence, and the likelihood of detecting the failure before there are visible effects. Use numerical scores as described in the following sections. Multiply these three scores together to determine a *criticality score* (also sometimes referred to as a *risk priority number*).

**Severity × Frequency × Detectability = Criticality Score**

Use a 1-5 scale for severity and frequency, and a 1-4 scale for detectability; the maximum possible criticality score is 100. The higher the criticality score, the more critical the failure mode; however, note that criticality scores are unique to each FMEA and cannot be compared from one FMEA to another. The following sections provide guidance for

evaluating severity, frequency, and detectability.

### SEVERITY: How severe is the effect of this failure mode?

This factor represents the seriousness and severity of the effect (to the patient or to the healthcare process or system) if the failure should occur. The team should base this score on a reasonable worst-case scenario. When doing an FMEA, it is easy to consider “death” as the worst-case scenario in all cases; however, in most cases this will not be the outcome—consider the most plausible worst-case outcome. Table 3 provides some guidance for rating severity.<sup>13</sup>

Table 3: Rating the severity of failure mode effects

Severity	Score	Description
No effect	1	Failure is not noticeable and does not affect the patient or process
Slight effect	2	Failure causes minor effects or is a nuisance to the patient or process, without injury or increase in level of care required
Moderate effect	3	Failure causes some performance loss and may increase the level of care provided to the patient (e.g., requiring hospitalization or increasing the length of hospital stay)
Major effect	4	Failure causes a high degree of performance loss, with permanent impact on the patient, resulting in reduced function; surgical intervention may be necessary
Severe or catastrophic effect	5	Failure causes death or major, permanent loss of function

**Always address items with a severity of 5, even if the likelihood of occurrence is low.**

### FREQUENCY: How often can this failure mode be expected to occur?

This factor represents the likelihood of a specific failure mode or the number of times it can be expected to occur. Depending on the type of failure mode analyzed, there may be data available to help determine the frequency; however, often this is determined based on the team’s best guess.

### DETECTABILITY: Will the failure be caught before the effect is known?

This factor represents the likelihood of detecting the failure or the effect of the failure **before** it actually occurs. As such, you are scoring the likelihood of detecting failure before the impact of the effect is realized. The more detectable a failure, the **lower the score**.

<sup>13</sup> Adapted from:

- McDermott, R.E., R.J. Mikaluk, and M.R. Beauregard. *The Basics of FMEA*. New York: Productivity Press, 1996. Print.
- DeRosier J. and Stalhandske, E. “Healthcare Failure Mode and Effect Analysis Training.” Department of Veterans Affairs National Center for Patient Safety. Phoenix, AZ. 18 Jan. 2007. PowerPoint.

Frequency	Score
Yearly	1
Monthly	2
Weekly	3
Daily	4
Hourly	5

Detectability	Score
Always	1
Likely	2
Unlikely	3
Never	4

#### Process tips:

- Ask whether or not someone else is likely to catch the failure—this can help make the situation “real” for team members.
- Remember that many events are detectable or obvious after they have occurred, but these aren’t considered “detectable” in an FMEA.

Some examples of medication system safeguards that allow for detection of potential failure modes include:

- *Freezer sensors:* The potential failure mode is the use of a product after thawing and refreezing. Freezer sensors indicate whether products have thawed and refrozen, alerting the user to a potentially defective product (e.g., insulin, vaccines).
- *Low-battery alarm on an infusion pump:* The failure mode is lack of power for the pump and resulting

inability of the pump to deliver the correct dose of drug or fluid; the low-battery alarm warns the user of impending power loss early enough to prevent failure of the pump.

- *Breakaway locks:* The potential failure mode is absence of urgently needed supplies from a device such as a code cart. In this situation, a breakaway lock system alerts the user in advance that the supplies may be incomplete, making the problem detectable.

The key to detectability in these examples is system design that makes it possible to discover a failure **before** it reaches the patient.

#### Process tips:

- Use the expertise of all team members.
- Talk things out. Don’t agree just for the sake of moving things along.
- Use a “reasonable worst-case” scenario. Since the individual ratings are multiplied together, a change in value of just one or two points can have a significant impact on the final criticality score.
- To resolve differences of opinion, consider voting, involving healthcare process experts, deferring to team member(s) with substantial expertise in the subject area, and ranking failures and effects within a rating category.<sup>14,15</sup>
- If the team cannot reach a consensus, always assign the higher rating. FMEA is a safety assessment—it is always better to overestimate than underestimate a failure mode.

#### 5b) Prioritize the failure modes

Once the team calculates the scores for all potential failure modes, determine what level of risk is acceptable and what measures are needed to address unacceptable risks. Consider each individual criticality score in the context of the whole FMEA; do not view these scores in isolation. In addition, recognize that you will likely not be able to address every item on the list.

There are two aspects to the prioritization step. First, any failure modes with a severity score of 5 require action, regardless of the total criticality score—if a failure could result in a catastrophic event, action is required, regardless of the frequency with which this might occur. Second, once the team has calculated the criticality scores for all the relevant sub-process components, they then determine a “cut-off” criticality score. The cut-off is based on an intention to take action on 60-70% of the identified failure modes with the highest criticality scores and cannot be determined in advance as the criticality scores will be different in every FMEA. This approach takes into account the fact that risk is inherent in almost every process. The key is to identify the risks that are unacceptable and have the greatest potential to cause patient harm so that the team can focus actions on areas where they will achieve the greatest benefit. See Figure 8 (next page) for an example of an FMEA spreadsheet with prioritization completed.

#### Plan to take action on:

- All failure modes with a severity score of 5 (regardless of the final criticality score), and
- 60-70% of identified failure modes with the highest criticality scores.

<sup>14</sup> McDermott, R.E., R.J. Mikaluk, and M.R. Beauregard. *The Basics of FMEA*. New York: Productivity Press, 1996. Print.

<sup>15</sup> Stamatis, D.H. *Failure Mode and Effect Analysis: FMEA From Theory to Execution*. 2nd ed. Milwaukee, WI: American Society for Quality, 2003. Print.

FMEA subject: Patient identification in the dispensing process						Process: #5: Prescription is released to patient			
Sub-process component: 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)									
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame
5d1	Pharmacy staff member does not request second identifier	Incorrect prescription released leading to risk of harm for patient receiving incorrect medication and loss of confidentiality for other patient re: medication prescribed	Incomplete identification	4	2	3	24	Yes	
5d2	Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building	Same as 5d1	Second identifier is not unique	4	2	3	24	Yes	

Figure 8: FMEA spreadsheet with prioritization section completed

## Step 6: Redesign the process to address the potential failure modes


Once the team has prioritized the failure modes and identified the items they will proceed to take action on, the next step is to redesign the process or develop interventions using the concepts of human factors engineering and systems theory. The criticality score, and thus the overall risk associated with a process, can be decreased by reducing the frequency of occurrence or severity of effect of a failure mode, or improving its detectability.

SOLP 6.7 states that a licensee must make changes or take preventative measures promptly in response to a drug error if the protection of the public requires it. Regardless of whether or not an incident has occurred, if the pharmacy team identifies a potential risk, the licensee will take preventive actions as appropriate to prevent incidents.

In redesigning processes, attempt to use higher leverage strategies whenever possible. These strategies include forcing functions and constraints, automation, standardization and simplification. Also consider relevant literature and ensure that you are meeting practice standards when developing risk reduction strategies.

Staff education and policy changes may be required, but, when used alone, these measures do not change the underlying conditions that lead to error and are not sufficient to ensure sustained change. See the *hierarchy of effectiveness* and earlier discussions in the section on application of human factors engineering principles. Educate the team about this hierarchy as part of the FMEA orientation, and encourage team members to recommend the most effective solution that is reasonable and/or possible given the circumstances.

### Options for change:

- 
- High leverage - most effective**
    - Forcing functions and constraints
    - Automation/computerization
  - Medium leverage**
    - Simplification/standardization
    - Reminders, checklists, double checks
  - Low leverage - least effective**
    - Rules and policies
    - Education and information

FMEA subject: Patient identification in the dispensing process							Process: #5: Prescription is released to patient		
Sub-process component: 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth)									
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame
5d1	Pharmacy staff member does not request second identifier	Incorrect prescription released leading to risk of harm for patient receiving incorrect medication and loss of confidentiality for other patient re: medication prescribed	Incomplete identification	4	2	3	24	Yes	<p>Educate all pharmacy staff on the importance of correct patient identification and need to follow proper procedures (1 month)</p> <p>Develop a standardized process requiring documentation of the second identifier used to verify the patient's identity (1-3 months)</p> <p>Post information for patients explaining the identity verification process and the rationale; request their assistance in ensuring it takes place (1-3 months)</p> <p>Implement a photo identification process for selected high alert medications (e.g., methadone) (3-6 months)</p> <p>Assess opportunity for automation (e.g., barcoding) as a long-term goal (more than 12 months)</p>
5d2	Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building	Same as 5d1	Second identifier is not unique	4	2	3	24	Yes	<p>Flag known patients with same name in the pharmacy computer system indicating requirement for date of birth identification for all prescriptions (1 month)</p> <p>Ensure addresses for multi-unit dwellings include the specific unit (1 month)</p>

Figure 9: FMEA spreadsheet with “Actions” section completed



FMEA subject: Patient identification in the dispensing process		Process: #5: Prescription is released to patient		Sub-process step: #5c: Pharmacy staff member requests second identifier	
Failure mode number	Recommended action	Strength of action	Timeframe for implementation	Individual(s) responsible	Measurement plan
5d1	Educate all pharmacy staff on the importance of correct patient identification and need to follow proper procedure	Low (policy development / education)	1 month	Licensee / senior pharmacist	Education sessions completed and written reminders posted and included in orientation information for new staff
5d1	Develop a standardized process requiring documentation of the second identifier used to verify the patient's identity	Medium (simplification / standardization)	1-3 months	Senior pharmacist / senior pharmacy technician	Periodic audits of documentation by senior pharmacist
5d1	Post information for patients explaining the identity verification process and the rationale and requesting their assistance in ensuring it takes place	Low (policy development / education)	1-3 months	Licensee	Information posted and visible to patients
5d1	Implement photo identification for selected high-alert medications (e.g., methadone)	Medium (reminders, checklists, double-checks)	3-6 months	Licensee, senior pharmacy technician	Periodic audit and patient satisfaction survey
5d1	Assess opportunity for automation (e.g., barcoding) as a long-term goal	High (automation / computerization)	More than 12 months	Licensee	Implemented and periodic system audits of overrides (i.e., electronic)
5d2	Flag known patients with the same or similar names in the pharmacy computer system indicating requirement for date of birth identification for all prescriptions	Medium (reminders / checklists / double checks)	1 month	Senior pharmacist / senior pharmacy technician	Periodic testing of known similar names to check that flagging system is in place and working by senior pharmacy technician
5d2	Ensure addresses for multi-unit dwellings include the specific unit	Low (policy development / education)	1 month	Senior pharmacy technician	Periodic audits by senior pharmacy technician of dispensed prescriptions to check that unit numbers are being recorded and entered by staff

Figure 10: Summary of recommended actions, timeframes, and measurement plan

#### Process tips:

Actions should:

- Target the identified underlying problems;
- Offer a long-term solution to the problem;
- Have a greater positive than negative impact on other processes, resources and schedules;
- Be objective and measurable;
- Be achievable and reasonable; and
- Be SMART<sup>16</sup>: Specific, Measurable, Attainable, Realistic, and Timely.

From a human factors standpoint, the strongest interventions are those that involve physical or architectural changes or forcing functions. An example of a strong intervention in a community pharmacy might be changing the prescription entry and exit locations for the dispensary to improve workflow. In any pharmacy setting, use of an automated attendant to triage telephone calls would be a high leverage strategy to reduce distractions. Other human factors interventions include strategies to reduce reliance on memory and vigilance, such as building in redundant cues and using warning labels.

When discussing potential actions, encourage the team to consider innovative ideas; just because things have always been done a particular way doesn't mean that is the only way to accomplish the work. Encourage the team to choose what they believe are the best solutions; the organizational leadership can make modifications if the suggested actions are deemed unattainable. During the action development step, reviewing available literature can offer solutions developed by similar organizations, providing an opportunity to build on the success of others. For our example analysis of the patient identification process, the team identified an ISMP (US) Community Pharmacy newsletter with useful recommendations.<sup>17</sup>

<sup>16</sup> Doran, G.T. "There's a SMART way to write management objectives." *Management Review*. 70.11 (1981): 35-36. Print.

<sup>17</sup> Institute for Safe Medication Practices. "Avoiding Wrong-Patient Errors at the Point of Sale." *ISMP Medication Safety Alert! Community/Ambulatory Care Edition*. 10.2 (2011). Print.

When planning actions, consider the time frame for implementation. Timing will depend on a number of factors including ease of implementation and urgency based on the level of risk identified. While the FMEA team members may not be responsible for implementing the recommended actions, the team leader should be sure to appropriately delegate responsibility for implementation.

Some opportunities for change may be beyond the control of the local team, but could be addressed externally. For example, the packaging and labelling of look-alike pharmaceuticals is beyond the control of an individual pharmacy, but the pharmacy team could forward their concerns to the manufacturer, Health Canada, and ISMP Canada.

See Appendix 3 for more examples of completed FMEA worksheets.

## Step 7: Analyze and test the new process

Analyzing and testing a new process minimizes the possibility of unintended consequences. Before implementing the recommended actions, it is important to assess the impact of the proposed changes on the calculated criticality scores.

For changes that affect individual process or sub-process components, re-score the failure mode on the FMEA spreadsheet. Assess each recommended action and consider whether the action will decrease severity, decrease frequency, and/or increase detectability of the failure mode. The recalculated criticality score should be lower than the original score.

When planning substantial changes to a process or sub-process, it is important that the team re-maps the process and sub-process components and re-assesses the potential failure modes to ensure that they do not inadvertently introduce additional failures into the redesigned process. Again, the criticality scores should be lower for the redesigned process than for the original one.

Additional testing methods include:

- Usability testing: “A method used to evaluate a product or process (a ‘system’) with its end users.... [providing] a way to observe how actual end users interact with the system and to measure how well the system meets its intended purpose.”<sup>18</sup>
- Pilot testing: Implementing changes in one location or on one section of the redesigned process.
- Using the Plan-Do-Study-Act (PDSA) cycle of the Model for Improvement.<sup>19</sup> (See Appendix 5)

## Step 8: Implement and monitor the redesigned processes

Full implementation of a new process will take time, and measuring for sustained improvement is critical to long-term success. Consider change management principles when planning and implementing changes:

- Communicate the reasons for process changes;
- Find “change agents” to champion the new process;
- Define process and outcome measures (how will you know you have been successful?);

- Share results; and
- Monitor changes over time.

At the conclusion of the FMEA, the team leader should provide a summary of all the actions the team considers reasonable to correct the identified failure modes to any senior leaders (e.g., licensee, district manager, applicable hospital supervisor or director) who may not have been involved in the analysis. The senior leaders will then make, or help make, decisions about prioritizing and implementing recommended actions, and will determine the allocation of required resources—this is not the responsibility of the analysis team. The senior leaders are also responsible for ensuring that the recommended actions will not impact compliance with legislative and practice standards.

For best success, assign one or two individuals to implement and monitor the actions. It is important to establish specific time frames for completion of each action, as it is easy to move on to other projects once the FMEA is complete. As stated earlier, the implementation plan needs to take into consideration the ease of implementation, resources required, and impact of various process changes on each other (e.g., some changes may be prerequisites to others).

The final step is to ensure that the team implements the planned changes, sustains improvements, and achieves the desired outcomes. Regular progress reports of implemented actions are vital to keep momentum going and staff engaged. It is important to recognize that sometimes when teams introduce changes for the purpose of reducing risk, they inadvertently introduce new risks. Ongoing monitoring is required because the new risk may not be identifiable until after the team implements the strategy. Alternatively, the process change may not be a good fit, resulting in workarounds that cause new errors.

<sup>18</sup> Institute for Safe Medication Practices Canada. “Proactively Assess Risk with Usability Testing.” *ISMP Canada Safety Bulletin*. 22 Nov. 2012. Web. <[http://ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-11\\_Usability\\_Testing.pdf](http://ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-11_Usability_Testing.pdf)>. Also provided in Appendix 6.

<sup>19</sup> Institute for Healthcare Improvement. “How to Improve.” *Institute for Healthcare Improvement*. 2012. Web. 30 July 2012. <<http://www.ihi.org/knowledge/Pages/HowtoImprove/default.aspx>>. Also provided in Appendix 5.

**When developing an action plan, it is important to consider how you will know you have been successful.**

SOLP 6.6 requires licensees to conduct a quarterly review of drug error reports and assess whether any changes implemented in follow-up were successful in advancing patient safety or resulted in new errors. FMEA provides a mechanism for assessing the error potential of strategies intended to enhance the safety of the system and can be used in response to an incident that has occurred, or prospectively based on identified areas of potential concern.

## Conclusion

The intention of the FMEA process is to provide a structured and consistent methodology to assist teams in assessing vulnerabilities in processes so that they can take steps at the system level to reduce the likelihood of an incident and potential adverse event.

The FMEA goals and processes align with the *Standards for the Operation of Licensed Pharmacies* and the *Standards of Practice for Pharmacists and Pharmacy Technicians* in Alberta; undertaking this type of analysis will assist pharmacy teams to meet the quality assurance objectives of the Standards.

With an understanding of the basics of conducting an FMEA, you will be prepared to participate on an FMEA team. With experience, you will be able to lead a team and teach the technique to others. As you practice your FMEA skills, keep in mind that healthcare providers are human, and as such are not perfect. Consider how the practice setting—taking into account the physical structure, required activities,

provider and recipient needs—could cause “failures.” Then consider how you can make the setting safer, given human limitations in work capacity, including memory and ability, and how all of these affect the patient. Using FMEA within your own practice setting will help you to more fully participate in optimizing safe practices in your environment, improving the ways in which you and your colleagues interact, and enhancing service delivery to your patients.

See Appendix 1 for a quick reference summary of the FMEA process.

### Tips for successful FMEA projects

- Start small and achieve success early.
- Keep the scope of the FMEA narrow.
- Engage front-line staff.
- Include team members with different perspectives and expertise.
- Focus on what and why, not who.

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# Appendix 1: FMEA process summary and quick reference guide

## Step 1 - Select a process to analyze and assemble a team (pp. 6–8)

- Define and narrow your topic
- Select team members
  - Include all appropriate disciplines
  - Include front-line staff
  - Determine team member roles and responsibilities
  - Identify any external consultants that may be required

## Step 2 - Diagram the process and sub-processes (pp. 8–10)

- Diagram the typical steps in the high level process (how the work is usually done)
  - Number the process components (approximately five to seven)
- Select one portion of the process at a time and diagram the sub-processes
  - Number the sub-process components

### Tips:

- Use sticky notes to support "fluid" thinking.
- Consider cognitive walkthrough.

## Step 3 - Brainstorm potential failure modes (pp. 10–12)

- Begin with one sub-process and brainstorm the potential failure modes (Ask, "What could go wrong?")
  - Consider people, materials, equipment, methods, and environment
  - Number the failure modes
- Transfer the failure modes to a failure mode spreadsheet

## Step 4 - Identify the effects and causes of the potential failure modes (pp. 12–14)

- Working with one failure mode at a time, brainstorm potential effects and causes

- Ask, "What would be the effect if the failure occurred?" and, "Why/how would the failure happen?"

## Step 5 – Prioritize the potential failure modes (pp. 14–16)

- Evaluate failure modes for **severity**, **detectability**, and **frequency**
  - Severity: 1=no effect, 2=slight, 3=moderate, 4=major, 5=severe
  - Frequency: 1=yearly, 2=monthly, 3=weekly, 4=daily, 5=hourly
  - Detectability: 1=always, 2=likely, 3=unlikely, 4=never
- Determine the criticality score for the failure modes
  - **Severity × frequency × detectability = criticality score**
- Assign priority to failure modes with a severity score of 5 and those with the highest criticality scores (aim to address the top 60-75%)

### Tips:

- Use the expertise of the team members.
- Use a "reasonable worst case" scenario.
- Use the higher rating if the team cannot reach a consensus.

## Step 6 - Redesign the process (pp. 16–19)

- Identify actions for change for the failures and causes the team identified as highest priority
- Specifically address potential vulnerabilities with objective and measurable actions that encourage system level changes

### Tips:

- Improve safety based on:
  - ↓ Severity
  - ↑ Detectability
  - ↓ Frequency
- Consider human factors engineering principles and the *hierarchy of effectiveness*



Forcing functions and constraints

Automation & computerization

Simplification and standardization

Protocols and standard order forms

Independent double check systems

Education and information

## Step 7: Analyze and test the new process (p. 19)

- Consider ways to analyze and test the changes
  - Conduct an FMEA of the redesigned process (criticality scores should be lower)
  - Conduct usability testing of the redesigned process
  - Conduct pilot testing in one area or on one section of the redesigned process
  - Use the Plan-Do-Study-Act (PDSA) cycle of the Model for Improvement to test and evaluate proposed changes

## Step 8 – Implement and monitor the redesigned process (pp. 19–20)

- Assign actions to specific individuals and specify timelines
- Plan carefully; consider barriers to implementation and results of pilot testing
- Use the PDSA model to evaluate changes



## Appendix 2: FMEA team charter

**This FMEA is focused on:**

**Start date:** \_\_\_\_\_

Target completion date: \_\_\_\_\_

[illegible]

Are all affected areas represented? ☐ Yes ☐ No

If **no**, why not?

Are different levels and types of knowledge represented on the team? ☐ Yes ☐ No

If **no**, what are the gaps?

**Information available for review by the team:**

- Results of cognitive walkthrough (including photos), if applicable
- Information on equipment and devices, as applicable (e.g., screenshots from pharmacy information system, blood glucose meters)
- Relevant policies and procedures
- Relevant standards of practice, best practice guidelines or other relevant literature

# Appendix 3.1: Everyday FMEA – morning routine

## Step 1: Select a process to analyze and assemble a team

When orienting new FMEA team members, it is sometimes helpful to use an easily understandable everyday example.

## Step 2: Diagram the process

Figure A below is a high level process map of a typical morning routine.

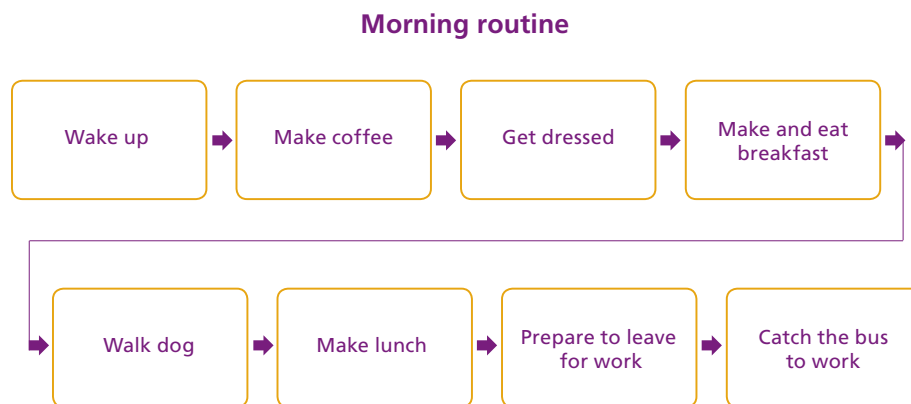


Figure A: High level process - block diagram (process map)

Once you have identified the high level steps, number them—while things look straightforward at this point, the numbering will help the team stay on track later in the process.

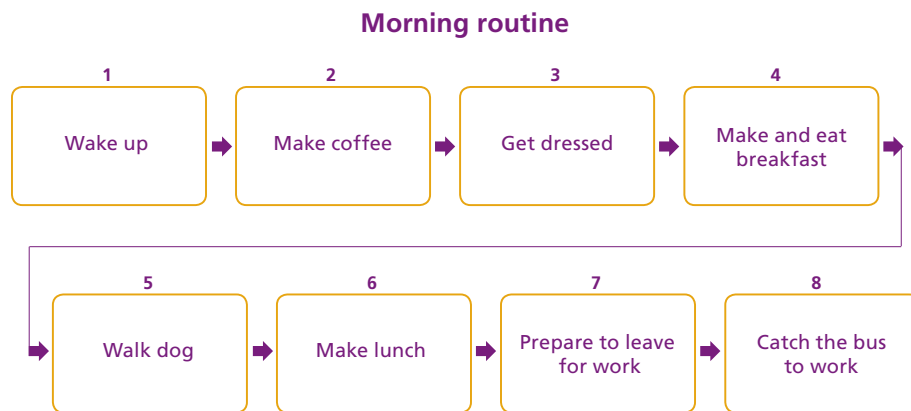
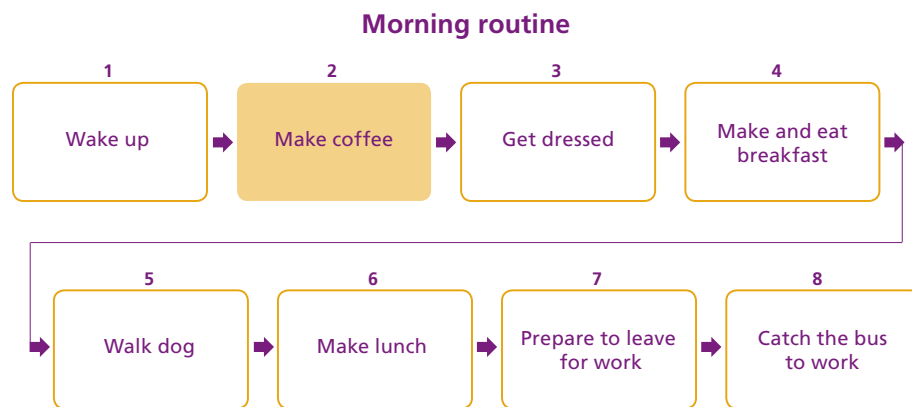


Figure B: Block diagram of the high level components, numbered

Once you have mapped the high level process, decide as a team whether to work on the whole process (ideal) or to select individual process components to analyze in detail. Analyze process components one at a time. Typically, based on available resources, a few key components are analyzed in detail. Figure C shows the first process component selected for detailed analysis—*make coffee* (considered by many to be a critical part of their morning routine).

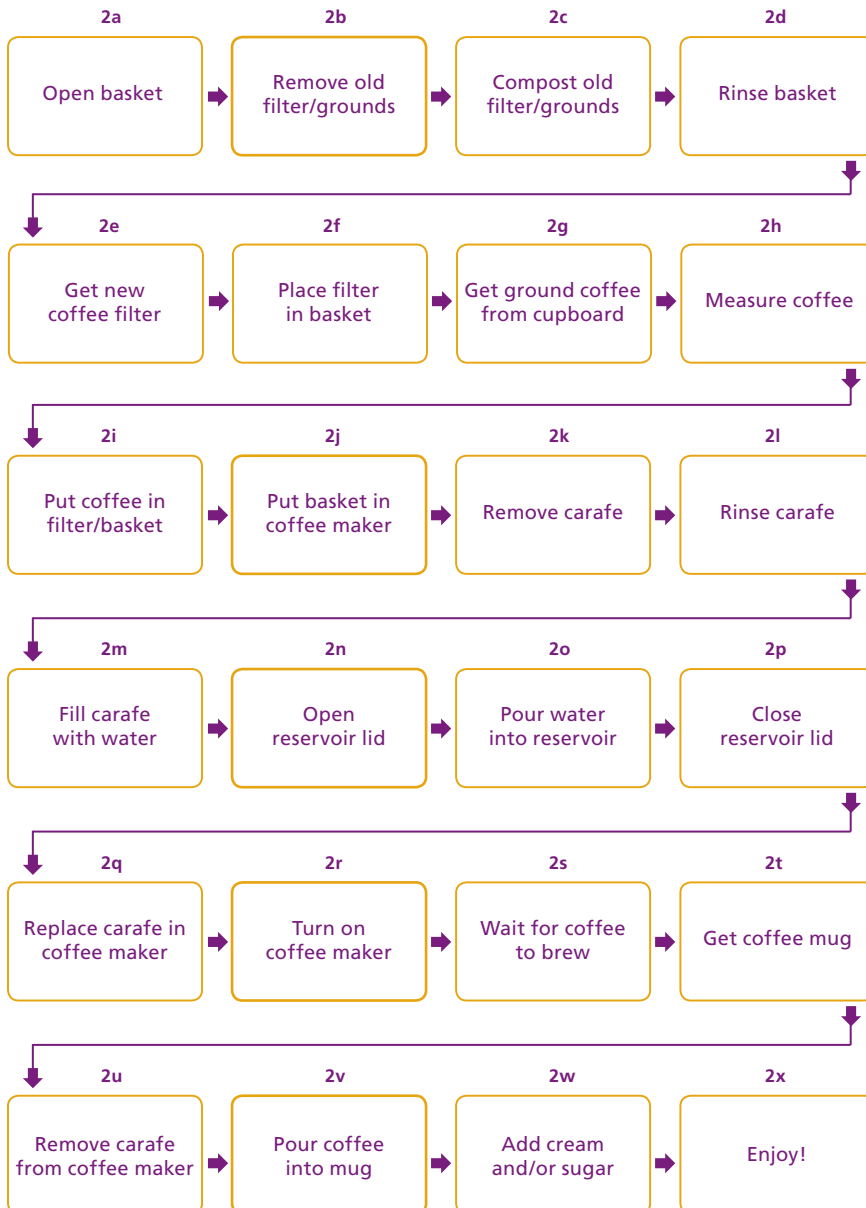


**Figure C: Block diagram showing the process component selected for more detailed analysis**

Without looking at the next page, write down on a piece of paper how many components you think there might be in making a cup of coffee. Label the components of the sub-process with the number from the main process and a letter to indicate the location in the sub-process; i.e., 2a, 2b, 2c, etc.

Now turn to Figure D on the next page to see how close you were.

## Morning routine: #2 – Make coffee Sub-process components



**Figure D: Sub-process components for Step 2: *Make coffee***

Who knew it was so complicated to make a cup of coffee? Imagine how complex healthcare processes are by comparison!

What is important here is to recognize that any process can be broken down into its individual components—before the potential risks in a process can be analyzed, it is important to have a clear understanding of the process components.

### Step 3: Brainstorm potential failure modes within the process

Figure E shows some potential failure modes the team has identified.

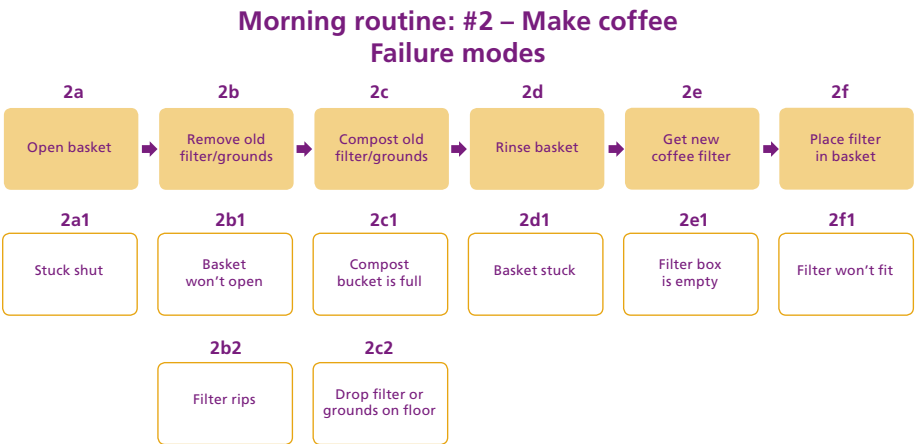


Figure E: Potential failure modes identified and numbered for each component of the sub-process

### Step 4: Identify the causes and effects of the potential failure modes

### Step 5: Prioritize the potential failure modes

### Step 6: Redesign the process to address the potential failure modes

Once you have identified the potential failure modes, move your work to the FMEA spreadsheet to document the effects of the failures and then identify the causes. Usually the team will work to identify the causes and effects of the identified failure modes for each component of the sub-process, then work through the prioritization process. This can also be done as a continuous process for each failure mode.

Once the team has assessed the severity, frequency, and detectability, and calculated criticality scores for each potential failure mode, consider whether or not to proceed with developing actions to address the causes of the identified failure modes.

Figure F shows a completed spreadsheet for sub-process 2b: *Remove filter/old grounds*. The team selected the severity ratings based on the impact of this sub-process component on the whole sub-process of making coffee. If new coffee cannot be added to the coffee maker because the latch is broken and the basket won't open, this will have a significant impact on the whole process, resulting in a severity rating of 4. If the filter rips, causing the old coffee to spill, this would result in a delay in the process—the team gave this a severity rating of 2. Based on the criticality scores, the team decided that only one of two failure modes required intervention.



FMEA subject: Morning routine				Process: #2: Make coffee					
Sub-process component: 2b – Remove old filter/grounds									
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame
2b1	Basket won't open	Cannot add new coffee	Latch broken	4	1	3	12	No	Not predictable; no action required– would likely require new coffee maker if occurred
2b2	Filter rips	Old coffee grounds spill, causing delay	Poor quality paper; mishandling	2	3	4	24	Yes	Purchase reusable filter (1 month)

Figure F: Completed FMEA spreadsheet for a single sub-process component

## Step 7: Analyze and test the changes

## Step 8: Implement and monitor the redesigned process

The selected intervention, purchasing a reusable filter, should eliminate the problem of ripped filters. When the criticality score is recalculated, the severity and detectability scores remain unchanged, but the frequency score decreases to 1, resulting in a new criticality score of 6 for this particular failure mode.

It is important to consider whether or not the change could result in any new potential failure modes that were not present with the previous process. In this case, the new filter might clog, resulting in overflow of hot water from the coffee maker, so other changes in process, such as a different cleaning routine, might be required. The team could implement this based on monitoring. For example, the team could pilot test reusable filters with one or two machines in the organization. If the change is successful in the pilot, the team can then implement the filters throughout the organization.

See Figure G on the following page for a completed action and measurement template for the sub-process component analyzed.

## Conclusion

This simple example is intended to provide an easy-to-understand simulation and illustrate that the principles of FMEA can be used to assess any process. The following two examples are intended to illustrate more complex processes in a pharmacy setting.

FMEA subject: Morning routine		Process: #2: Make coffee			Sub-process step: 2b – Remove old filter/grounds	
Failure mode number	Recommended action	Strength of action	Timeframe for implementation	Individual(s) responsible	Measurement plan	
2b2	Purchase reusable filter	High (physical / architectural change)	1 month	Senior pharmacy technician	Follow up with staff in six weeks to see if there are any problems with the new filters	

Figure G: Completed action and measurement template for sub-process 2b: *Remove old filter/grounds*

## Appendix 3.2: Operational pharmacy example – managing drug shortages<sup>20</sup>

Step 1: Select a process to analyze and assemble a team

Step 2: Diagram the process

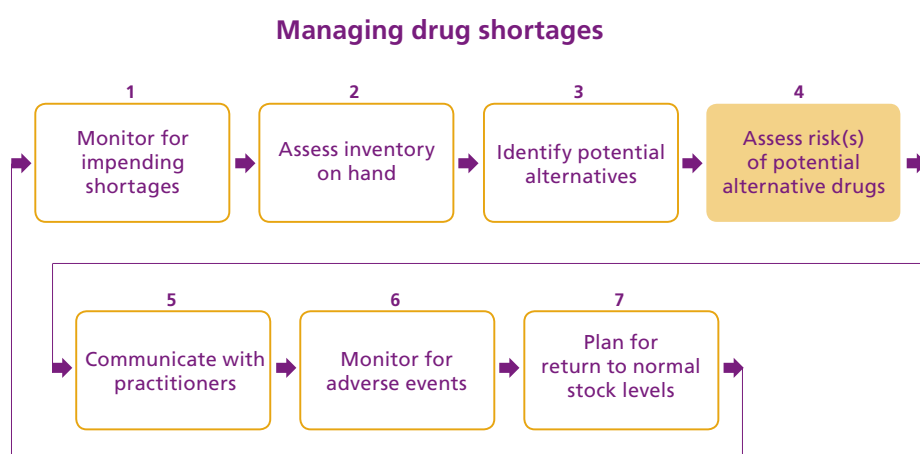


Figure A: High level process components for *Managing drug shortages*

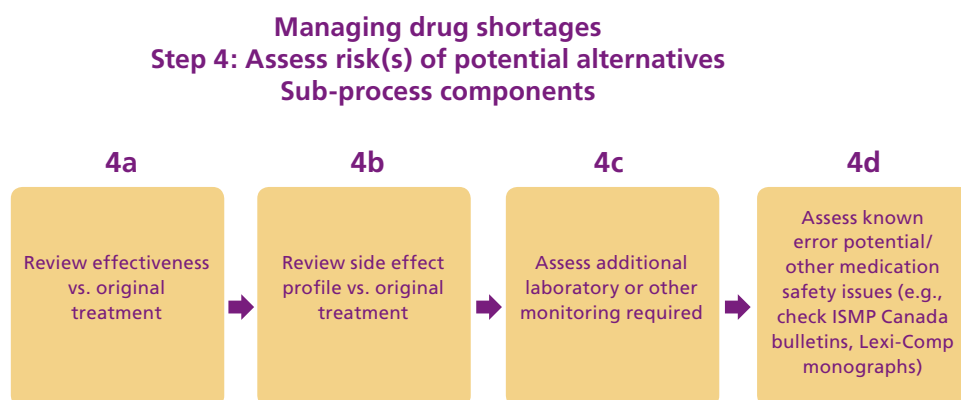


Figure B: Sub-process components for Step 3: *Assess risk(s) of potential alternatives*

<sup>20</sup> Content for this FMEA example was adapted from:

- Institute for Safe Medication Practices. "Weathering the Storm." *ISMP Medication Safety Alert*. ISMP: 7 Oct. 2010. Web. <<http://ismp.org/newsletters/acutecare/articles/20101007.asp>>
- Institute for Safe Medication Practices Canada. "Drug Shortages and Medication Safety Concerns." *ISMP Canada Safety Bulletin*. ISMP Canada: 20 Mar. 2012. Web. <[http://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-03\\_Drug\\_Shortages.pdf](http://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-03_Drug_Shortages.pdf)>
- Canadian Pharmacists Association. *Drug Shortages: A Guide for Assessment and Patient Management*. Canadian Pharmacists Association: 2010. PDF. <<http://pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/DrugShortagesGuide.pdf>>

Step 3: Brainstorm potential failure modes within the process



Figure C: Potential failure modes for Step 4: Assess risk(s) of potential alternatives

Step 4: Identify the effects and causes of the potential failures modes

Step 5: Prioritize the potential failure modes

Step 6: Redesign the process to address the potential failure modes

Step 7: Analyze and test the changes

FMEA subject: Managing drug shortages							
Sub-process component: 4a – Review effectiveness vs. original treatment							
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score
4a1	Effectiveness information not reviewed	Sub-optimal treatment/ treatment failure	Seen as responsibility of prescriber; insufficient time available in the pharmacy workflow	4	2	3	24
							Proceed? Yes or no
							Actions to reduce risk and time frame
4a2	Unable to find/ access effectiveness information	Sub-optimal treatment/ treatment failure	Unsure how to access	4	3	3	36
							Post quick reference instructions for accessing online resources on or adjacent to computer stations
							Provide training for all staff on how to access online resources

Figure D: Completed FMEA spreadsheet for sub-process component 4a: Review effectiveness vs. original treatment



FMEA subject: Managing drug shortages									
Sub-process component: 4b – Review side effect profile vs. original treatment									
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame
4b1	Side effect profile not reviewed	Patient does not identify early warning signs and experiences serious toxicity or discontinues treatment due to side effects	Assumption that side effect profile is same/ similar to previous medication regimen	4	2	4	32	Yes	Develop checklist for risk assessment as part of drug shortages protocol so that important components not omitted (Repeat of 4a1)
4b2	Information not available/is incomplete	Information provided to patient is incomplete; results same as 4b1	Reliance on hard copy library vs. online resources (available information is not up-to-date)	3	1	2	6	No	Addressed by 4a2

Figure E: Completed FMEA spreadsheet for sub-process component 4b: Review side effect profile vs. original treatment

FMEA subject: Managing drug shortages		Process: #4: Assess risk(s) of potential alternatives							
Sub-process component: 4c – Assess additional laboratory or other monitoring required									
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame
4c1	Need for monitoring not assessed	Patient does not identify early warning signs and experiences serious toxicity or discontinues treatment due to side effects	Seen as responsibility of prescriber; lack of collaborative practice	5	3	3	45	Yes	Develop checklist for risk assessment as part of drug shortages protocol so that important components not omitted (repeat of 4a1)  Provide education for pharmacy staff on roles and responsibilities related to drug shortages (repeat of 4a1)  Work with local prescribers to identify collaborative opportunities regarding therapeutic drug monitoring (6-9 months)
4c2	Information available is incomplete	Information provided to patient is incomplete	Reliance on hard copy library vs. online	5	1	3	15	Yes	Assign a pharmacist to review library content vs. recommendations; remove outdated references and replace with current required references from ACP's list (1 month)

Figure F: Completed FMEA spreadsheet for sub-process component 4c: Assess additional laboratory or other monitoring required

FMEA subject: Managing drug shortages		Process: #4: Assess risk(s) of potential alternatives							
Sub-process component: 4d – Assess known error potential/other medication safety issues (e.g., high-alert drug; look-alike names/packaging)									
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and timeframe
4d1	Safety assessment not completed	Safeguards not implemented (e.g., independent double check for high alert medications)	Staff unaware of medication safety considerations and principles and/or resources available	4	2	3	24	Yes	Provide education for all pharmacy staff regarding high-alert medications and other common medication safety issues (e.g., look-alike, sound-alike medications/packaging) as well as available resources (e.g., ISMP Canada Safety Bulletins, Lexi-Comp drug monographs) (1 month)  Disseminate ISMP Canada Safety Bulletins to all pharmacy staff (1 month)
4d2	Literature reviewed; no medication safety issues identified	Medication incident occurs with potential for patient harm	Potential problems not previously identified (e.g., new product/new packaging)	4	1	4	16	Yes	Report medication incident(s) according to local procedures; consider reporting via ISMP Canada/CIHI as applicable  Ensure analysis of medication incident(s)

Figure G: Completed FMEA spreadsheet for sub-process component 4d: Assess known error potential/other medication safety issues (e.g., high-alert drug, look-alike names/packaging)

FMEA subject: Managing drug shortages		Process: #4: Assess risk(s) of potential alternatives			Sub-process step: n/a	
Failure mode number	Recommended action	Strength of action	Timeframe for implementation	Individual(s) responsible	Measurement plan	
4a1 4b1 4c1	Develop a checklist for risk assessment as part of drug shortages protocol so that important components are not omitted	Medium (Reminders/double checks)	1 month	Senior pharmacist and inventory technician	Periodic audit by licensee of process for managing drug shortages	
4a1 4c1	Provide education for pharmacy staff on roles and responsibilities related to drug shortages	Low (Policy development/education)	1 month	Licensee/manager	Education session(s) completed and information available in an accessible location for reference	
4a2	Post quick reference instructions for accessing online resources on or adjacent to computer stations	Medium (Reminders/double checks)	1 month	Senior pharmacist	Information is posted in an accessible location	
4a2	Provide training for all staff on how to access online resources	Low (Policy development/education))	1 month	Senior pharmacist	Staff can demonstrate competency after training; periodic observation/check-in with staff regarding ongoing use	
4c1	Work with local prescribers to identify collaborative opportunities regarding therapeutic drug monitoring	Medium (Simplification/standardization)	6-9 months	Licensee and delegated pharmacist	Collaborative protocol(s) developed Audit of patient records to assess pharmacist monitoring/follow up	
4c2	Assign a pharmacist to review library contents vs. recommendations; remove outdated references and replace with text or online resources as appropriate	Low (Education/information)	1 month	Delegated pharmacist	Annual audit for outdated references	
4d1	Provide education for all pharmacy staff regarding high-alert medications and other common medication safety issues (e.g., look-alike, sound-alike medications/packaging) as well as available resources (e.g., ISMP Canada Safety Bulletins, Lexi-Comp drug monographs)	Low (Education/information)	1 month	Delegated pharmacist	Education session(s) completed and information available in an accessible location for reference  <i>Continued</i>	

Figure H: Completed action and measurement template for Process Step 4: Assess risk(s) of potential alternatives (continued on next page)

FMEA subject: Managing drug shortages		Process: #4: Assess risk(s) of potential alternatives			Sub-process step: n/a	
Failure mode number	Recommended action	Strength of action	Timeframe for implementation	Individual(s) responsible	Measurement plan	
4d1	Disseminate ISMP Canada Safety Bulletins to all pharmacy staff	Low (Education/information)	1 month	Licensee	All staff receive ISMP Canada Safety Bulletins via internal email system or hard copy placed in communication book with sign-off	
4d2	Report medication incident(s) according to local procedures; consider reporting via ISMP Canada/CIHI as applicable	Low (Policy development)	1 month (process in place)	Licensee	Review of reported medication incidents as standing item for pharmacy staff meetings	
4d2	Ensure analysis of medication incident(s)	Low–high depending on issues identified Low if solely policy related	1 month (process in place)	Licensee	Quarterly review reports completed per ACP policy	

Figure H: Completed action and measurement template for Process Step 4: Assess risk(s) of potential alternatives

## Appendix 3.3: Clinical pharmacy example – patient assessment process

Step 1: Select a process to analyze and assemble a team

Step 2: Diagram the process

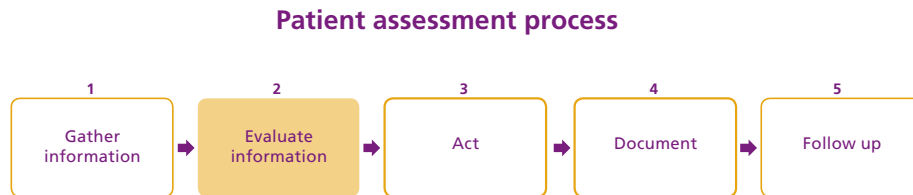


Figure A: High level process components for *Patient assessment process*

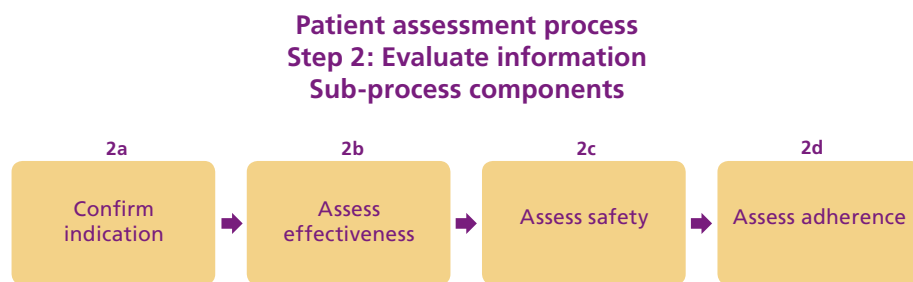


Figure B: Sub-process components for Step 2: *Evaluate information*

### Step 3: Brainstorm potential failure modes within the process

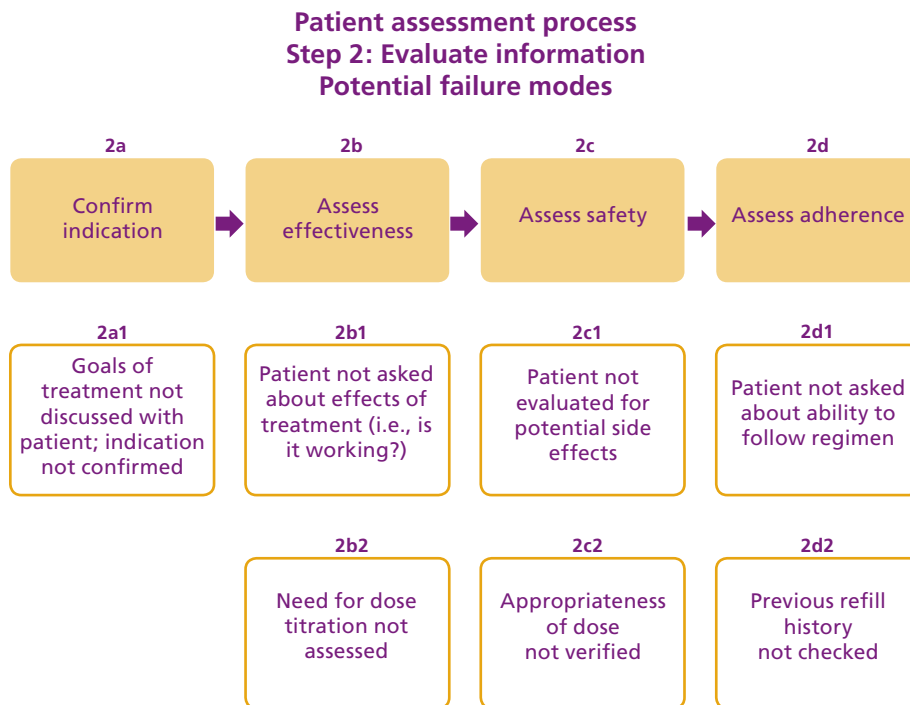


Figure C: Potential failure modes for Step 2: *Evaluate information*

### Step 4: Identify the effects and causes of the potential failure modes

### Step 5: Prioritize the potential failure modes

### Step 6: Redesign the process to address the potential failure modes

### Step 7: Analyze and test the changes



FMEA subject: Patient assessment process							Process: #2: Evaluate information			
Sub-process component: 2a – Confirm indication							Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame	
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)				
2a1	Goals of treatment not discussed with patient; indication not obtained	Unable to assess effectiveness; patient receives incorrect dose for indication	Non-standard approach to patient interviews; expectation that patient understands treatment goals	4	3	3	36	Yes	Develop a checklist to facilitate standardized patient interview process (1-3 months)	

Figure D: Completed FMEA spreadsheet for sub-process component 2a: *Confirm indication*

FMEA subject: Patient assessment process							Process: #2: Evaluate information			
Sub-process component: 2b – Assess effectiveness							Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame	
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)				
2b1	Patient not asked about effects of treatment (i.e., is it working?)	Range from treatment failure to serious toxicity	Non-standard approach to patient interviews; expectation that patient will indicate concerns about treatment to pharmacist	4	2	3	24	Yes	Develop a checklist to facilitate standardized patient interview process (1-3 months)	
2b2	Need for dose titration not assessed	Range from treatment failure to serious toxicity	Dose titration considered to be physician responsibility	4	3	3	36	Yes	Work collaboratively with local prescribers to develop titration protocols for commonly used medications, including criteria for patient to return to prescriber (6-12 months)	

Figure E: Completed FMEA spreadsheet for sub-process component 2b: *Assess effectiveness*

FMEA subject: Patient assessment process										Process: #2: Evaluate information	
Sub-process component: 2c – Assess safety											
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame		
2c1	Patient not evaluated for potential side effects	Patient becomes non-adherent due to side effects; patient develops serious toxicity	Non-standard approach to patient interviews; expectation that patient will indicate concerns about treatment to pharmacist	5	3	3	45	Yes	Develop a checklist to facilitate standardized patient interview process (1 month)  Provide written information about possible side effects and indications of toxicity to support dialogue with patient at time of initial prescription and applicable information when prescriptions are refilled (1 month)		
2c2	Appropriateness of dose not verified	Range from treatment failure to serious toxicity	Pharmacy software does not support automated dose range checking <i>Continued</i>	5	4	3	60	Yes	Work with pharmacy information system vendor to implement automated dose range checking (9-12 months)  <i>Continued</i>		

Figure F: Completed FMEA spreadsheet for sub-process component 2c: *Assess safety* (continued on next page)



FMEA subject: Patient assessment process								Process: #2: Evaluate information			
Sub-process component: 2d – Assess adherence											
Failure mode number	Potential failure modes	Effect(s) of failure	Cause(s) of failure	Severity (1-5)	Frequency (1-5)	Detectability (1-4)	Criticality score	Proceed? Yes or no	Actions to reduce risk and time frame		
2d1	Patient not asked about ability to follow regimen	Range from treatment failure to serious toxicity	Non-standard approach to patient interviews; expectation that patient will indicate concerns about treatment to pharmacist	5	3	3	45	Yes	Routinely review the prescription history prior to dialogue with patient (1 month)		
2d2	Previous refill history not checked (failure to evaluate information from Netcare)	Potential lost opportunity to identify adherence issues	Workload; not part of routine process to print prescription history for pharmacist review	3	5	3	45	Yes	Routinely review the prescription history prior to dialogue with patient (1 month)		

Figure G: Completed FMEA spreadsheet for sub-process component 2d: *Assess adherence*

FMEA subject: Patient assessment process		Process: #2: Evaluate information		Sub-process step: n/a	
Failure mode number	Recommended action	Strength of action	Timeframe for implementation	Individual(s) responsible	Measurement plan
2a1 2b1 2c1 2d1	Develop a checklist to facilitate a standardized patient interview process	Medium (Reminders/checklists/double checks)	1-3 months	Senior pharmacist and delegated pharmacist	Checklist in place and available for use Periodic audits of checklist documentation by licensee
2b2	Work collaboratively with local prescribers to develop titration protocols for commonly used medications, including criteria for patients to return to prescriber	Medium (Simplification/standardization)	6-12 months	Licensee and delegated pharmacist	Protocols in place Survey of collaborating prescribers to assess satisfactions with new process
2c1	Provide written information about possible side effects and indications of toxicity to support dialogue with patients at time of initial prescription and review this information when prescriptions are refilled <ul style="list-style-type: none"> <li>Develop standardized process for pharmacy technician to print information when entering prescriptions into computer system</li> </ul>	Low (Education/information)	1 month	Senior pharmacist and senior pharmacy technician	Periodic audits by licensee to ensure drug information sheets are routinely printed and provided to patients
2c2	Work with pharmacy information system vendor to implement automated dose range checking (if not already in place)	High (Automation/computerization)	9-12 months	Licensee and delegated pharmacist	Routine testing process for new medications to ensure dose range checking is generating appropriate alerts
2c2	Work with pharmacy information system vendor to flag vulnerable populations for additional checks	High (Automation/computerization)	9-12 months	Licensee and delegated pharmacist	Periodic audits by delegated pharmacist to ensure system is working as expected
2c2	In the absence of automated systems, educate pharmacy staff about patient groups/drugs that require additional review	Low (Education/information)	1-3 months	Delegated pharmacist	Education session(s) completed and information available for reference in an easily accessible location
2d1 2d2	Routinely review the prescription history prior to dialogue with the patient	Medium (Simplification/standardization, reminders/double checks)	1 month	Senior pharmacy technician	Periodic audits by senior pharmacy technician to ensure history is routinely reviewed

Figure H: Completed action and measurement plan spreadsheet

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Pharmacy



## Appendix 4.1: FMEA process spreadsheet



Alberta  
College of  
Pharmacy

acp

irmp  
CANADA

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Pharmacy

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CANADA

# Appendix 5: Model for improvement

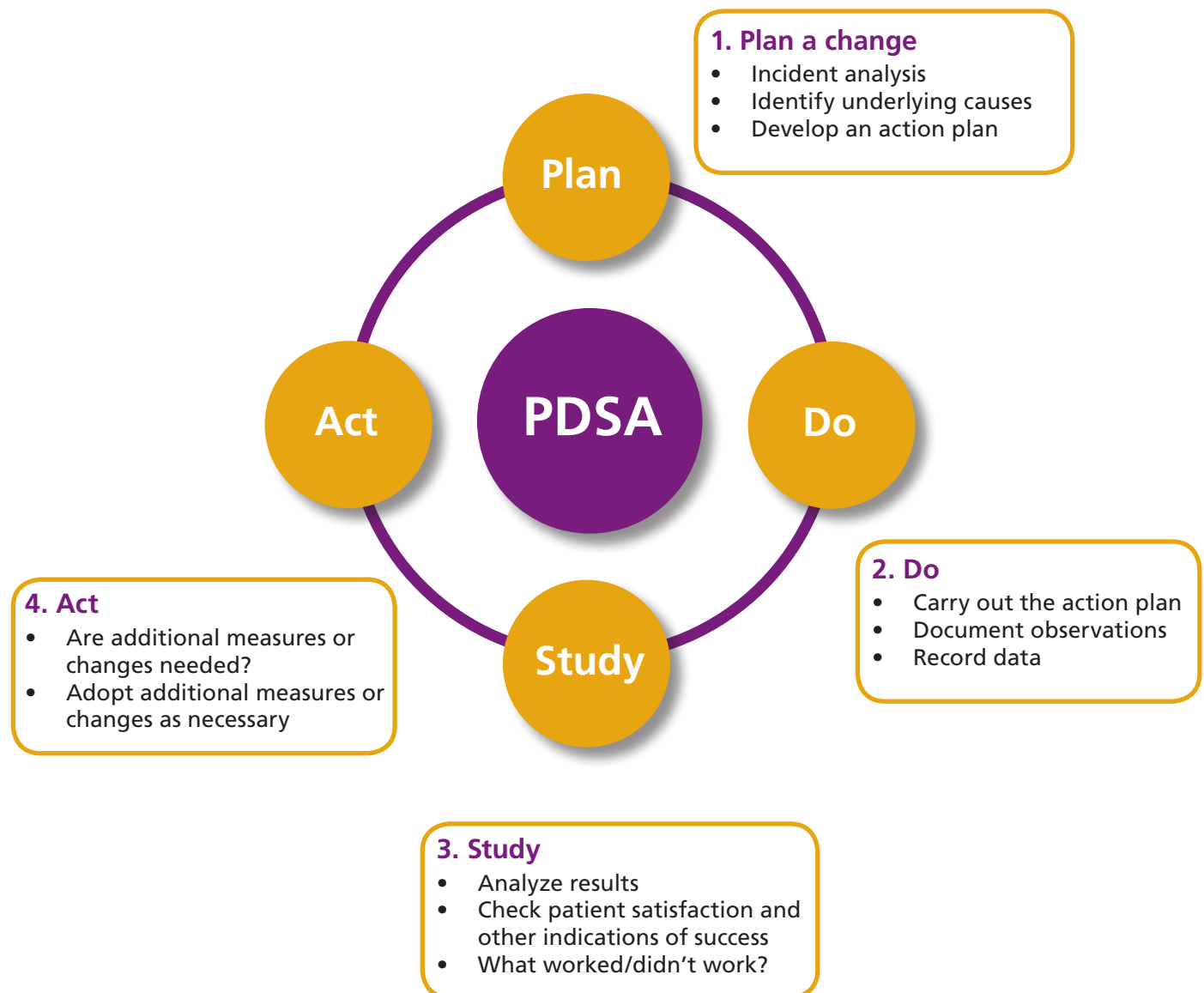
Developed by Associates in Process Improvement (<http://www.apiweb.org>), the Model for Improvement is a simple yet powerful tool for accelerating improvement in health care processes and outcomes. Hundreds of health care organizations have used it successfully. The Model has two parts:

- Three fundamental questions that guide improvement teams to:
  1. Set clear aims;
  2. Establish measures that will tell if changes are leading to improvement; and
  3. Identify changes that are likely to lead to improvement;
- The Plan-Do-Study-Act (PDSA) cycle, which is used to conduct small-scale tests of change in real work settings by planning a test, trying it, observing the results and acting on what is learned. This is the scientific method used for action-oriented learning (available at <http://ihi.org>). After testing a change on a small scale, learning from each test and refining the change through several PDSA cycles, the team can implement the change on a broader scale.

**What are we trying to accomplish?**

**How will we know that a change is an improvement?**

**What changes can we make that will result in improvement?**



## Usability Testing in Proactive Risk Assessments

Success in conducting a prospective analysis, such as a failure mode and effects analysis (FMEA), is contingent upon identifying risks or “accidents waiting to happen”. A previous bulletin introduced a human factors engineering method called *cognitive walkthrough* and described how such a method can be included in an FMEA.<sup>1</sup> The current bulletin discusses a complementary method known as *usability testing*, which can be employed to identify risks, evaluate interventions designed to mitigate risks, and identify potential unintended consequences.<sup>2</sup> ISMP Canada uses both of these methods in conducting its analyses of medication incidents.

### What Is Usability Testing?

Usability testing is a method whereby end-users participate in evaluating a product or process (a “system”). This method allows observation of how end-users will interact with the system and measurement of how well the system fulfills its intended purpose.

In a typical usability test, an end-user is asked to complete a task or set of tasks with the system in question (e.g., a new process or device) while specific performance variables are measured. These performance measures quantify the ease or difficulty with which the end-user can operate or use the system, and hence the risk of error. Examples of variables that might be measured include the time required to complete a certain task, the number of steps in the process, the number of steps that cause confusion, the number and nature of errors made by users, and any deterioration in competence after periods of non-use. User feedback can also be gathered to augment the usability measures.

The results of usability testing can complement the information gathered during cognitive walkthrough. Unlike the more qualitative findings from a cognitive walkthrough, usability testing yields quantitative data for evaluating or comparing systems (or the interventions designed to mitigate risks).

### Why Conduct Usability Testing?

The goal of usability testing is to identify aspects of a system that may lead to inefficiency, high mental or physical workload, and errors. Usability testing supports the identification of potential risks (e.g., failure modes) and their likely causes. During a prospective analysis (e.g., an FMEA), information from usability testing can further the team’s understanding of the system from the practitioner’s perspective. Unlike interviews and brainstorming, which

are inherently subjective and can be biased by preference or opinion, usability testing is based on observation and measurement of actual human performance and is therefore an objective method of collecting information about potential risks.

### When and Where Should Usability Testing be Conducted?

Usability testing can be conducted as part of any risk analysis or evaluation process. It is a helpful addition to the planning of process changes and can be applied to written instructions (e.g., policies and procedures) or to equipment and devices (e.g., infusion pumps) before procurement or implementation. Usability testing can also be used iteratively. In other words, improvements to the system are repeatedly tested with usability testing. It is an essential tool for any team wanting to understand the potential for errors, to learn about practitioners’ frustrations with a particular system, and to identify any mismatches or conflicts with current work processes.

Any healthcare setting, from acute care to home care, can benefit from usability testing. ISMP Canada has employed usability testing in a variety of projects, including both prospective and retrospective risk assessments, to gain an in-depth understanding of the potential for errors. Two projects in particular illustrate the value of usability testing in risk assessment.

In one project, usability testing was applied to evaluate the risks associated with carrying out 2 methods of independent double checks. The usability tests examined how the steps in each double-check method might impose a mental burden on the practitioner, which helped to understand how errors might occur. The results highlighted unanticipated problems with each method and provided insight into the design requirements needed to support the 2 types of independent double check.<sup>3</sup>

In the second project, usability testing was conducted to evaluate the potential for errors with an infusion pump that had been involved in a fatal error related to a chemotherapy infusion. This usability test was part of a retrospective (root cause) analysis. In a typical root cause analysis, the analysis team, including practitioners with detailed knowledge, helps in determining the most likely contributing factors on the basis of known facts and expert opinion. In this case, usability testing was also employed. During the testing, the same error was observed as had occurred during the fatal

incident, which gave investigators the opportunity to directly observe and understand contributing factors related to the device.<sup>4</sup>

### Who Can Facilitate a Usability Test?

Any individual, even someone without extensive human factors training, can conduct a simple usability test, which might consist of measuring the number of errors made or the time required to complete a task. However, evaluation of an intricate system will usually entail more complex testing, such as concurrent observation of more than one participant. Alternatively, it may be desirable to evaluate the process or device in great detail. In these situations, the expertise and guidance of a human factors expert is beneficial.

Similar to the requirements for cognitive walkthrough, the person facilitating usability testing or acting as the test director should be someone who will not influence the participant's performance during the test. The aim is to observe "actual" performance, rather than "ideal" performance. The facilitator should be impartial and should not have a vested interest in the process, task, or device under review, so that participants can perform their tasks without fear of criticism.

### Who Should Act as Participants?

Participants should be representative end-users who typically use (or will be expected to use) the device or carry out the task. The usability testing is intended to help uncover problems that an end-user might encounter or errors that could occur. It is often important to recruit at least 2 types of participants: those who are highly experienced with the system or device being evaluated and those who are new to it. Another type of participant that may be important to consider is an end-user who uses the device or process infrequently.

### How Should a Usability Test be Conducted?

#### *Step 1: Gather Information*

Obtain a general understanding of the process or task, the people performing it, and the typical work environment. This can be done by conducting field observations and interviews or undertaking a cognitive walkthrough to gain information that will inform the focus of the usability test. Whenever possible, create a diagram of each step of the process or device operation (a process often referred to by human factors engineers as the "task analysis").

#### *Step 2: Develop a Test Plan*

(a) *Identify the participants (end-users).* Use the information gathered in Step 1 to identify the end-users. Consider involving end-users with a variety of characteristics (e.g., different professions, different levels of experience, different goals, different physical abilities, different frequency of use of the process or device). A small usability test might involve 4 to 6 participants.

(b) *Identify the task to be performed.* The target task, also

based on information gathered in Step 1, is the set of activities that each participant will perform. Tasks selected for evaluation are typically those that carry a high risk or those that are performed frequently. The task could consist of carrying out a specific part of a process or setting up a device for a specific purpose.

(c) *Create the scenario.* The scenario represents the context for the task and should also be based on the information gathered in Step 1. The scenario might specify the events that transpire before the task begins, the amount of training provided, the tools to be used, the people or information available to the participant during execution of the task, and the nature of the work environment (e.g., noisy, dim lighting, multiple concurrent tasks, time pressure).

(d) *Identify the environment of use.* Use of a simulation centre, with a mock-up of the typical work area, is ideal. However, if such a setting is not available, usability testing can be conducted in a location that is fairly representative of the work environment in question, so long as the test can be completed without interruptions or distractions. (Although interruptions and distractions are sometimes part of the real-life scenario, their presence is not recommended for inexperienced facilitators, because inclusion of these features in usability testing requires careful planning and orchestration.) Any additional materials or tools that would typically accompany the task being evaluated should be available to participants.

(e) *Specify performance measures and methods of data capture.* Performance measures and methods of collecting the data must be determined before testing begins. A usability test typically involves measuring the time required to complete a task and the number of errors that occur. Other measures might include training time (e.g., how many trials are needed to achieve competence), the number of steps involved, the perceived mental workload (using a well-accepted survey such as the NASA task load index<sup>5</sup>), the number of times participants refer to the user's manual, and user satisfaction. Capturing measurement data generally requires additional equipment (e.g., video cameras, screen-capture software, or custom spreadsheets) and sometimes even additional people.

#### *Step 3: Conduct a Pilot Test*

No matter how much planning has gone into a usability test, a pilot test (or test run) is needed to ensure that testing runs smoothly. Facilitators often find that portions of the test plan, such as data capture, need to be refined. Pilot testing helps the facilitator to work out any problems before running the actual usability test.

#### *Step 4: Revise the Test Plan*

Issues identified during the pilot test must be rectified before the usability test is conducted. Once the test plan has been revised, another pilot test should be run, to ensure that all issues have been addressed.

*Step 5: Conduct the Usability Test*

Once participants have been recruited, the pilot tests have been completed, and the test plan has been refined, the usability testing can be conducted.

*Step 6: Assimilate the Information*

The results of the usability test will give rich insights into the system being evaluated, including identification of typical errors, some of the conditions that make such errors more likely, and the specific aspects of the process or task leading to these potential errors. In situations where 2 processes or devices are being compared, usability testing can help the team to understand the relative risks associated with each. In instances where a usability test is being conducted to improve an existing process or product, usability testing can generate an in-depth understanding of the improvements

needed. Furthermore, if testing is conducted iteratively (i.e., repeatedly) after each stepwise improvement, decisions and improvements can be based on objective data, which improves the chance that the intervention or process improvements will be effective.

**Conclusion**

Usability testing is a powerful method for identifying risks. This type of testing evaluates processes or devices with the help of actual end-users. This approach can yield quantifiable and objective data on how intuitive a system is to use and thus how error-prone it may be. In-depth information can be obtained about a process, device, or system to help enhance the team's understanding of where risks exist and how they can be mitigated before patients experience any harm.

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### **Eliminating Harmful Medication Errors at Transitions: Medication Reconciliation—A National Priority**

Reducing medication-related errors is a priority for advancing safe, high-quality health care in Canada. In early November 2012, Accreditation Canada, the Canadian Institute for Health Information, the Canadian Patient Safety Institute (CPSI), and the Institute for Safe Medication Practices Canada (ISMP Canada) released a report entitled *Medication Reconciliation in Canada: Raising the Bar* which describes an important approach to reducing such errors.

Medication reconciliation is the formal process of identifying a complete and accurate list of the medications that a particular patient is taking and then using that list to ensure that the patient continues to receive appropriate medications at each transition of care. This new report identifies populations at high risk of experiencing medication-related errors and effective approaches to medication reconciliation, as well as the challenges of, trends in, and advances toward ensuring that drug-related errors are avoided.

The following are some of the insights included in the report:

- One quarter of seniors have 3 or more chronic conditions, many of which must be treated with multiple medications. These seniors are at higher risk of adverse events related to medication use and unplanned visits to emergency departments and hospitals.
- Of the 288 health care organizations surveyed by Accreditation Canada in 2011, only 60% had a process for medication reconciliation at admission, and only 50% had a process for medication reconciliation at transfer or discharge.
- Medication reconciliation practices showed the highest improvement from 2010 to 2011, yet this aspect of care continues to represent one of the greatest challenges to overall patient safety.
- The National Medication Reconciliation Strategy, co-led by CPSI and ISMP Canada, supports the development of a curriculum for health care practitioners, and has created tools, resources, and technology supports, including medication checklists, an interactive web-based map of innovative medication reconciliation resources by region, and a mobile app to help patients better manage their own medications.

More information about medication reconciliation is available from ISMP Canada at [www.ismp-canada.org/medrec](http://www.ismp-canada.org/medrec)

The full report is available from ISMP Canada in both [English](#)<sup>1</sup> and [French](#)<sup>2</sup>

<sup>1</sup> [www.ismp-canada.org/download/MedRec/20121101MedRecCanadaENG.pdf](http://www.ismp-canada.org/download/MedRec/20121101MedRecCanadaENG.pdf)

<sup>2</sup> [www.ismp-canada.org/download/MedRec/20121101MedRecCanadaFRE.pdf](http://www.ismp-canada.org/download/MedRec/20121101MedRecCanadaFRE.pdf)

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**(i) through the website: [http://www.ismp-canada.org/err\\_report.htm](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](mailto: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.

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## Include *Cognitive Walkthrough* in Proactive Risk Assessments

One of the goals of a robust medication safety culture is to create systems in which potential failures or risks can be identified and addressed before a patient experiences any actual harm. This is only possible if one can proactively identify the precise nature of any “accidents waiting to happen”, along with interventions to address these situations that do not unintentionally introduce other potential risks. The discipline of human factors engineering\* is increasingly being adopted to help with this process. Within this discipline, a method called cognitive walkthrough is a useful technique to identify risk. This bulletin provides information about cognitive walkthrough and offers a practical introduction on how it should be carried out for a proactive risk assessment such as failure mode and effects analysis (FMEA).<sup>1,2</sup>

### What Is a Cognitive Walkthrough?

A cognitive walkthrough involves physically walking through the process or task of interest, examining the mental activities required at each step and the challenges experienced. This method goes beyond the current practice in healthcare of relying on incident data, individual opinion, or collective “brainstorming” by a team to identify potential risks, errors, or failure modes. It is one of many tools employed by human factors engineers to gain an in-depth understanding of a process or task from the perspective of the primary end-user (e.g., front-line practitioner).

A cognitive walkthrough can be used to help identify risks and assess solutions. In this technique, a participant (i.e., a representative user, such as a front-line practitioner) is asked to simulate all or part of a task and to “think out loud” while performing the simulation. The intent of thinking out loud is to allow observers to comprehend the task from the participant’s viewpoint as it is being carried out. The participant expresses the reasons for any decisions

made or actions taken during the simulated task, as well as any frustrations, confusion, or doubts. The cognitive walkthrough can help to identify specific parts of the process or task that may not match the participant’s goals, understanding, or abilities, along with aspects that may be inefficient or that pose an excessive cognitive or physical burden.

### Why Conduct a Cognitive Walkthrough?

A cognitive walkthrough helps the FMEA team to better understand, from the perspective of the practitioner, the process or task under review. Its approach to identifying failure modes (potential risks) is more structured than that of brainstorming, and can be complementary to brainstorming. Interestingly, it can also help to identify potential failure modes not recognized through incident reports or reviews.

### When Should a Cognitive Walkthrough be Conducted?

This technique should be used anytime there is an interest in understanding the potential risks associated with a particular task or set of tasks. An organization may encounter many situations in which it will want to conduct a cognitive walkthrough, such as during a prospective risk assessment, before implementing a new process or policy, when learning about a practitioner’s frustrations, or even retrospectively, after discovering a close call or an error (e.g., through a root cause analysis).

A cognitive walkthrough can be easily utilized in any setting, from acute care to home care. In fact, this method has been employed by ISMP Canada in a number of FMEA projects, such as one involving emergency medical services (EMS).<sup>3</sup> Cognitive walkthrough analyses in the EMS project were used to proactively evaluate a medication kit and protocol forms, all of which had been recently redesigned. The goal of this project was to improve the usability of materials involved in the medication use process and, ultimately, to reduce the potential for errors.<sup>2</sup>

### Who Can Facilitate a Cognitive Walkthrough?

Any individual on the FMEA team or within the organization that wants to learn about potential risks can facilitate a cognitive walkthrough, even someone without specialized knowledge of the process, task, or equipment being evaluated. However, it is important that the facilitator

\* Human factors engineering is the discipline concerned with understanding how humans interact with the world around them. It draws upon applied research in many areas, such as biomechanics, kinesiology, physiology, and cognitive science, to define the parameters and restraints that influence human performance. This knowledge can be used to design systems so that they are compatible with human characteristics. Conversely, if systems are not compatible with human characteristics, performance can be adversely affected.<sup>1</sup>



be someone in whose presence the participant (the person who will be thinking out loud) feels comfortable when expressing their thoughts. Therefore, it is preferable that the facilitator be impartial, without any vested interest in the process or task under review. It is also important that the participant be allowed to “think out loud” without the facilitator voicing any criticism.

### **Who Should Act as the Participant?**

The participant (the person who “thinks out loud” during the cognitive walkthrough) should be representative of the population that typically carries out the task. Avoid recruiting people who are biased, for example, the person who designed the process or selected the equipment being evaluated. Sometimes it is worthwhile to recruit 2 types of participants, someone who is highly experienced with the task and someone who is new to the task, as their differing perspectives can help in identifying a broad range of potential risks.

### **How Is a Cognitive Walkthrough Conducted?**

#### ***Step 1: Create the Scenario***

A scenario is created to provide context for the task that the participant will be performing. In order to create the scenario it may be useful for the facilitator to observe the processes of interest to identify task-related information. Information that will be helpful for the participant might include the practice location, any events occurring just before initiation of the process, the tools or information that will be available to carry out the process, the presence of other individuals who are available to help, details of the task, and perhaps other contextual information, such as time constraints or other demands (e.g., multitasking).

For example, the following scenario was developed for the participants in the FMEA for the EMS project mentioned above. The paramedic (the participant for the walkthrough) and his/her partner are responding to a call for a patient who is complaining of chest pain. The participant is asked to think out loud while simulating the activities that would usually be performed when such a call is received.

#### ***Step 2: Identify the Location***

When possible, a cognitive walkthrough should be conducted in the work area where the activity is typically performed in order to provide a realistic scenario. This allows the members of the FMEA team to gather information about the setting, including the layout of the work area(s), the equipment used, the people involved, and any other relevant sources of information. If it is not possible to conduct the walkthrough in the actual work area, a quiet room may suffice but is not ideal. If the walkthrough is conducted away from the usual practice site, any supporting material typically used when

performing the process or task should be brought to the test location.

For example, materials used in the EMS cognitive walkthrough included medication kits containing real medications, as well as syringes, a calculator, forms, clipboards, writing instruments, and communication equipment.

#### ***Step 3: Walk Through the Task or Activity***

The facilitator should explain the scenario to the participant and describe the task to be performed. The participant is then asked to think out loud while performing the task.

To encourage participants’ verbal reflection, the facilitator should emphasize that it is the system (e.g., a form, a piece of equipment, or a process) that is being assessed, not the participant. The facilitator should note points of confusion or difficulties experienced by the participant and should help the FMEA team to identify any aspects of the system that may be causing a potential risk or failure mode. The facilitator may need to give the participant some examples of what is meant by the instruction to “think out loud”.

A number of other things should be kept in mind during a cognitive walkthrough:

- The facilitator should avoid leading the participant and should instead allow the participant to carry out the process or task without specific instructions.
- The facilitator may need to remind the participant to verbalize his or her thoughts. Helpful prompts include questions like the following: “What are you trying to decide?” “What are you looking at right now?” or “What are you thinking of doing next?”
- If the participant appears to be struggling or experiencing confusion or frustration, the facilitator can ask questions such as “What made that difficult?” “What made you think that?” or “How did you decide to do that?”
- The facilitator should only help the participant to complete a specific step in the task if the participant is completely perplexed after having had the opportunity to try various approaches.
- Participation is voluntary. Therefore, participants may withdraw if desired or if they feel uncomfortable at any time during the cognitive walkthrough.

#### ***Step 4: Assimilate the Information***

All information gathered from the walkthrough should be assimilated to proactively identify any weak areas in the activity or task. Processes, policies, forms, and even the layout of the work area can be redesigned with the newly acquired information. The outcomes of the walkthrough also provide a more complete understanding of the challenges that participants face in their daily work.

For example, in the EMS project, redesigning the medication order form helped to mitigate the risk of administering incorrect medications by making the algorithm and corresponding medication choices clearer.<sup>3</sup>

### Conclusion

A cognitive walkthrough provides a structured, systematic approach to getting at information that might otherwise be

missed. It can be a vital part of an FMEA, yielding valuable information for FMEA teams. The information gained may include the context in which a process is used, the nature of the physical and mental activities involved, the way in which the task fits into overall workflow, interactions or communications with others, and the usability of materials required to complete each task. In short, a cognitive walkthrough can help organizations to recognize additional opportunities to improve safety.

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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.<sup>1</sup> The MSSA provides insights into the characteristics of a safe medication use system.<sup>2</sup> 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.<sup>3</sup> 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).<sup>4</sup> 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”<sup>5</sup> 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<sup>6</sup>, 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*.<sup>7</sup>

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.<sup>8</sup> 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.<sup>9</sup> 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).<sup>10</sup>

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.

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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](mailto:fmea@ismp-canada.org) or by phone: 1-866-544-7672.

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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](mailto:mssa@ismp-canada.org).

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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](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](mailto: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***

# ISMP Canada Safety Bulletin

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## How to Use ‘Failure Mode and Effects Analysis’ to Prevent Error-Induced Injury with Potassium Chloride

In this bulletin we will briefly describe reports of sentinel events and near miss incidents with potassium chloride that have been reported to ISMP Canada during the past two years. The literature is replete with reports of similar errors worldwide (Medline search) and selected case reports are referenced.<sup>1-5</sup> We will present the concept of Failure Mode and Effects Analysis (FMEA) and show how it can be used to prevent injury with potassium chloride in hospital medication use systems. We conclude this bulletin with a recommendation for change.

### The following incidents with potassium chloride have been reported to ISMP Canada:

1. 10 mL potassium chloride (KCl) concentrate was administered direct IV when the intended action was to flush an intravenous line with 10 mL 0.9% sodium chloride. Result: patient fatality.
2. 10 mL KCl concentrate was used to reconstitute a drug for parenteral administration when the intended diluent was sterile water. Result: Near miss (error was noted before administration).
3. 10 mL KCl concentrate was administered as a bolus injection by a health care professional who was unaware that KCl concentrate cannot be given as a bolus but must be diluted in a minibag and given as an infusion. Result: patient fatality.
4. A one-liter IV solution was prepared with 400 mEq of potassium chloride and although it was administered at a very low rate, the incident was felt to be a near miss because of the potential for accidental overdose.(error was noted during administration).
5. IV solutions containing KCl were administered as a fluid replacement in a patient requiring several liters of fluid in a short time frame. Result: hyperkalemia, patient fatality.

Many Canadian hospitals continue to have weaknesses in their medication use systems that place their patients at risk of serious consequences from errors with potassium chloride. The purpose of FMEA is to discover the potential for risk in a product or system by analysis of the possible failures, their consequences and their possible risk factors. 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?”** The concept was first introduced in the engineering literature in the early 1960’s<sup>6</sup>. It is now a standard procedure in many industries. The

time for its application to the Canadian healthcare industry is overdue. The application of this mode of analysis to the use of potassium chloride could have forestalled the accidents and near-accidents described above.

The following examples of post accident analysis, showing what would have been detected by FMEA, will serve as a guide to you for use in your hospital, in order to identify risks to your patients and to assist in targeting areas for improvement.

In the KCl incidents #1 and #2, the fundamental human failure (error mode) was an error of substitution. The substitution was expressed in the picking up of a vial of KCl when the intent was to pick up sodium chloride or sterile water. The effect of such a substitution error, if injection follows, is almost always fatal.

### System Remedy:

The system remedy is to remove potassium chloride concentrate from all patient care areas; to purchase pre-mixed IV solutions containing potassium chloride; and to standardize prescribing practices to match available pre-mixed solutions. Most medical conditions can be appropriately treated with the commercially available pre-mixed solutions. For those solutions determined to be necessary, but unavailable commercially, have Pharmacy prepare admixed solutions.

There are many references<sup>3,7,8</sup> that describe similar errors with concentrated KCl and advocate for removal of potassium chloride concentrate from patient care areas.

Concentrated potassium chloride, even if stocked only in the Pharmacy, has the potential for error-induced injury. We suggest the following stratagems aimed at making the potassium chloride concentrate product ‘look and feel different’ from other products:

- (i) Add an auxiliary label to the concentrated KCl product such as:

**\*\* CAUTION \*\***  
Concentrated KCl  
**Fatal if Injected Undiluted**  
DILUTE before use

- (ii) Remove the 10 mL size of the potassium chloride concentrate from all hospital inventories. The larger 20 mL size “looks and feels different”.



In the KCl incident #3 where KCl concentrate was administered as a bolus dose, the failure mode was determined to be an error of omission: forgetting about the lethality of concentrated KCl.

**System Remedy:**

In addition to the system remedy described above, clearly stated and easily accessible information on the prescribing, the administration and the monitoring of potassium chloride should be readily available. Orders such as “KCl 40 mEq IV now” must be considered incomplete and unacceptable. Guidelines for the maximum rate of infusion, the required frequency of serum potassium monitoring, the use of an infusion pump and cardiac monitoring, along with renewed and continuous training, provide system safeguards.

In the KCl incident #4, the failure mode was determined to be an error of omission: a failure to institute and/or apply a safe potassium chloride use policy. In addition to the system remedies described above, a clear policy on a maximum content of potassium chloride in an IV bag should be developed and well communicated.

In the KCl incident #5, the failure mode is difficult to ascertain because of the lack of detailed information in the report submitted.

**Recommendation:**

ISMP Canada recommends that hospitals create a ‘high-level’ multidisciplinary Task Force dedicated specifically to identifying the system weaknesses that could potentially result in patient injury with the use of potassium chloride. The Task Force needs to develop a mandate to reduce the error potential with potassium chloride and to define a strategy to implement the necessary changes in your organization, with target timelines. In addition, efforts to educate all hospital staff about the safety initiatives will serve as an example of a system re-design and will demonstrate a culture of patient safety.

If you would like assistance from ISMP Canada with your hospital initiatives please write to us at [info@ismp-canada.org](mailto:info@ismp-canada.org). If you have system improvement ideas or ‘successes’ to share we would appreciate hearing from you. ISMP Canada believes that one person can make a difference. If you have read this bulletin, you can lead the way for change in your place of work!

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# Appendix 7: Additional resources

## Publications

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Institute for Safe Medication Practices Canada. Web. 1. Aug. 2012. <<http://www.ismp-canada.org/fmea.htm>>.



# Appendix 8: Glossary<sup>21</sup>

## Adverse event

Undesired and unplanned occurrence, directly associated with the care or services provided to a patient/client in the health care system. Includes both preventable and non-preventable injuries.

**From:**

Davies, J.M, Hébert, P., and C. Hoffman. "Canadian Patient Safety Dictionary." *Royal College of Physicians and Surgeons of Canada*. Royal College of Physicians and Surgeons of Canada, 2003. Web. 1 Aug. 2012. <[http://rcpsc.medical.org/publications/PatientSafetyDictionary\\_e.pdf](http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf)>.

## Adverse drug event

An injury from a medicine or lack of an intended medicine. Includes adverse drug reactions and harm from medication incidents.

**Adapted from:**

Bates, D.W., Spell, N., Cullen, D.J., Burdick, E., Laird, N., Petersen, L.A., Small, S.D., Sweitzer, B.J. and L.L. Leape. "The Costs of Adverse Drug Events in Hospitalized Patients. Adverse Drug Events Prevention Study Group." *Journal of the American Medical Association* 277 4 (1997): 307–11. Print.

Developed by the collaborating parties<sup>22</sup> of the Canadian Medication Incident Reporting and Prevention System, 2005.

## Cognitive walkthrough

"A cognitive walkthrough involves physically walking through the process or task of interest, examining the mental activities required at each step and the challenges experienced.... It is one of many tools employed by human factors engineers to gain an in-depth understanding of a process or task from the perspective of the primary end-user (e.g., front-line practitioner)."

**From:**

Institute for Safe Medication Practices Canada. "Include Cognitive Walkthrough in Proactive Risk Assessments." *ISMP Canada Safety Bulletin*. 2009. Web. 23 Jan. 2012. <[http://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-01-Cognitive\\_Walkthrough.pdf](http://www.ismp-canada.org/download/safetyBulletins/2012/ISMPCSB2012-01-Cognitive_Walkthrough.pdf)>.

## Critical incident

An incident resulting in serious harm (loss of life, limb, or vital organ) to the patient, or the significant risk thereof. Incidents are considered critical when there is an evident need for immediate investigation and response. The investigation is designed to identify contributing factors and the response includes actions to reduce the likelihood of recurrence.

**From:**

Davies, J.M, Hébert, P., and C. Hoffman. "Canadian Patient Safety Dictionary." *Royal College of Physicians and Surgeons of Canada*. Royal College of Physicians and Surgeons of Canada, 2003. Web. 1 Aug. 2012. <[http://rcpsc.medical.org/publications/PatientSafetyDictionary\\_e.pdf](http://rcpsc.medical.org/publications/PatientSafetyDictionary_e.pdf)>.

<sup>21</sup> Definitions reprinted from the ISMP Canada Definitions webpage (<http://www.ismp-canada.org/definitions.htm>), with permission.

<sup>22</sup> Collaborating parties for the development and implementation of the Canadian Medication Incident Reporting and Prevention System (CMIRPS) are: Institute for Safe Medication Practices Canada, the Canadian Institute for Health Information, and Health Canada.

## Harm

Harm is defined as a temporary or permanent impairment in body functions or structures. Includes mental, physical, sensory functions and pain.

Developed by the collaborating parties<sup>22</sup> of the Canadian Medication Incident Reporting and Prevention System, 2005.

## High-alert medications

High-alert medications are drugs that bear a heightened risk of causing significant patient harm when they are used in error.

**From:**

ISMP's List of High-Alert Medications. <<http://www.ismp.org/Tools/highalertmedications.pdf>>.

## Human factors engineering

Human factors engineering is the discipline concerned with understanding how humans interact with the world around them. It draws upon applied research in many areas, such as biomechanics, kinesiology, physiology, and cognitive science, to define the parameters and restraints that influence human performance. This knowledge can be used to design systems so that they are compatible with human characteristics. Conversely, if systems are not compatible with human characteristics, performance can be adversely affected.

**From:**

Failure mode and effects analysis (FMEA): A framework for proactively identifying risk in healthcare. Version 1. Toronto (ON): ISMP Canada; 2006.

## Medication incident

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

**Adapted with permission from:**

The National Coordinating Council for Medication Error Reporting and Prevention. "What Is A Medication Error?" The National Coordinating Council for Medication Error Reporting and Prevention: 2012. Web. <<http://www.nccmerp.org/aboutMedErrors.html>>

Developed by the collaborating parties<sup>22</sup> of the Canadian Medication Incident Reporting and Prevention System, 2001.

**Similar term:** *Medication error*

## Medication safety

Freedom from preventable harm with medication use.

**From:**

Institute for Safe Medication Practices Canada. "Definitions of Terms." ISMP Canada: 2007. Web. <<http://www.ismp-canada.org/definitions.htm>>

## Near miss or close call

An event that could have resulted in unwanted consequences, but did not because either by chance or through timely intervention the event did not reach the patient.

Developed by the collaborating parties<sup>22</sup> of the Canadian Medication Incident Reporting and Prevention System, 2005.

**Similar terms:** *Near hit or good catch*

## No harm event

An incident occurs which reaches the patient, but results in no injury to the patient. Harm is avoided by chance or because of mitigating actions.

Developed by the collaborating parties<sup>22</sup> of the Canadian Medication Incident Reporting and Prevention System, 2005.

## Root cause analysis

An analytic tool that can be used to perform a comprehensive, system-based review of critical incidents. It includes the identification of the root and contributory factors, determination of risk reduction strategies, and development of action plans along with measurement strategies to evaluate the effectiveness of the plans.

**From:**

Canadian Patient Safety Institute, Institute for Safe Medication Practices Canada, Saskatchewan Health.  
*Canadian Root Cause Analysis Framework*. Edmonton: Canadian Patient Safety Institute, March 2006.  
Print.

## Safety

Freedom from accidental injuries.

**From:**

Kohm, L.T., Corrigan, J.M., and M.S. Donaldson. *To err is human: Building a safer health system*. Washington: National Academy Press, 1999.

## System

A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.

**From:**

World Alliance for Patient Safety. *WHO draft guidelines for adverse event reporting and learning systems*. Geneva: World Health Organization, 2005.