# Canadian Failure Mode and Effects Analysis Framework

## Proactively Assessing Risk in Healthcare

Version III, 2018

ISMP CANADA

**The Institute for Safe Medication Practices Canada (ISMP Canada)** is an independent national not-for-profit organization committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the healthcare community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices. ISMP Canada's mandate includes analyzing medication incidents, making recommendations for the prevention of harmful medication incidents, and facilitating quality improvement initiatives.
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# Introduction

Errors can and do happen, sometimes leading to patient harm. 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 proactively evaluate processes and products to identify and correct vulnerabilities before a harmful incident occurs. There are several tools available with which to conduct proactive analysis. This document will describe the use of Failure Mode and Effects Analysis (FMEA) to evaluate processes.

## 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 techniques such as root cause analysis. FMEA is based on the premise that all processes may contain embedded 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.

**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 component 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. Teams consider ways to eliminate or reduce failure and its associated risks, with a focus on preventing or minimizing harm.

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.

FMEA is not a new concept.[1] In 1949, the US military developed FMEA as a reliability evaluation technique to determine the effects of system and equipment failures. The National Aeronautics and Space Administration (NASA) adopted FMEA in the 1960s, and through the 1960s and 1970s, reliability engineers in US 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 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 proactive risk assessment annually has increased awareness and use of FMEA in hospitals and long-term care homes over the past few years.

**Why is FMEA a good technique for healthcare?** 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.

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. This premise is supported by the following sections that describe work of James Reason on the "system approach,"[2] David Marx on "Just culture,"[3] and application of human factors engineering principles.

## System approach

In healthcare environments, we have historically expected practitioners to maintain professional competence and exercise due care in day-to-day practice to assure safe care. 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 system 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 many healthcare practice settings, it is common for people to multi-task – for example, entering information into a computer system while talking on the phone or waiting on hold, or while chatting with other staff. Marx would consider these to be "at risk" behaviors – and we should recognize that they increase the risk of error. However, the healthcare environment is highly distracting – phones are ringing, interruptions are frequent, and workload is not predictable – and these things are not within the control of individual staff members. The concept of a just culture recognizes that in designing systems and processes, the individual and system factors must achieve a balance.

Things that individual care providers can do from a system design perspective to reduce the likelihood of error in their practice settings may be limited. With that in mind, everyone needs to understand how safe behavioral choices are within individual control and affect the safety of the system overall.

## 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 improvement.

The healthcare cultural focus on individual care and vigilance to prevent errors has resulted in approaches to error prevention that often rely 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 summary of the *hierarchy of effectiveness*[4,5] illustrates the types of strategies that are likely to be more effective. A more detailed graphic is provided on the following page.

**Summary of 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 or prescriber order entry computer system will not process a medication order 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 in 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 proactive analysis.

> 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 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.

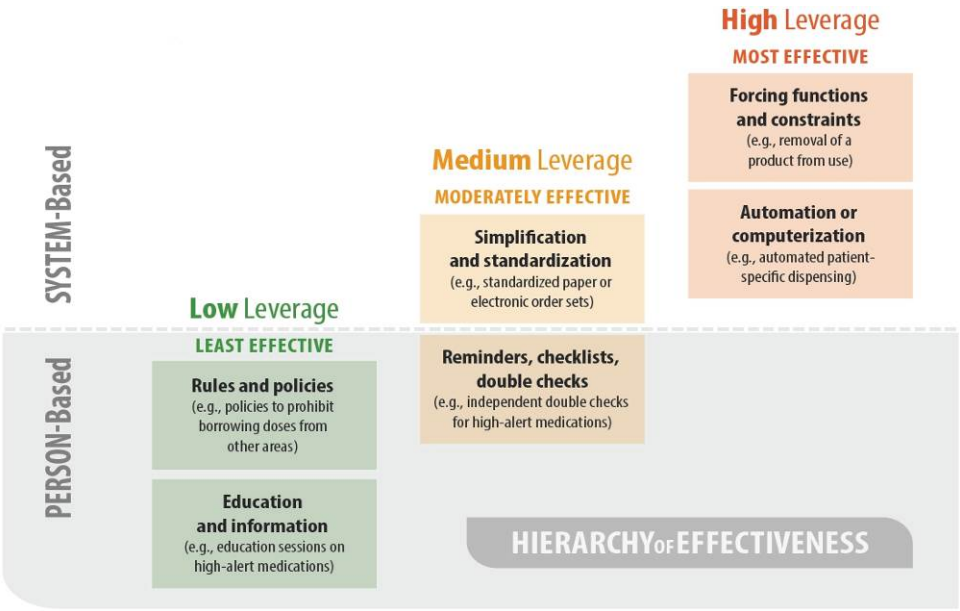


***Figure 1: Risk mitigation strategies ordered by hierarchy of effectiveness[6]***

## When should you consider an FMEA?

Organizations can use FMEA to assess existing processes and products and also to determine the potential for negative consequences in new processes or products. This document will describe the use of FMEA to evaluate a process.

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 healthcare processes that could be targeted for FMEA review include:

- Implementing a new computer system
- Communicating patients' allergy information
- Communicating medical orders
- Processing critical laboratory results
- Unit-dose packaging in a pharmacy
- Using patient-controlled analgesia pumps
- Improving team based care for patients with chronic diseases (e.g., diabetes, chronic obstructive pulmonary diseases)
- Setting up any new care program

These sample topics are examples of processes that include sub-processes, and each will be prone to a variety of problems.

FMEA is useful for identifying system vulnerabilities so that organizations can implement proactive process and workflow changes.

The ultimate goal of FMEA in healthcare 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 safeguards that we all encounter in everyday life, such as seat belts, baby safety devices, and traffic safety interventions were developed using FMEA concepts.

# Conducting an FMEA

When conducted in a systematic,[7,8] step-wise manner, the FMEA process is straight-forward. A typical FMEA includes eight steps as shown below in Table 1.

## 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.

It is important to clearly define the topic and specific process(es) for analysis at the outset. In one method for topic selection, the organizational leadership selects the general topic area and teams then select 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 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 proposed changes. |
| 8 | Implement and monitor the redesigned process(es). |

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

| Examples of "mega" topics | Possible Sub-topics |
|---|---|
| Diabetes care | Process for identifying new diabetic patients |
| | Training process for blood glucose meters |
| | Medication reconciliation process for diabetic patients |
| | Patient assessment process for diabetic patients |
| Patient identification | Process for identifying patients at various points in the care process |

One benefit of using the mega-topic approach is that everyone can benefit from the smaller learning experiences of the individual projects. For larger projects, it is important for team members to review the topic definition frequently throughout the FMEA 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 an interdisciplinary approach and fulfill required roles:

- *Leader*: Someone with a vested interest in the anticipated improvements
- *Subject matter expert(s)*: Team member(s) with knowledge of the process under analysis
- *Advisor*: Someone who can coach the team and keep the FMEA process going
- *Recorder*: Ideally someone with computer skills
- *Naïve person*: Individual not directly involved in the process being analyzed.

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

- front-line practitioners (e.g., nurses, physicians, pharmacists and other allied health professionals)
- technicians (e.g., pharmacy, radiology, anaesthesia)
- unit clerks or admitting staff
- buyers or other procurement technicians
- departmental information system staff
- physical facilities staff
- security
- housekeeping staff

Involvement of organizational management in an FMEA helps to demonstrate commitment to a system-based approach to providing care. Additionally, those responsible for overseeing the implementation of recommendations for system change need to fully understand the rationale and level of urgency for recommendations made by the FMEA team.

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 analysis of certain processes, a former patient or a community member who can provide the patient perspective may be valuable.

In a hospital setting, it is helpful to include individuals from other departments and professional backgrounds relevant to the topic for analysis. See the next page for some examples of FMEA teams.

***FMEA topic:***
***Blood administration on a patient care unit***
Team composition
- blood bank supervisor
- staff nurse
- physician
- medical laboratory technologist
- risk management representative

***FMEA topic:***
***Search for contraband during admission of psychiatric patients through the emergency department***
Team composition
- nurse manager of the emergency department
- psychiatric social worker
- crisis centre psychiatrist
- unit clerk of the emergency department
- security
- housekeeping employee
- patient advocate

***FMEA topic:***
***Antibiotic prescribing in an ambulatory care clinic***
Team composition
- staff nurse from the clinic
- laboratory technician who performs microbiology testing
- community/outpatient pharmacist
- infectious disease/family practice physician
- unit clerk
- information technology representative

It is important to provide orientation for the team before beginning the FMEA. Orientation should include:
- An overview of the FMEA approach;
- 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 healthcare-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, as this process will be familiar to anyone who has had a prescription filled.

### 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 2.

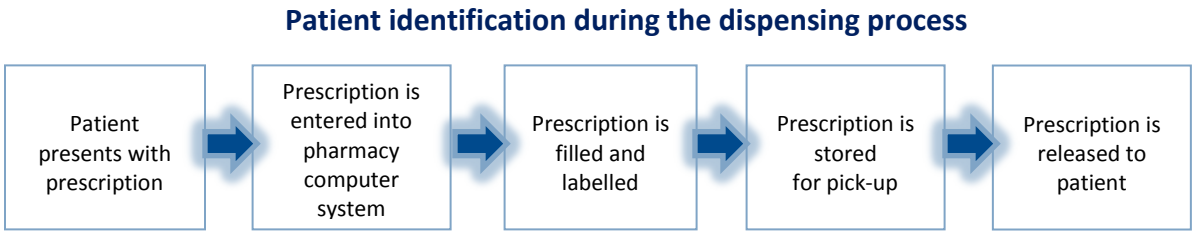


*Figure 2: High level process block diagram*

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 mapping 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.

### 2b) Number the components of the process

Identify all of the high level components in the process and number each component (Figure 3). Because the processes themselves tend to be complex, the resulting diagram can also be complex, and numbering will help your team stay organized.

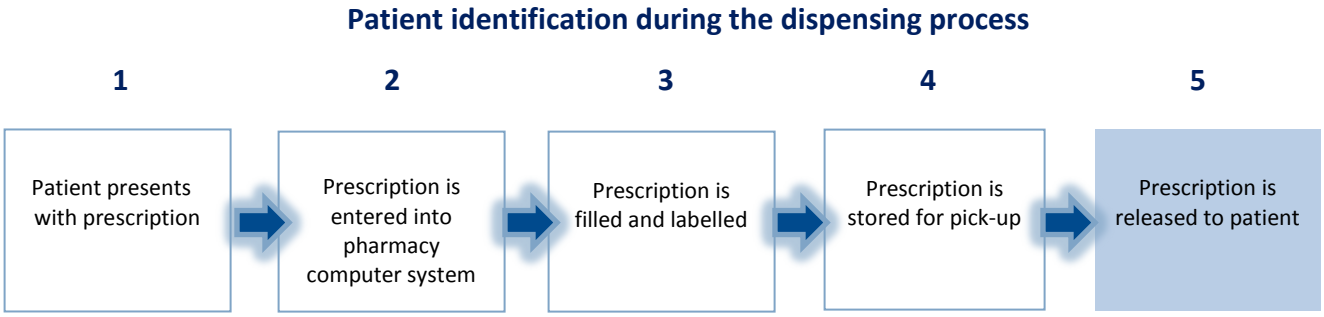


*Figure 3: Block diagram of the high level components, labelled with numbers (# 5 is selected to diagram in more detail)*

### 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 4). If the original topic selected is too big, the team may be able to complete the FMEA on only one of the process components (process steps), because that component or step is complex enough that it warrants its own FMEA. Our example will focus on Step 5: *Prescription is released to patient.*

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

Break down the selected components of the high-level process and diagram the sub-processes (Figure 4). Label each sub-process component with the step number and an alphabetical identifier; e.g., 5a, 5b, 5c.

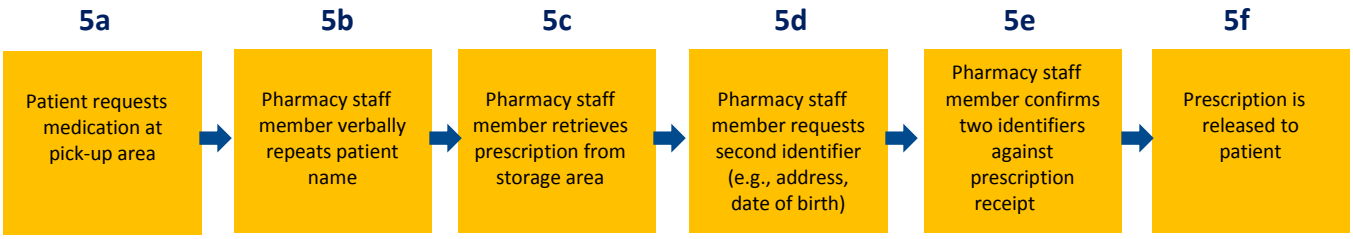


***Figure 4: Block diagram of the sub-process components, labelled with the high level component number and an alphabetic identifier***

These beginning steps are often 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 diagram of the larger process 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)

**More process mapping tips:**

- Label and number all process and sub-process components as you go through the mapping process to keep the team organized.
- Use different colored sticky notes as you move through the FMEA 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 relying on what exists in 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."[9]

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 5).

### 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 5 for an example of a completed failure mode diagram.

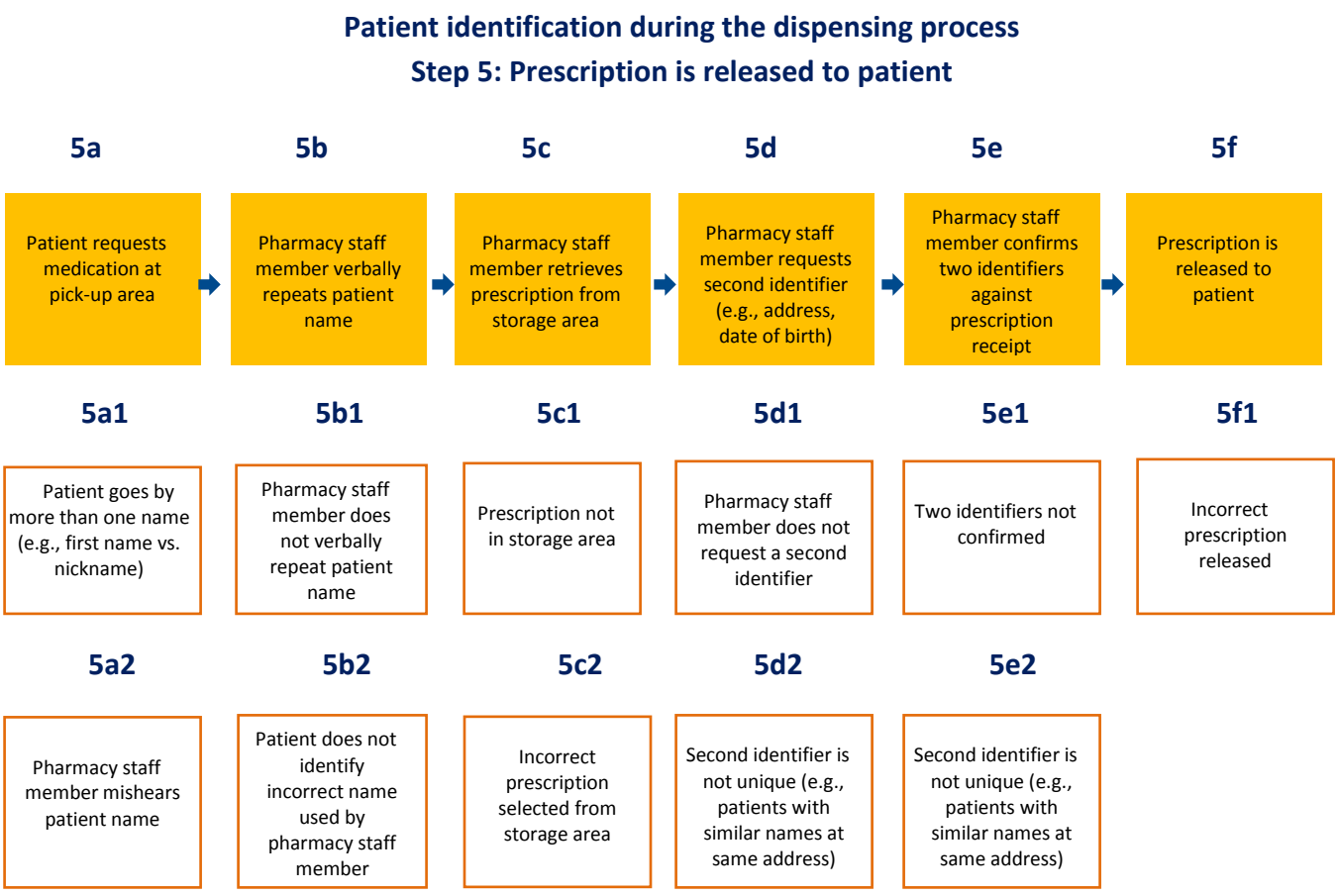


***Figure 5: Diagram showing sub-process components and failure modes (numbered)***

### Notes about brainstorming

Brainstorming is a structured, creative process where a group of people generate as many ideas as possible in a short period of time without judgement of the value of each idea. Brainstorming stimulates ingenuity and encourages many perspectives on an issue, as well as "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, 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 valuable 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 failure 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.

**Brainstorming 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 potential failure modes is not important (Figure 5).

### 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 6).

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, 5d: *Pharmacy staff member requests second identifier (e.g., address, date of birth).* See Appendix 3 for more examples of completed spreadsheets.

**Spreadsheet 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 topic:** Patient identification process for a community pharmacy | | | | | | | **Process component:** #5: Prescription is released to patient | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth) | | | | | | | | | |
| **Failure Mode #** | **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 6: 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 a 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 7). 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).

### 4b) Identify the causes of the failure modes

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 8.

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.

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

**Failure mode causes are the WHYs.**

**Tips:**
- Focus on processes and systems, not on individuals.
- Ask "why?" not "who?"
- Try to identify all possible causes.

This is sometimes referred to as *proactive 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 can therefore 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 is working to understand how the various failure modes relate to each other and ensuring that the analysis has progressed far 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.

| **FMEA topic:** Patient identification process for a community pharmacy | | | | | | | | | | **Process component:** #5 Prescription is released to patient |
|---|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth) | | | | | | | | | | |
| **Failure Mode #** | **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<br>• 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 5d-1 | | | | | | | | |

***Figure 7: FMEA spreadsheet with "Effects" section completed***

| **FMEA subject:** Patient identification process for a community pharmacy | | | | | | | | | | **Process component:** #5 Prescription is released to patient |
|---|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth) | | | | | | | | | | |
| **Failure Mode #** | **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<br>• Loss of confidentiality for other patient re: medication prescribed. | Forgot; distracted; knowledge deficit. | | | | | | | |
| 5d2 | Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building. | Same as 5d-1 | Second identifier is not unique. | | | | | | | |

***Figure 8: FMEA spreadsheet with "Causes" section completed***

## 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, a prioritization step is used to help determine which failure modes are most critical.

As a team, assess the severity of the effect, the estimated frequency of occurrence of the failure mode, 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 x Frequency x Detectability = Criticality Score**

Using a 1-5 score of 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?**

The factor represents the seriousness and severity of the effect (to the patient, provider or 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.[10]

**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, provider or process. |
| Slight effect | 2 | Failure causes minor effects or is a nuisance to the patient, provider 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 anecdotal experience.

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

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

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

| Detectability | Score |
|---|---|
| Always | 1 |
| Likely | 2 |
| Unlikely | 3 |
| Never | 4 |

Cassano Piché et al[11] provide the following questions that can be used to assist in assessing detectability:

1. There is no possible way to detect the error→ Score 4.
2. The failure can be detected only through inspection and is not feasible or readily done → Score 4.
3. Error can be detected with manual inspection but there is no process in place so the detection is left to chance → Score 3.
4. There is a process for double checks or detection but the process relies on vigilance and/or is applied to a sample → Score 3.

In order to score 2 (likely) or 1 (always) there must be reliable processes in place or a subsequent step that makes it readily apparent to the provider that a failure has occurred in the process.

**Detectability 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:

- *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.
- *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 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.

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

**Scoring 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.[7]
- 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 the effects of a failure mode.

### 5b) Prioritize the failure modes

Once the team calculates the scores for all potential failure modes, the next step is to determine what level of risk is acceptable, if any, 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. This 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 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 for an example of an FMEA spreadsheet with the prioritization step 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.

| **FMEA topic:** Patient identification process in a community pharmacy | | | | | | | | | **Process component:** #5 Prescription is released to patient |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 5d: Pharmacy staff member requests second identifier (e.g., address, date of birth) | | | | | | | | | |
| **Failure Mode #** | **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** |
| 5d1 | Pharmacy staff member does not request second identifier. | • Incorrect prescription released leading to risk of harm for patient receiving incorrect medication<br>• Loss of confidentiality for other patient re: medication prescribed. | Forgot; distracted; knowledge deficit. | 4 | 3 | 3 | 36 | Yes | |
| 5d2 | Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building. | Same as 5d-1 | Second identifier is not unique. | 4 | 2 | 3 | 24 | Yes | |

***Figure 9: FMEA spreadsheet with prioritization section completed***

## Step 6: Redesign the process to address 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 principles of human factors engineering and a system approach.

The criticality score, and thus the overall risk associated with a process, can be decreased by reducing the severity of effect or the frequency of occurrence of a failure mode, or improving its detectability.

Decrease risk by:

↓ severity

↓ frequency

↑ detectability

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* illustrated in Figure 1 on page 5 and summarized below in: Designing effective recommendations. Also review the Ontario Critical Incident Learning Bulletin on this topic provided in Appendix 6. Educate the team about the hierarchy of effectiveness 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.

**Designing effective recommendations**

**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

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 location for the dispensary to improve workflow. In any healthcare 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.[12,13]

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, or hospital but the analysis team could forward their concerns to the manufacturer, Health Canada, and ISMP Canada.

See Figure 10: FMEA spreadsheet with "Action" section completed and Figure 11: Summary of recommended actions, timeframes, and measurement plan. See Appendix 3 for more examples of completed FMEA worksheets.

**Action development 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[14,15]; **S**pecific, **M**easurable, **A**ttainable, **R**ealistic, and **T**imely.

| **FMEA subject:** Patient identification process in a community pharmacy<br><br>**Sub-process component:**<br>5d: Pharmacy staff member requests second identifier (e.g., address, date of birth) | | | | | | | **Process component:**<br>#5 Prescription is released to patient | | |
|---|---|---|---|---|---|---|---|---|---|
| **Failure Mode #** | **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** |
| 5d1 | Pharmacy staff member does not request second identifier. | • Incorrect prescription released leading to risk of harm for patient receiving incorrect medication<br>• Loss of confidentiality for other patient re: medication prescribed. | Forgot; distracted; knowledge deficit. | 4 | 3 | 3 | 36 | Yes | Educate all pharmacy staff on the importance of correct patient identification and need to follow proper procedures.<br><br>Develop a standardized process requiring documentation of the second identifier used to verify the patient's identity.<br><br>Post information for patients explaining the identity verification process and the rationale; request their assistance in ensuring it takes place.<br><br>Implement a photo identification process for selected high alert medications (e.g., methadone).<br><br>Assess opportunity for automation (e.g., barcoding) as a long-term goal. |
| 5d2 | Patients with similar names at same address, e.g., family members with same name (Jr./Sr.); apartment building. | Same as 5d-1 | Second identifier is not unique. | 4 | 2 | 3 | 24 | Yes | Flag known patients with same name in the pharmacy computer system indicating requirement for date of birth identification for all prescriptions.<br><br>Ensure addresses for multi-unit dwellings include the specific unit. |

***Figure 10: FMEA spreadsheet with "Action" section completed***

| **FMEA Topic:** Patient identification process in a community pharmacy | | **Process component:** #5: Prescription is released to patient | | **Sub-Process component:** #5d: Pharmacy staff member requests second identifier | |
|---|---|---|---|---|---|
| **Failure mode #** | **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 | Owner/manager, senior pharmacist | Education sessions completed and written reminders posted and included in orientation information for new staff. |
| | Develop a standardized process requiring documentation of the second identifier used to verify the patient's identify. | Medium (simplification/ standardization) | 1-3 months | Senior pharmacist, senior pharmacy technician | Periodic audits of documentation by senior pharmacist. |
| | Post information for patients explaining the identify verification process and the rationale and requesting their assistance in ensuring it takes place. | Low (policy development/ education) | 1-3 months | Owner/manager | Information posted and visible to patients. |
| | Implement photo identification for selected high-alert medications (e.g., methadone). | Medium (reminders, checklists, double-checks) | 3-6 months | Owner/manager, senior pharmacy technician | Periodic audit and patient satisfaction survey. |
| | Assess opportunity for automation (e.g., barcoding) as a long-term goal. | High (automation/ computerization) | More than 12 months | Owner/manager | 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 by senior pharmacy technician of known similar names to check that flagging system is in place and working. |
| | 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 11: Summary of recommended actions, timeframes, and measurement plan***

## Step 7: Analyze and test the proposed 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-map the process and sub-process components and reassess 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."[16]
- 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.[17] (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 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 a small group of individuals to implement and monitor the actions. It is important to establish specific time frames for completion of each action. 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 new risks 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.

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

# Conclusion

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

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 patient care. 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.

**Tip 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

# Appendices



*Please note that examples are provided for learning purposes only and may not fully reflect typical clinical circumstances and current best practices for the selected topics.

# 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. 8-11)

- 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. 11-13)

- 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.13-15)

- 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.15-18)

- 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 x frequency x 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 60-70%)

**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. 18-21)

- 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 change

**Tips:**

- Improve safety based on:
  - ↓ Severity
  - ↓ Frequency
  - ↑ Detectability
- 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. 22)

- 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 (p. 22)

- 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:** _____

| Team members | Position |
|---|---|
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| | |
| **Team leader(s)** | |
| | |
| | |
| **Recorder(s)** | |
| | |
| | |

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: FMEA spreadsheet

| FMEA topic: | | | | | | | Process component: | | |
|---|---|---|---|---|---|---|---|---|---|
| Sub-process component: | | | | | | | | | |
| Failure Mode # | 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 |
| | | | | | | | | | |
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## Appendix 3.2: FMEA action and measurement plan summary

| FMEA topic: | | Process component: | | Sub-process component: | |
|---|---|---|---|---|---|
| Failure Mode number | Recommended Action | Strength of action | Time frame for implementation | Individual(s) responsible | Measurement plan |
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## Appendix 4: FMEA Examples

# Appendix 4.1: 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 of a typical morning routine.

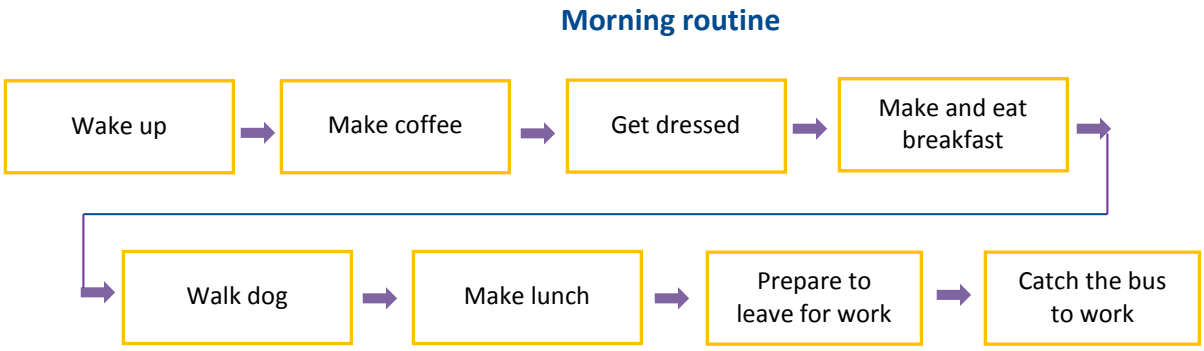


***Figure A: High level process – block diagram (process map)***

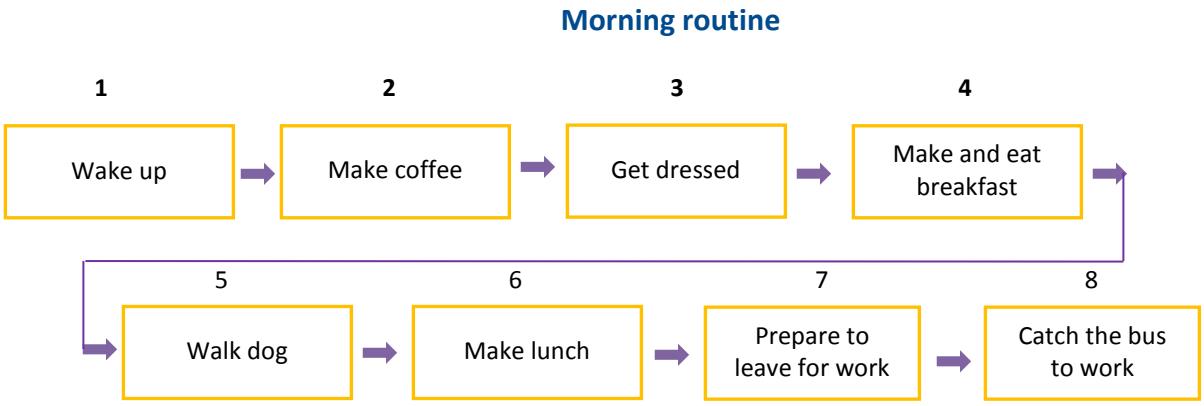


***Figure B: Block diagram of the high level components, numbered***

Once you have mapped the high level process, decide as a team whether or 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 (next page) shows the first process component selected for detailed analysis – *make coffee* (considered by many to be a critical part of their morning routine ☺).

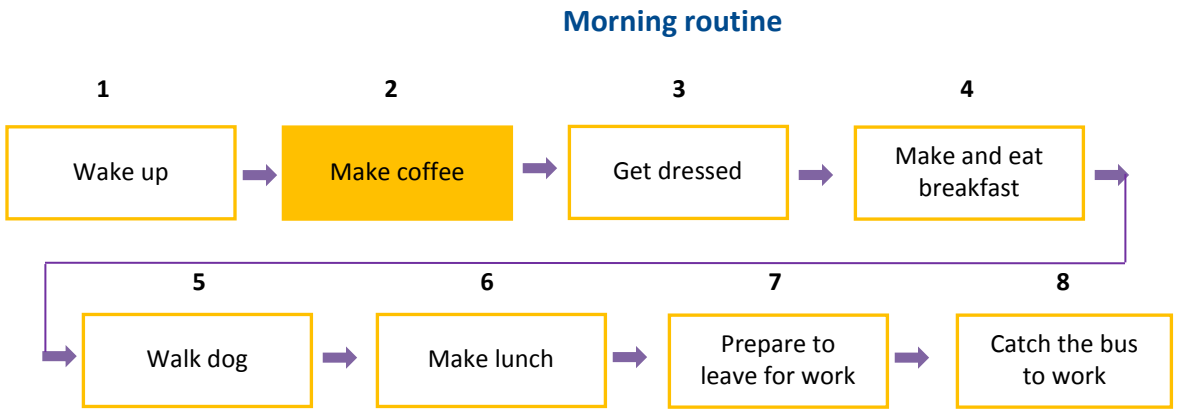


***Figure C: Block diagram showing the process components selected for more detailed analysis***

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.

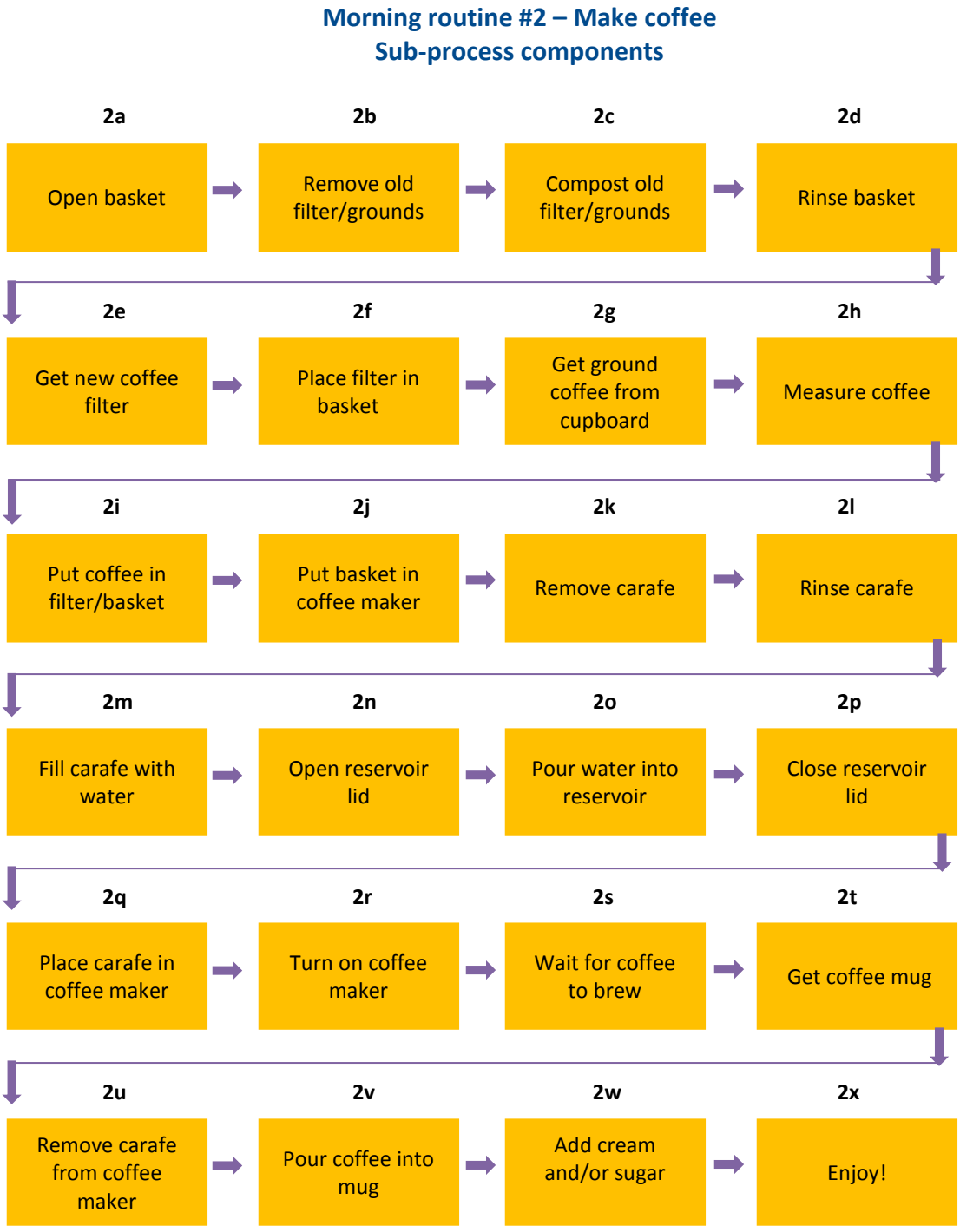


***Figure D: Sub-process components for Step 2: Make coffee***

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.

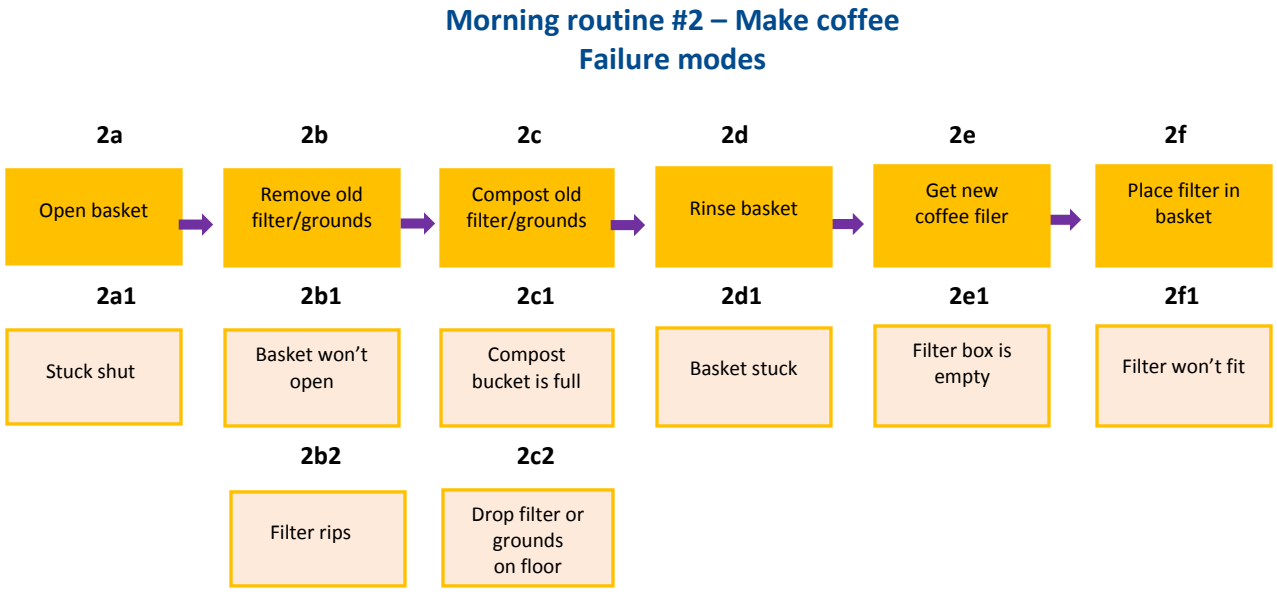


***Figure E: Potential failure modes identified and numbered for each component of the sub-process***

## 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 modes, 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 topic:** Morning routine | | | | | | | **Process component:** #2 Make coffee | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 2b: Remove old filter/grounds | | | | | | | | | |
| **Failure Mode #** | **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** |
| 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 re-usable filter. |

***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 (decreased from 24).

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 for a completed action and measurement template for the sub-process component analyzed.

| **FMEA topic:** Morning routine | | **Process component: #2:** Make coffee | | **Sub-process component:** 2b – Remove old filer/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 | Administrative Assistant | Follow up with staff in 6 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***

## 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 examples are intended to illustrate more complex processes in healthcare settings.

# Appendix 4.2: Managing drug shortages – pharmacy process[18,19,20]

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

## Step 2: Diagram the process

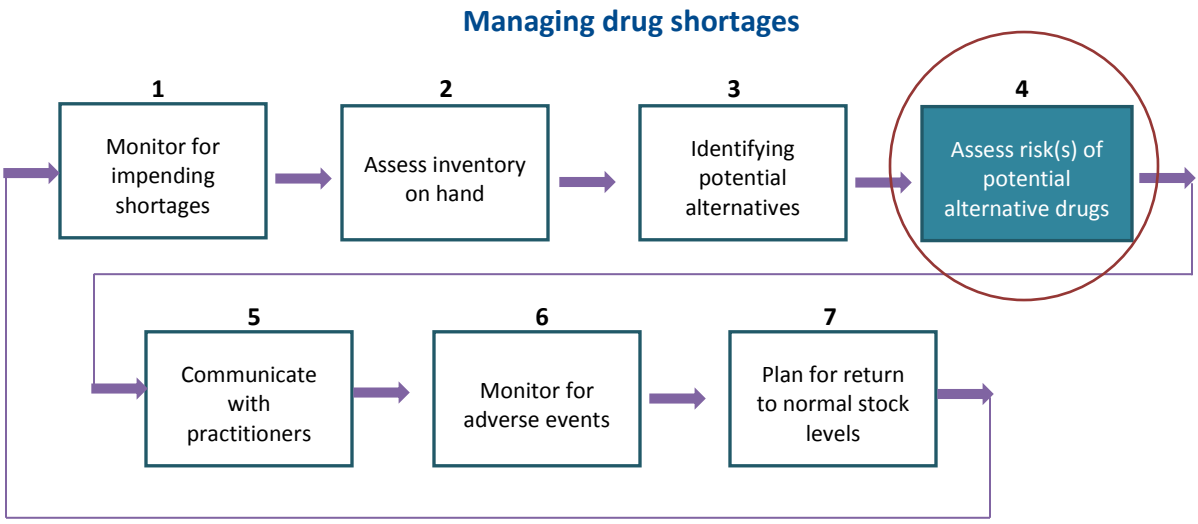


*Figure A: High level process components for Managing drug shortages*

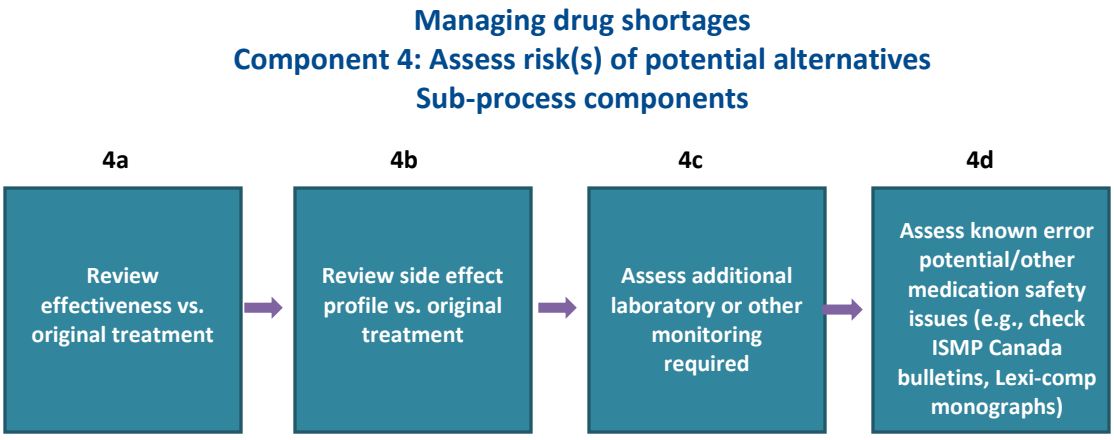


*Figure B: Sub-process components for Step 3: Assess risk(s) of potential alternatives*

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

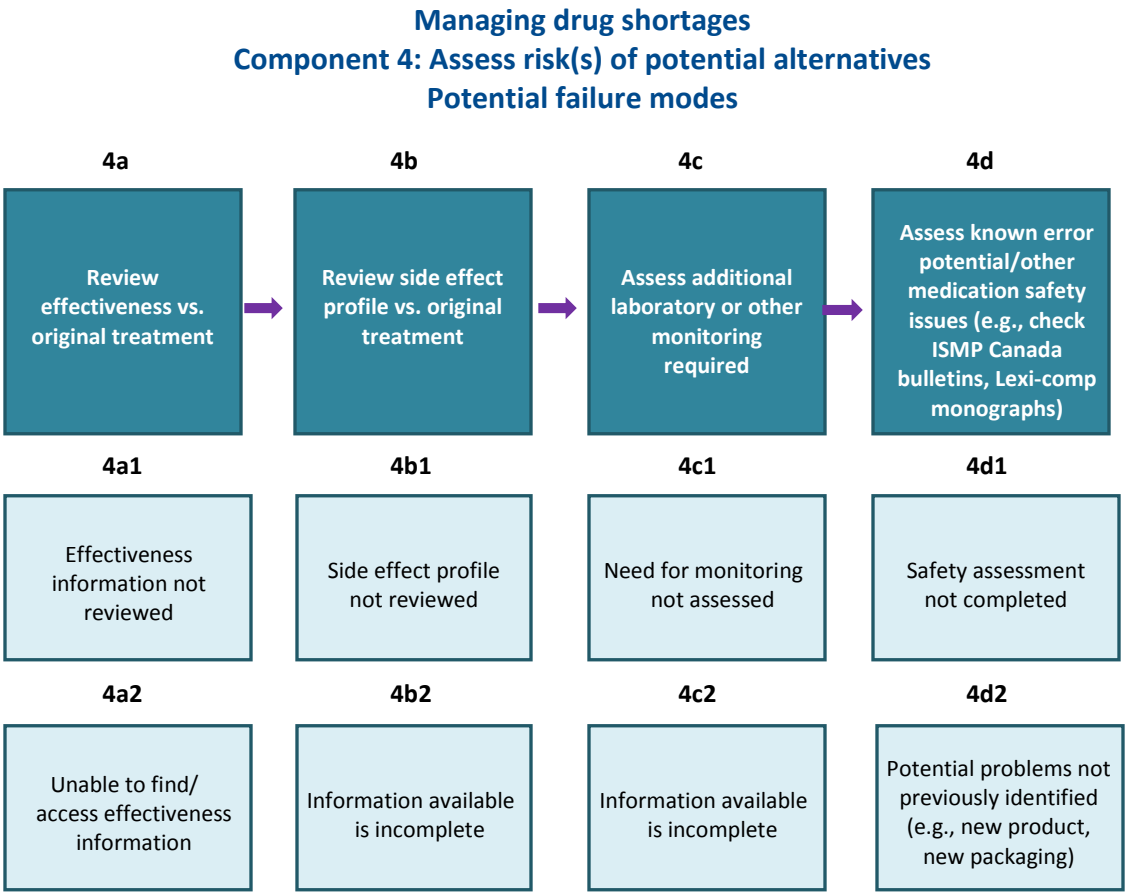


***Figure C: Potential failure modes for Component 4: Assess risk(s) of potential alternatives***

## 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 topic:** Managing drug shortages | | | | | | | **Process component:** #4: Assess risk(s) of potential alternatives | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 4a: Review effectiveness vs. original treatment | | | | | | | | | |
| **Failure Mode #** | **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** |
| 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 | Yes | Develop checklist for risk assessment as part of drug shortages protocol so that important components not omitted. |
| 4a2 | Unable to find/access effectiveness information | Sub-optimal treatment/treatment failure | Unsure how to access. | 4 | 3 | 3 | 36 | Yes | Post quick reference instructions for accessing online resources on or adjacent to computer stations.<br><br>Provide training for all staff on how to access online resources. |

***Figure D: Completed FMEA spreadsheet for sub-process***

| **FMEA topic:** Managing drug shortages | | | | | | | **Process component:** #4: Assess risk(s) of potential alternatives | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 4b: Review side effect profile vs. original treatment | | | | | | | | | |
| **Failure Mode #** | **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** |
| 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 topic:** Managing drug shortages | | | | | | | **Process component:** #4: Assess risk(s) of potential alternatives | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 4c: Assess additional laboratory or other monitoring required | | | | | | | | | |
| **Failure Mode #** | **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** |
| 4c1 | Need for monitoring not assessed | Patient does not identify early earning 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).<br><br>Provide education for pharmacy staff on roles and responsibilities related to drug shortages (Repeat of 4a1).<br><br>Work with local prescribers to identify collaborative opportunities regarding therapeutic drug monitoring. |
| 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 and remove/replace outdated references. |

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

| **FMEA topic:** Managing drug shortages | | | | | | | **Process component:** #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 #** | **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** |
| 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).<br><br>Disseminate ISMP Canada Safety Bulletins to all pharmacy staff. |
| 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.<br><br>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 topic:** Managing drug | | **Process component: #4:** Assess risk(s) of potential alternatives | | **Sub-process component:** n/a | |
|---|---|---|---|---|---|
| **Failure Mode #** | **Recommended action** | **Strength of action** | **Timeframe for implementation** | **Individual(s) responsible** | **Measurement plan** |
| 4a1<br>4b1<br>4c1 | Develop a checklist for risk assessment as part of drug shortages protocol so that important components are not omitted. | Medium (Reminders/ checklists/double checks) | 1 month | Senior pharmacist and inventory technician | Periodic audit by Owner/manager of process for managing drug shortages. |
| 4a1<br>4c1 | Provide education for pharmacy staff on roles and responsibilities related to drug shortages. | Low (policy development/ education) | 1 month | Pharmacy owner/ department manager | Educations sessions(s) completed; information available in an accessible location or reference. |
| 4a2 | Post quick reference instructions for accessing online resources on or adjacent to computer stations. | Medium (reminders/ checklists/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 | Pharmacy owner/ department manager and delegated pharmacist | Collaborative protocol(s) developed.<br>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. |
| 4d1 | Disseminate ISMP Canada Safety Bulletins to all pharmacy staff. | Low (Education/ Information) | 1 month | Pharmacy owner/ department manager | All staff receives ISMP Canada Safety Bulletins via internal email system or hard copy placed in communication book with sign off.<br>*Continued…* |

| **FMEA topic:** Managing drug | | **Process: #4:** Assess risk(s) of potential alternatives | | **Sub-process step:** n/a | |
|---|---|---|---|---|---|
| **Failure Mode #** | **Recommended action** | **Strength of action** | **Timeframe for implementation** | **Individual(s) responsible** | **Measurement plan** |
| 4d2 | Report medication incident(s) according to local procedures; consider reporting via ISMP Canada/ CIHI as applicable. | Low<br>(Policy development) | 1 month<br>(process in place) | Owner/ manager | Review of reported medication incidents as standing item for pharmacy staff meetings. |
| 4d2 | Ensure analysis of medication incident(s). | Low-high depending on issued identified<br>Low if solely policy related | 1 month<br>(process in place) | Owner/ manager | Quarterly review reports completed. |

***Figure H: Completed action and measurement template for process component 4: Assess risk(s) of potential alternatives***

# Appendix 4.3: Patient assessment process (related to medication use)

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

## Step 2: Diagram the process

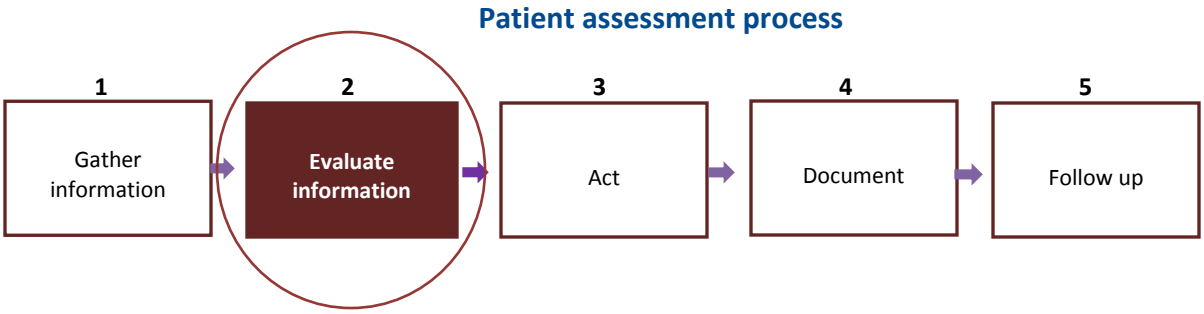


*Figure A: High level process components for Patient assessment process*

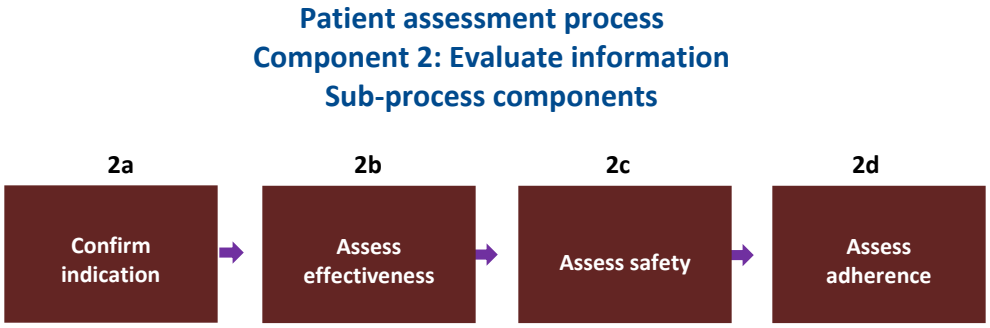


*Figure B: Sub-process components for Step 2: Evaluate information*

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

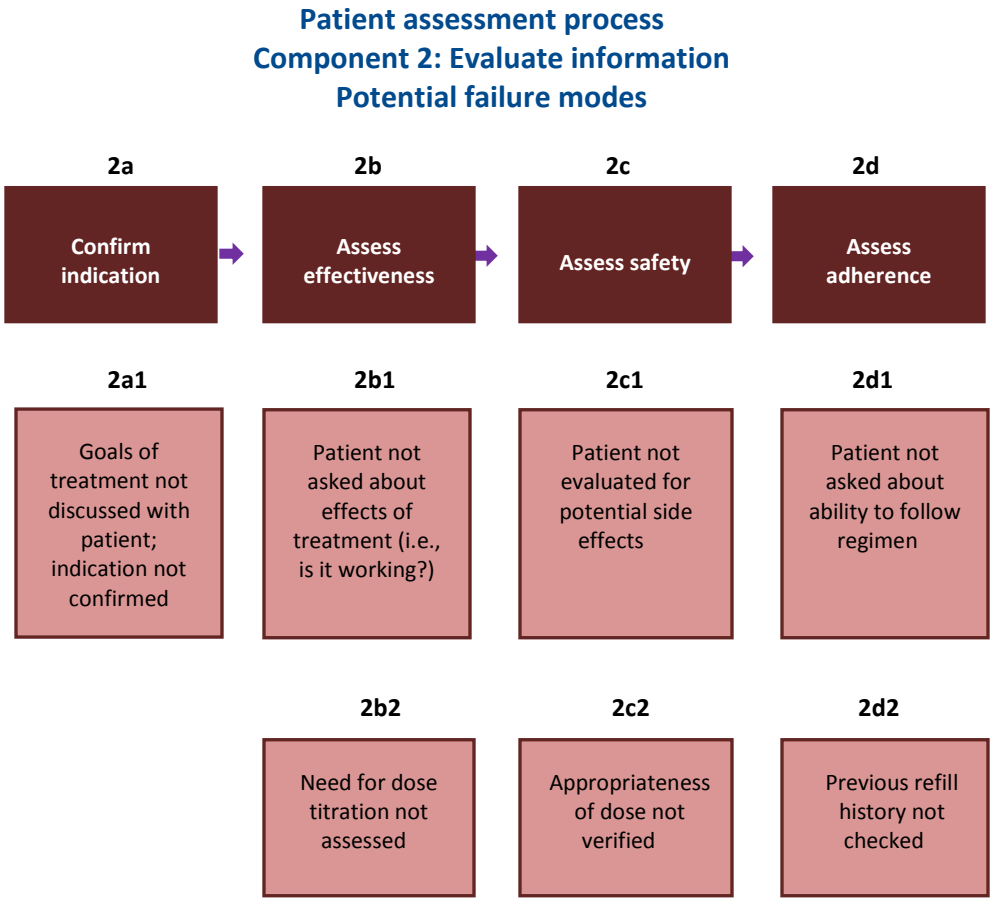


***Figure C: Potential failure modes for Component 2: Evaluate information***

## 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 topic: Patient assessment process re medication use** | | | | | | | **Process component:** #2: Evaluate information | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 2a – Confirm indication | | | | | | | | | |
| **Failure Mode #** | **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** |
| 2a1 | Goals of treatment not discussed with patient; indication not obtained | Unable to assess effectiveness; patient received 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, e.g., 5 questions to ask about your medications http://www.ismp-canada.org/medrec/5questions.htm |

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

| **FMEA topic:** Patient assessment process re medication use | | | | | | | **Process component:** #2: Evaluate information | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 2b – Assess effectiveness | | | | | | | | | |
| **Failure Mode #** | **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** |
| 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 healthcare provider. | 4 | 2 | 3 | 24 | Yes | Develop a checklist to facilitate standardized patient interview process, e.g. 5 questions to ask about your medications http://www.ismp-canada.org/medrec/5questions.htm |
| 2b2 | Need for dose titration not assessed. | Range from treatment failure to serious toxicity. | Slip, lapse seen as responsibility of a different member of care team. | 4 | 3 | 3 | 36 | Yes | Work collaboratively with other health team members to develop titration protocols for commonly used medications, including criteria for patient to return to prescriber. |

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

| **FMEA topic:** Patient assessment process re medication use | | | | | | | **Process component:** #2: Evaluate information | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 2c – Assess safety | | | | | | | | | |
| **Failure Mode #** | **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** |
| 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 healthcare provider. | 5 | 3 | 3 | 45 | Yes | Develop a checklist to facilitate standardized patient interview process.<br>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. |
| 2c2 | Appropriateness of dose not verified. | Range from treatment failure to serious toxicity. | Pharmacy/prescriber software does not support automated dose range checking.<br>No standardized expectation to verify dosing for particularly vulnerable populations such as pediatrics, oncology, known renal failure, etc. | 5 | 4 | 3 | 60 | Yes | Work with pharmacy information system vendors to implement automated dose range checking.<br>Work with information system vendor to implement ability to "flag" vulnerable populations for addition checks.<br>In the absence of automated systems, develop a manual checklist to alert providers about patients/drugs that require additional review. |

***Figure F: Completed FMEA spreadsheet for sub-process component 2c: Assess safety***

| **FMEA topic:** Patient assessment process re medication use | | | | | | | **Process component:** #2: Evaluate information | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 2d – Assess adherence | | | | | | | | | |
| **Failure Mode #** | **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** |
| 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 healthcare provider. | 5 | 3 | 3 | 45 | Yes | Routinely review the prescription history during dialogue with patients. |
| 2d2 | Previous refill history not checked (failure to review information from provincial prescription records (e.g., ODB viewer, Netcare, Pharmanet). | Potential lost opportunity to identify adherence issues. | Workload; not part of routine process. | 3 | 5 | 3 | 45 | Yes | Routinely review the prescription history where available to support patient dialogue re adherence. |

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

| **FMEA topic:** Patient assessment process re medication use | | **Component: #2:** Evaluate information | | **Sub-process component:** n/a | |
|---|---|---|---|---|---|
| **Failure Mode #** | **Recommended action** | **Strength of action** | **Timeframe for implementation** | **Individual(s) responsible** | **Measurement plan** |
| 2a1<br>2b1<br>2c1<br>2d1 | Develop a checklist to facilitate a standardized patient interview process. | Medium (Reminders/ checklist/double checks) | 1-3 months | Senior pharmacist and delegated pharmacist | Checklist in place and available for use.<br>Periodic audits of checklist documentation by owner/manager. |
| 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 | Owner/ manager and delegated pharmacist | Protocols in place.<br>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.<br>• Develop standardized process for pharmacy technician to print information when entering prescriptions into computer system. | Low (Education/ Information) | 1 month | Senior pharmacist and senior pharmacy technician | Periodic audits by owner/manager 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 | Owner/ manager 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 | Owner/ mnaager 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<br>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 for a community pharmacy****

** Actions provided in Figures D, E, F have been generalized for any care provider. Figure H provides specific actions for a community pharmacy.*

# Appendix 4.4: IV Patient Controlled Analgesia (PCA)*

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

## Step 2: Diagram the process

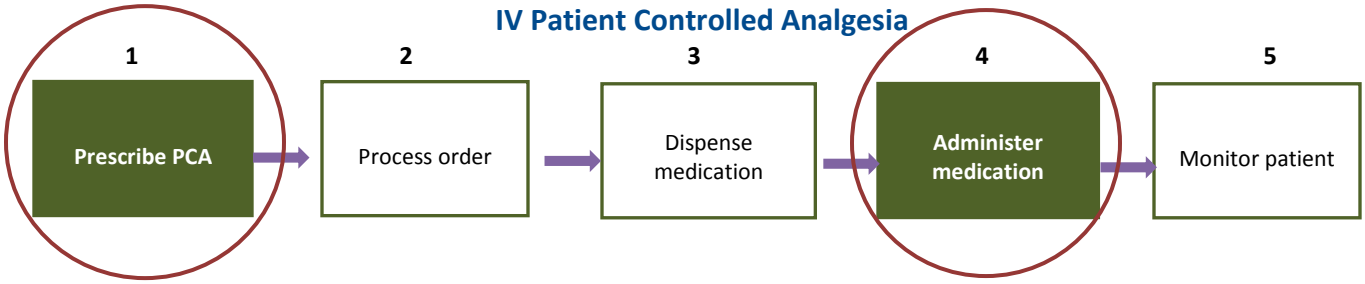


*Figure A: High level process components for IV Patient Controlled Analgesia (PCA)*

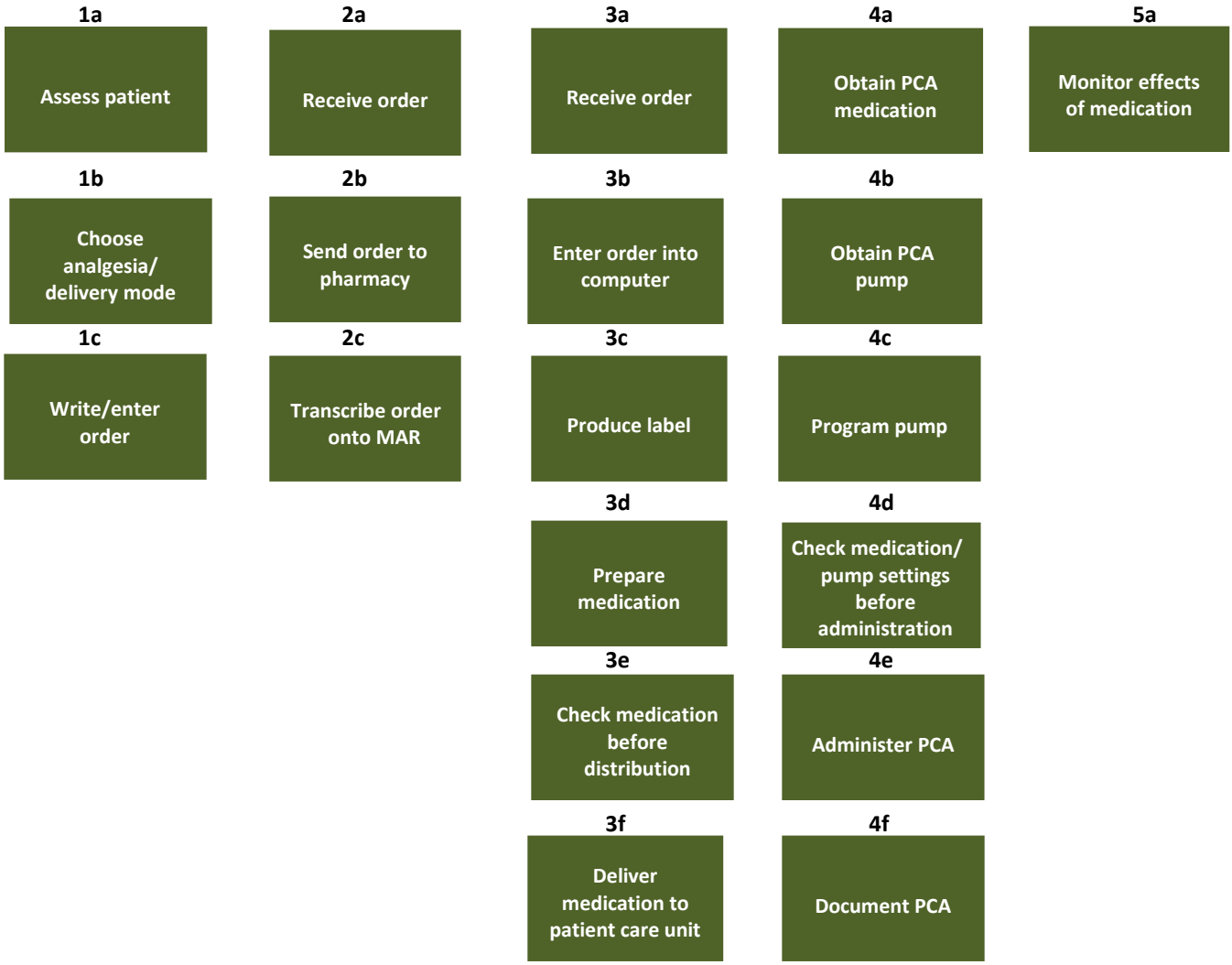


*Figure B: Sub-process components for Steps 1 to 5*

*Adapted with permission, from: Institute for Safe Medication Practices (US), 2005.[21]

In this case example, the prescribing and administration components #1 (Prescribe PCA) and # 4 (Administer medication) have been selected for detailed analysis. See https://www.ismp.org/tools/FMEAofPCA.pdf for the original FMEA from which this example was adapted.

## Component # 1: Prescribe PCA

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

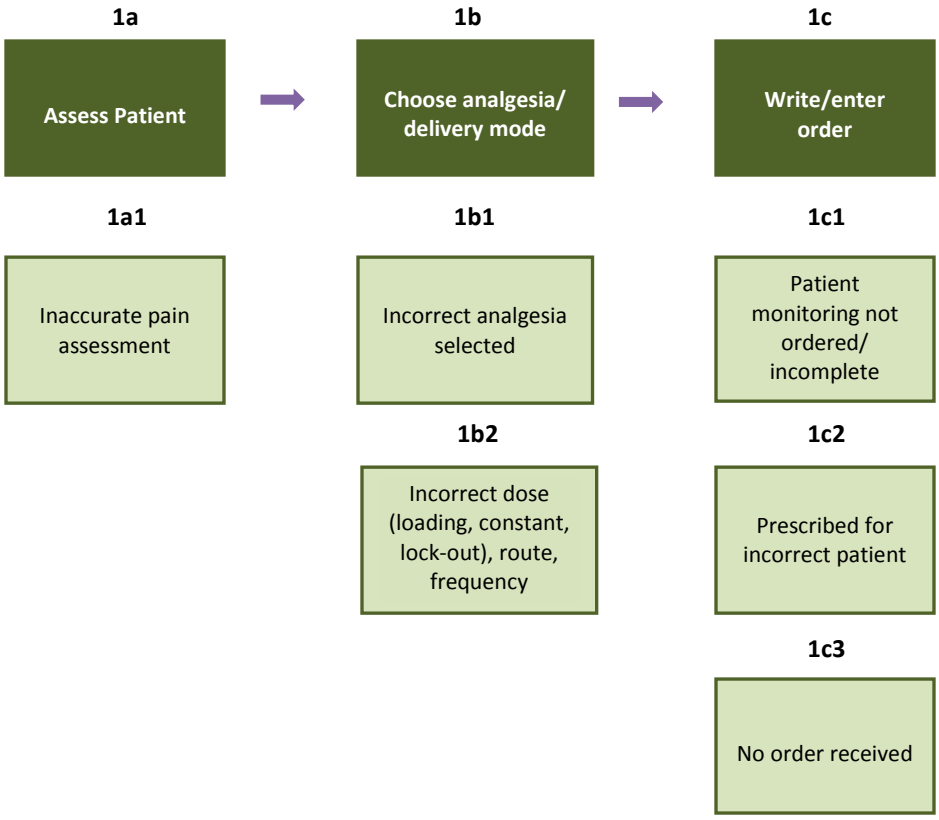


*Figure C: Potential failure modes for Step 1: Prescribe PCA*

### Step 4 – Identify the effects and causes of the failure modes
### Step 5 – Prioritize the potential failure modes
### Step 6 – Redesign the process

| **FMEA topic:** IV Patient Controlled Analgesia (PCA) | | | | | | | **Process component:** #1: Prescribe PCA | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 1a – Assess patient | | | | | | | | | |
| **Failure Mode #** | **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** |
| 1a1 | Inaccurate pain assessment | Poor pain control | Cultural influences; patient unable to articulate pain level | 3 | 2 | 2 | 12 | N | No action planned – below cut-off score of 16; usually detectable. |

***Figure D: Completed FMEA spreadsheet for sub-process component 1a: Assess Patient***

*Note: Based on evaluation of all criticality scores, failure modes with a criticality score of 16 or higher were selected for action.*

| **FMEA topic:** IV Patient Controlled Analgesia (PCA) | | | | | | | **Process component:** #1: Prescribe PCA | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 1b – Choose analgesia/delivery mode | | | | | | | | | |
| **Failure Mode #** | **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** |
| 1b1 | Incorrect analgesia selected | Suboptimal dosing/ treatment (dose too high/too low); allergy | Patient factors (e.g. age, renal function, tolerance to opioids, concomitant use of other opioids) not assessed; standard PCA protocols not followed (or not available); unclear criteria for patient selection for PCA; knowledge deficit. | 4 | 2 | 3 | 24 | Y | *Short term*<br>• Selection criteria for PCA.<br>• Standard PCA protocol with education on use.<br>• Point of care access to drug information.<br>*Medium term*<br>• Enhanced clinical pharmacy support.<br>*Long term*<br>• CPOE with decision support. |
| 1b2 | Incorrect dose (loading, continuous lock-out), route, frequency | Overdose; under-dose; ADR | Knowledge deficit; mental slip; incorrect selection from list; information about drug not available. | 4 | 2 | 2 | 16 | Y | *Short term*<br>• Standard PCA protocol.<br>*Medium term*<br>• Enhanced clinical pharmacy support.<br>*Long term*<br>• CPOE with decision support. |

***Figure E: Completed FMEA spreadsheet for sub-process component 1b: Choose Analgesia/Delivery Mode***

| **FMEA topic:** IV Patient Controlled Analgesia (PCA) | | | | | | | **Process component:** #1: Prescribe PCA | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 1c – Write / Enter Order | | | | | | | | | |
| **Failure Mode #** | **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** |
| 1c1 | Patient monitoring not ordered/incomplete | Missed opportunity to prevent /mitigate harm | Knowledge deficit; mental slip; lack of standardized order sets | 5 | 2 | 2 | 20 | Yes | *Short term:*<br>• Standard PCA order sets with monitoring guidelines. |
| 1c2 | Prescribed for incorrect patient | Incorrect patient received; inappropriate drug and dose; ADR; allergy | Similar patient names; patient identifier not clear; patient name does not appear on screen when ordering medication | 4 | 2 | 3 | 24 | Yes | *Long term:*<br>• Visible demographic information on order entry screens.<br>• Alerts for look-alike patient names. |
| 1c3 | No order received | Poor pain control | Unable to reach covering physician; order transmission failure | 3 | 2 | 2 | 12 | No | No action planned – below cut-off score of 16; usually detectable. |

***Figure F: Completed FMEA spreadsheet for sub-process component 1c: Write/Enter Order***

| **FMEA topic:** IV patient controlled analgesia (PCA) | | **Process component #1:** Prescribe PCA | | | |
|---|---|---|---|---|---|
| **Failure Mode #** | **Recommended action** | **Strength of action** | **Timeframe for implementation** | **Individual(s) responsible** | **Measurement plan** |
| 1b1 | Selection criteria for PCA | Medium (Simplification/ Standardization) | 3-6 months | Pain Service | Criteria completed and included in order sets |
| | Point of care access to drug information | High (Automation/ Computerization) | 6-12 months | Clinical Informatics Dept. | Audit of care are computers |
| 1b1<br>1b2 | Standardized PCA protocol with education on use | Low (Education/ Information) | 3-6 months | Unit educators | Education complete for 75% of affected team members |
| | Enhanced clinical pharmacy support for PCA management | Medium (Reminders/ Double checks) | 6-12 months | Director of pharmacy | Audit for clinical pharmacist consultation for patients receiving PCA |
| | CPOE with decision support | High (Automation/ Computerization) | More than 12 months | Clinical Informatics Dept. | Program implementation and ongoing testing of functionality |
| 1c2 | Visible demographic information on order entry screens. | Medium (Reminders/ Double checks) | More than 12 months | Clinical Informatics Dept. | Demographic information available on order entry screens |
| | Alerts for look-alike patient names. | | | | Look alike patient name alerts implemented |

***Figure G: Completed action and measurement plan spreadsheet for Step 1: Prescribe PCA***

## Component # 4: Administer medication

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

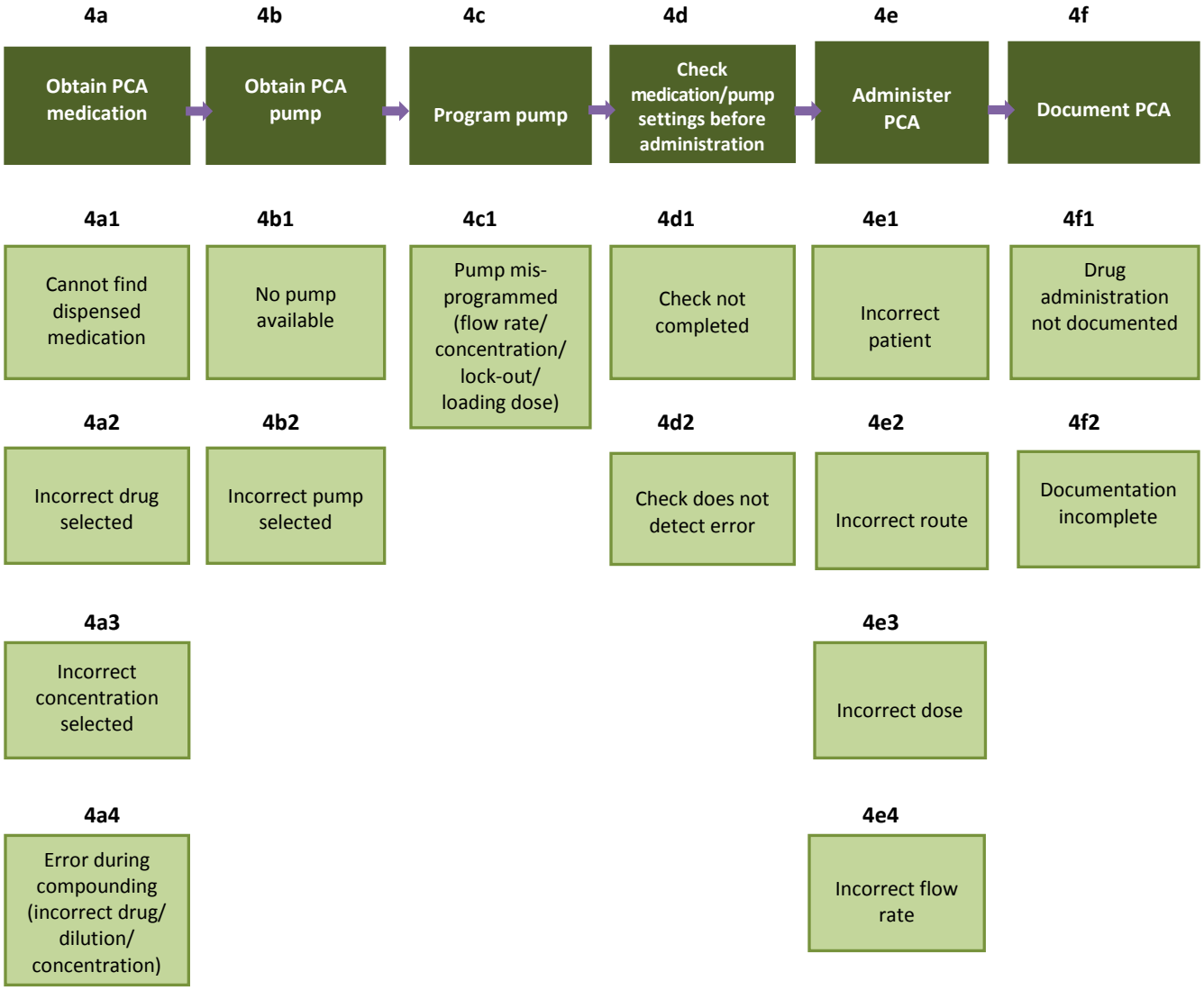


*Figure H: Potential failure modes for Component 4: Administer Medication*

### Step 4 – Identify the effects and causes of the failure modes
### Step 5 – Prioritize the potential failure modes
### Step 6 – Redesign the process

| **FMEA topic:** IV Patient Controlled Analgesia (PCA)<br>**Sub-process component:**<br>4a – Obtain PCA Medicatin | | | | | | | **Process component:**<br>#4: Administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Failure Mode #** | **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** |
| 4a1 | Cannot find dispensed medication | Delay in therapy; poor pain control | Pharmacy delivery problem; no communication to nurse that medication delivered | 2 | 3 | 1 | 6 | No | No action planned – below cut-off score of 16; usually detectable |
| 4a2 | Incorrect drug selected | Overdose; under-dose; allergic reaction; poor pain control | Look-alike products stored near each other (automated dispensing cabinets, floor stock, refrigerator); knowledge deficit. | 4 | 2 | 3 | 24 | Yes | *Short term:*<br>• Segregate look alike/ sound alike drug names.<br>• Consider labelling safeguards (e.g. TALLman lettering).<br>*Medium term:*<br>• Standardize PCA protocols and concentrations to limit choices. Independent double checks |
| 4a3 | Incorrect concentration | Overdose; under-dose; poor pain control | Same as above; unnecessary multiple concentrations available; calculation error | 4 | 3 | 3 | 36 | Yes | Same as above |
| 4a4 | Error during compounding (incorrect drug/ dilution/ concentration) | Overdose/under-dose; allergic reaction | Inconsistent centralized IV admixture procedures; bedside preparation during off hours; failure of double check systems. | 4 | 4 | 4 | 64 | Yes | *Short term:*<br>• Review centralized IV admixture process, ensure standardized approach.<br>• Review process for after hour access.<br>*Medium term:*<br>• Prepare prefilled syringes/cassettes or purchase from outsource vendor. |

***Figure I: Completed FMEA spreadsheet for sub-process component 4a: Obtain PCA Medication***

| **FMEA topic:** IV Patient Controlled Analgesia (PCA)<br>**Sub-process component:**<br>4b – Obtain PCA Pump | | | | | | | **Process component:**<br>#4: Administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Failure Mode #** | **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 | No pump available | Delay in therapy leading to poor pain control; use of incorrect pump; overdose/underdose | Inadequate pump supply; bottlenecks with cleaning process. | 3 | 2 | 1 | 6 | No | No actions planned; low frequency event; low criticality score. |
| 4b2 | Incorrect pump selected | Delay in therapy; poor pain control; programming error leading to incorrect dose (overdose/ underdose). | Multiple types of pumps, PCA pumps not specifically identified. | 4 | 2 | 3 | 24 | Yes | *Medium term*:<br>• Review number of pumps available.<br>• Plan to involve pharmacy and nursing staff in future purchasing decisions. |

***Figure J: Completed FMEA spreadsheet for sub-process component 4b: Obtain PCA Pump***

| **FMEA topic:** IV Patient Controlled Analgesia (PCA)<br>**Sub-process component:**<br>4c – Program Pump | | | | | | | **Process component:**<br>#4: Administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Failure Mode #** | **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 | Pump mis-programmed (flow rate, concentration, lockout, loading dose) | Overdose; under-dose leading to poor pain control or adverse event | Pump design problem leading to programming errors; lack of standard concentrations; failure to limit variety of products used; knowledge deficit; confusion between units of measure (mg vs. mcg); mechanical failure. | 4 | 3 | 3 | 36 | Yes | *Short term:*<br>• Independent check of programming at bedside.<br>*Medium term:*<br>• Limit variety of pumps in use.<br>• Ensure staff training prior to use.<br>• Standardize medications and concentrations used.<br>*Long term:*<br>• Involve staff in purchasing decisions for new pumps.<br>• Purchase pumps that are easy to use.<br>• Use FMEA process to determine potential failure modes for new pumps. |

***Figure K: Completed FMEA spreadsheet for sub-process component 4c: Program Pump***

| **FMEA topic:** IV Patient Controlled Analgesia (PCA)<br>**Sub-process component:**<br>4d – Check medication/pump settings before administration | | | | | | | **Process component:**<br>#4: Administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Failure Mode #** | **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** |
| 4d1 | Check not completed | Potential error not detected and likely to reach the patient | Inadequate staffing patterns; check not seen as a priority; check process not integrated into the way care is delivered. | 4 | 3 | 3 | 36 | Y | *Medium term:*<br>• Engage staff in developing culture of safety.<br>• Review staffing patterns and workflow to eliminate barriers to consistent checks (i.e. build check process into care delivery model). |
| 4d2 | Check does not detect error | Overdoes/under-dose/incorrect medication leading to adverse event | Environmental factors (distractions, space, lighting, noise); inefficient workflow; human factors (e.g. slip, lapse); check not completed at beside (to ensure check of pump settings, patient, line attachments). | 4 | 3 | 3 | 36 | Y | *Short term*<br>• Provide training for staff on how to conduct independent checks (e.g., include verbalizing check so staff "see and hear" critical information). |

***Figure L: Completed FMEA spreadsheet for sub-process component 4d: Check medication/pump settings before administration***

| **FMEA topic:** IV Patient Controlled Analgesia (PCA) | | | | | | | **Process component:** #4: Administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 4e – Administer PCA | | | | | | | | | |
| **Failure Mode #** | **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** |
| 4e1 | Incorrect patient | Overdose; under-dose; allergic response; ADR; delay in therapy; poor pain control | Failure of double checks at bedside; failure to check/ absent name bracelet; ordered for incorrect patient/ transcribed on incorrect MAR. | 4 | 2 | 3 | 24 | Yes | *Short term:*<br>• Ensure 2 identifiers for all medication administrations<br>*Medium term:*<br>• Provide patient education regarding need for 2 identifiers and engage patients/ family caregivers to participate in identification process. |
| 4e2 | Incorrect route | ADR; poor pain control | Catheter attachment confusion; failure of double checks at bedside. | 4 | 23 | 3 | 24 | Yes | *Short term*<br>• Provide training (see 4d2). |
| 4e3 | Incorrect dose | Overdose; under-dose; adverse drug event/ poor pain control | Failure of double checks; family/nurse activation instead of patient activation; inadequate patient/ family education before use; use on patients who cannot activate their own PCA; patient/ staff/family tampering (drug diversion); patient misuse (accidental activation due to confusion with call-bell, etc.) | 4 | 2 | 3 | 24 | Yes | *Short term*<br>• Provide training (see 4d2).<br>*Medium term:*<br>• Engage staff in developing culture of safety.<br>• Review staffing patterns and workflow to eliminate barriers to consistent checks (i.e. build check process into care delivery model). |
| 4e4 | Incorrect flow rate | Same as above | Failure of double checks; pump not protected from free flow; mechanical failure; insufficient preventive maintenance of pump; inaccurate pump calibration; insufficient power source for pump. | 4 | 3 | 2 | 24 | Yes | *Short term*<br>• Provide training (see 4d2)<br>• Review processes for routine pump maintenance.<br>• Review processes for power backup for infusion pumps.<br>*Medium/Long term*<br>• Same as 4e3.<br>• Ensure all new pumps purchased have free flow protection |

***Figure M: Completed FMEA spreadsheet for sub-process component 4e: Administer PCA***

| **FMEA topic:** IV Patient Controlled Analgesia (PCA)<br>**Sub-process component:**<br>4f – Document PCA | | | | | | | **Process component:**<br>#4: Administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Failure Mode #** | **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** |
| 4f1 | Drug administration not documented | Inability to fully evaluate pain management; potential duplicate therapy. | Human factors/ environmental (e.g. distractions; workload; workflow process; multiple MAR pages/ screens). | 3 | 2 | 3 | 18 | Y | *Short term*:<br>• Ensure review of documentation for completeness prior to end of shift.<br>*Medium term*:<br>• Implement bedside documentation (e.g. flow sheets, computers on wheels) of PCA monitoring parameters.<br>*Long term*:<br>• Periodically review MAR format (paper/electronic) with direct care staff to assess usability and make revisions as recommended. |
| 4f2 | Documentation incomplete | Inability to fully evaluate pain management; potential duplicate therapy. | Human factors/ environmental (e.g. distractions; workload; workflow process; multiple MAR pages/ screens). | 3 | 3 | 3 | 27 | Y | Same as above. |

***Figure N: Completed FMEA spreadsheet for sub-process component 4f: Document PCA***

| **FMEA topic:** IV patient controlled analgesia (PCA) | | **Process component #1:** Prescribe PCA | | | |
|---|---|---|---|---|---|
| **Failure Mode #** | **Recommended action** | **Strength of action** | **Timeframe for implementation** | **Individual(s) responsible** | **Measurement plan** |
| 1b1 | Selection criteria for PCA | Medium (Simplification/ Standardization) | 3-6 months | Pain Service | Criteria completed and included in order sets |
| | Point of care access to drug information | High (Automation/ Computerization) | 6-12 months | Clinical Informatics Dept. | Audit of care are computers |
| 1b1 1b2 | Standardized PCA protocol with education on use | Low (Education/ Information) | 3-6 months | Unit educators | Education complete for 75% of affected team members |
| | Enhanced clinical pharmacy support for PCA management | Medium (Reminders/ Double checks) | 6-12 months | Director of pharmacy | Audit for clinical pharmacist consultation for patients receiving PCA |
| | CPOE with decision support | High (Automation/ Computerization) | More than 12 months | Clinical Informatics Dept. | Program implementation and ongoing testing of functionality |
| 1c2 | Visible demographic information on order entry screens. | Medium (Reminders/ Double checks) | More than 12 months | Clinical Informatics Dept. | Demographic information available on order entry screens |
| | Alerts for look-alike patient names. | | | | Look alike patient name alerts implemented |

***Figure O: Completed action and measurement plan spreadsheet for Step 1: Prescribe PCA***

| **FMEA topic:** IV patient controlled analgesia (PCA) | | **Process component #4:** Administer medication | | | |
|---|---|---|---|---|---|
| **Failure Mode #** | **Recommended action** | **Strength of action** | **Timeframe for implementation** | **Individual(s) responsible** | **Measurement plan** |
| 4a2<br>4a3<br>4c1 | Segregate look alike/ sound alike drug names. | Medium (Simplification/ Standardization; Reminders/ Double Checks) | 3-6 months | Pharmacy Technicians with Clinical Pharmacists and Nursing Unit Managers | Medication room audits |
| | Consider labelling safeguards (e.g. TALLman lettering). | | 6-12 months | Director of Pharmacy; P&T Committee | |
| | Standardize PCA protocols and concentrations to limit choices. | | 6-12 months | P&T Committee | Annual review of PCA protocols |
| | Implement independent double checks at the bedside. | | 6-12 months | P&T Committee; Nursing Leadership | Practice audits |
| 4a4 | Review centralized IV admixture process, ensure standardized approach. | Medium (Simplification/ Standardization) | 3-6 months | Director of Pharmacy; CIVA lead | Practice audits |
| | Review process for after-hours access | | | | Audit of after-hours requests for medications |
| | Prepare prefilled syringes/cassettes or purchase from outsource vendor | | 6-12 months | | Review product availability post-process changes |
| 4b2<br>4c1 | Review number of pumps available; limit variety of pumps in use | Medium (Simplification/ Standardization) | 3-6 months | Task force: pharmacy/ nursing/ purchasing | Audit completed; results shared |
| | Plan to involve pharmacy and nursing staff in future purchasing decisions; purchase pumps that are easy to use; use FMEA to determine potential failure modes for new pumps | Medium (Simplification/ Standardization) | More than 12 months | | Pharmacy and nursing involvement documented for future purchases |
| 4c1 | Standardize medications and concentrations used. | Medium (Simplification/ Standardization) | 6-12 months | P&T Committee | Audit of number of concentrations before and after standardization; review of incident reports re unanticipated consequences |
| 4d1<br>4e3<br>4e4 | Engage staff in developing culture of safety. | Low (Education/ Information) | Ongoing attention required | All levels of organization | Periodic culture surveys; review of incident reporting (improved safety culture should increase reporting, especially of near miss incidents) |
| | Review staffing patterns and workflow to eliminate barriers to consistent checks (i.e. build check process into care delivery model). | Medium (Simplification/ Standardization) | More than 12 months | Nursing leadership | Practice audits |

*Continued….*

| **FMEA topic:** IV patient controlled analgesia (PCA) | | **Process component #4:** Administer medication | | | |
|---|---|---|---|---|---|
| **Failure Mode #** | **Recommended action** | **Strength of action** | **Timeframe for implementation** | **Individual(s) responsible** | **Measurement plan** |
| 4d2<br>4e2<br>4e3<br>4e4 | Provide training for staff on how to conduct independent checks (e.g., include verbalizing check so staff "see and hear" critical information). | Medium (Simplification/ Standardization) | 6-12 months | Staff educators | Education completion for 75% of affected team members; practice audits |
| 4e1<br>4e1 | Ensure 2 identifiers for all medication administrations | Low (Education/ Information); unless automated (i.e., bar coding) | 0-3 months | Staff educators; admitting staff | Practice audits; wrong patient incident reports |
| | Provide patient education regarding need for 2 identifiers and engage patients/ family caregivers to participate in identification process. | Low (Education/ Information) | | | Education completion for 75% of affected team members; practice audits |
| 4e4 | Review processes for routine pump maintenance. | Medium (Simplification/ Standardization) | 6-12 months | Biomedical staff | Audit maintenance records |
| | Review processes for power backup for infusion pumps. | | | | |
| | Ensure all new pumps purchased have free flow protection. | | More than 12 months | | Free flow protection part of RFP criteria |
| 4f1<br>4f2 | Ensure review of documentation for completeness prior to end of shift. | Low (Education/ Information) | 0-3 months | Staff educators | Health record audits |
| | Implement bedside documentation (e.g. flow sheets, computers on wheels) of PCA monitoring parameters. | Medium (Simplification/ Standardization) | More than 12 months | Nursing leadership | Practice audits once implemented |
| | Periodically review MAR format (paper/electronic) with direct care staff to assess usability and make revisions as recommended. | | Annually | Nursing leadership/ Pharmacy leadership/ Clinical informatics | Documentation of review and changes implemented |

***Figure P: Completed action and measurement plan spreadsheet for Step 4: Administer medication***

# Appendix 4.5: Anticoagulant prescribing and monitoring*

## Step 1: Select a process to analyze and assemble a team
## Step 2: Diagram the process

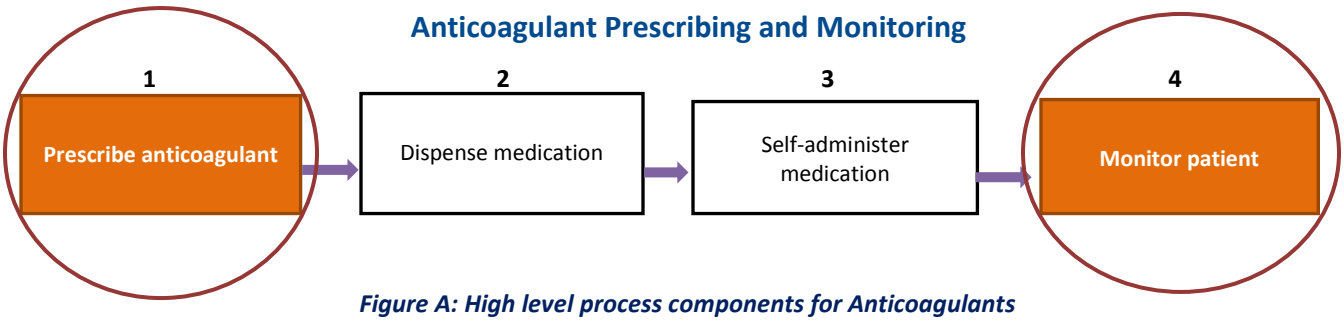


*Figure A: High level process components for Anticoagulants*

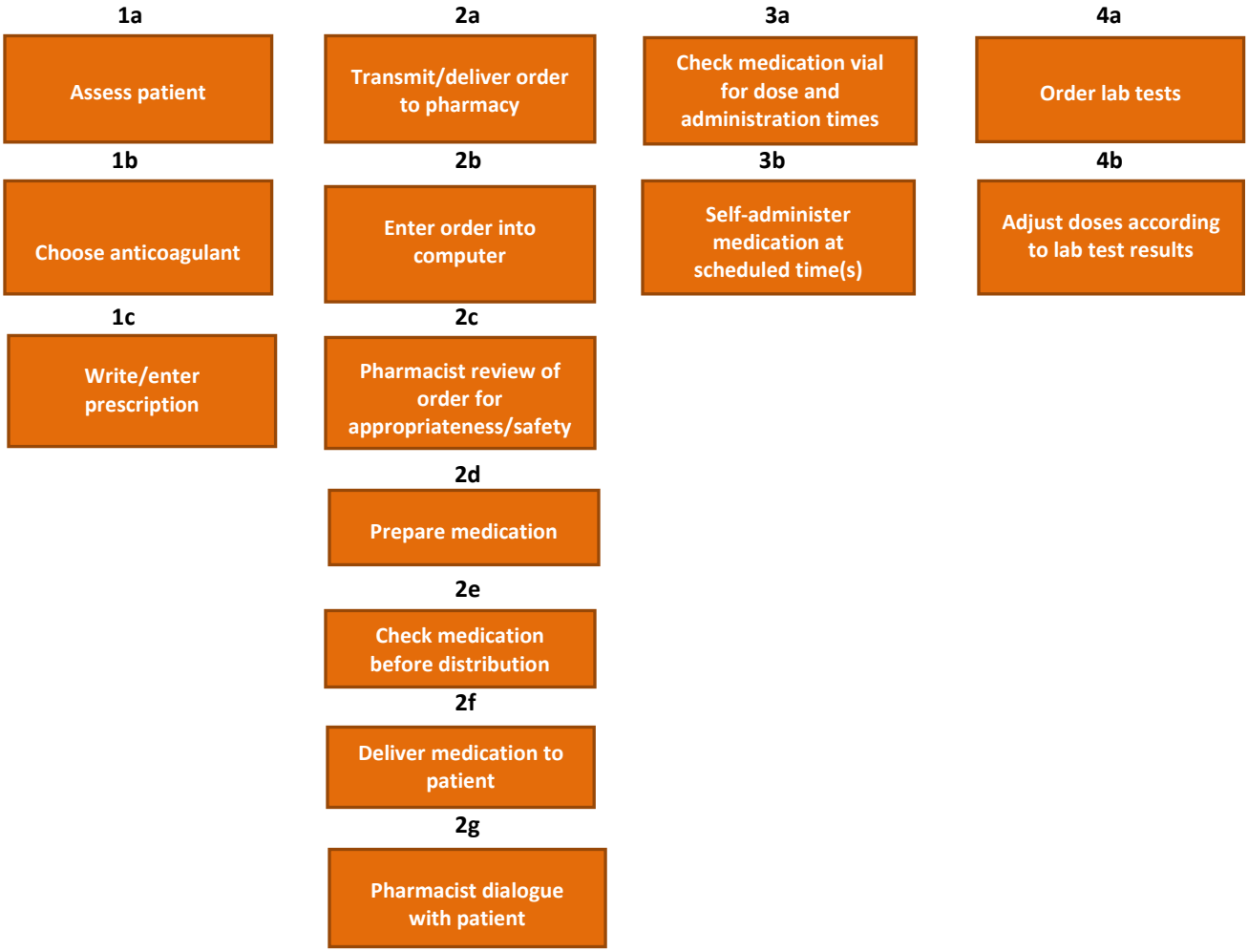


*Figure B: Sub-process components*

*Adapted, with permission, from Institute for Safe Medication Practices (US), 2000.[22]

In this case example, the prescribing and monitoring steps (components 1 and 4) have been highlighted from an ambulatory/ primary care perspective and spreadsheets and action plans have been completed for Step 4B. See https://www.ismp.org/tools/FMEAofAnticoagulants.pdf for the original FMEA form which this example was adapted.

## Component # 1: Prescribe anticoagulant

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

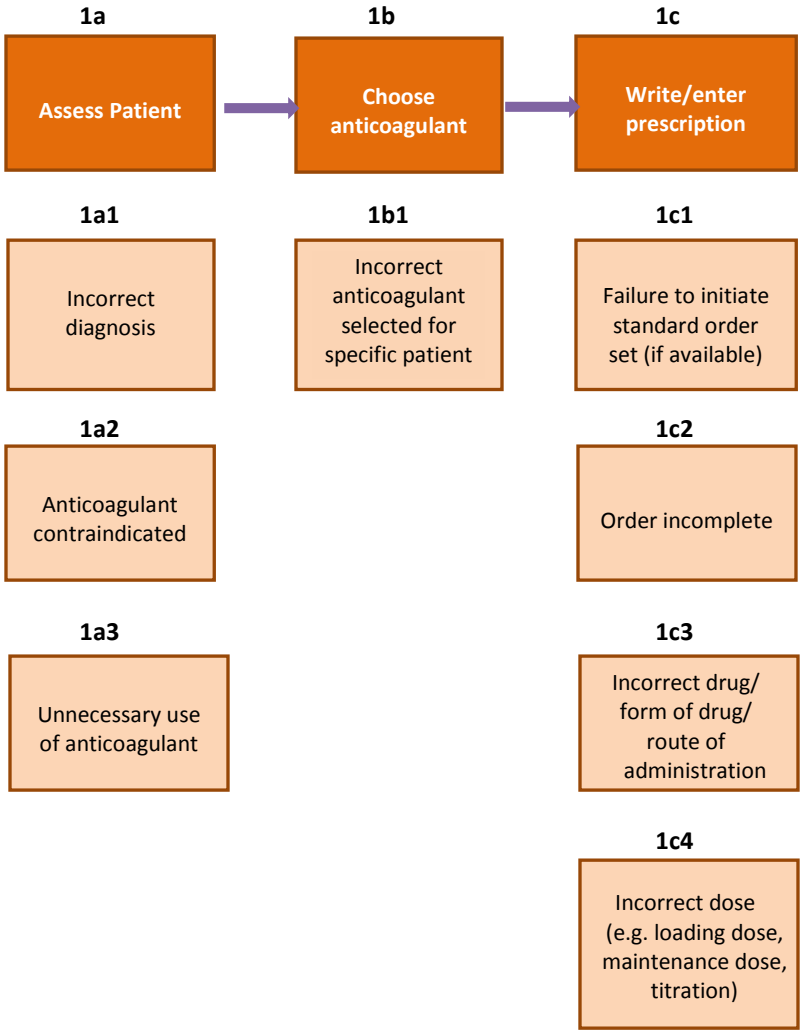


***Figure C: Potential failure modes for component #1: Prescribe anticoagulant***

### Step 4 – Identify the effects and causes of the failure modes
### Step 5 – Prioritize the potential failure modes
### Step 6 – Redesign the process

| **FMEA topic:** Anticoagulant prescribing and monitoring<br>**Sub-process component:**<br>1a – Assess Patient | | | | | | | **Process component:**<br>#1: Prescribe anticoagulant | | |
|---|---|---|---|---|---|---|---|---|---|
| **Failure Mode #** | **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** |
| 1a1 | Incorrect diagnosis:<br>- *leading to unnecessary treatment* | Bleeding | • Diagnostic tests are not performed.<br>• Incorrect diagnostic tests are performed<br>• Diagnostic tests are misinterpreted.<br>• Diagnostic tests from the wrong patient are used during assessment.<br>• Diagnostic tests not available in timely manner. | 4 | 2 | 2 | 16 | Y | *Short term:*<br>• Use of 2 identifiers when communicating diagnostic test results.<br>• Use of "read back" for any test results delivered by phone.<br>• Review timelines for critical test results.<br>*Medium term:*<br>• Develop standard testing protocols for patients when present with signs of thrombosis.<br>• Develop standardized Interdisciplinary guidelines for anticoagulant therapy that include prescribing guidelines (indications, contraindications, dosing), monitoring requirements and plan. |
| | - *leading to lack of treatment* | Thrombosis/emboli | | 5 | 2 | 2 | 20 | Y | |
| 1a2 | Anticoagulant contraindicated | Patient received anticoagulant when contraindicated leading to bleeding, other adverse drug event | • Unaware of current/prior treatment.<br>• Unaware of disease interactions, drug interactions, other contraindications and incompatibilities<br>• Incomplete patient history. | 5 | 2 | 2 | 20 | Y | *Short term:*<br>• Test alerts in medication order entry system for significant drug interactions/ incompatibilities (and disease interactions, if possible).<br>*Medium term:*<br>• Ensure medication reconciliation processes for patients prescribed anticoagulants.<br>• Review data available to pharmacy (such as allergies, height, weight) as well as comorbid conditions and develop processes to collect missing info to support pharmacist review of anticoagulant orders. |
| 1a3 | Unnecessary use of anticoagulant | *See 1a1.* | | | | | | | |

***Figure D: Completed FMEA spreadsheet for sub-process component 1a: Assess patient***

| **FMEA topic:** Anticoagulants | | | | | | | **Process component:** #1: Prescribe anticoagulant | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 1b – Choose anticoagulant | | | | | | | | | |
| **Failure Mode #** | **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** |
| 1b1 | Incorrect anticoagulant selected for specific patient | Allergy, adverse drug event | • Patient-specific parameters not available/not considered (e.g., renal and hepatic function, allergies, platelet count).<br>• Knowledge deficit about drug indications/contra-indications.<br>• Drug specific contraindications not known.<br>• Mental slip/lapse.<br>• Standard protocols/ prescribing guidelines not followed or do not exist. | 4 | 2 | 3 | 24 | Y | *Short term*:<br>• Provide point-of-care access to drug information.<br>*Medium term*:<br>• Develop standardized interdisciplinary treatment guidelines for anticoagulant therapy (see 1a1).<br>• Involve clinical pharmacists in dosing and monitoring of anticoagulants.<br>• Develop anticoagulant teams to manage patients with complicated thrombosis episodes.<br>*Long term*:<br>• Implement CPOE with decision support<br>• Implement an inter-face between CPOE/ Pharmacy order entry and laboratory services to support immediate availability of laboratory results. |

***Figure E: Completed FMEA spreadsheet for sub-process component 1b: Choose anticoagulant***

| **FMEA topic:** Anticoagulants | | | | | | | **Process component:** #1: Prescribe anticoagulant | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 1c – Write / Enter prescription | | | | | | | | | |
| **Failure Mode #** | **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** |
| 1c1 | Failure to initiate standard order set | Suboptimal treatment – over/under-dose | • Standardized order set not available<br>• Unaware of standardized order sets<br>• Order sets outdated/ inaccurate | 3 | 3 | 2 | 18 | Y | *Medium term*:<br>• Gain consensus from the medical staff and establish standard order sets/preprinted orders or protocols for anticoagulants including monitoring requirements. |
| 1c2 | Order incomplete | Suboptimal treatment, treatment delay | • Unfamiliarity with process<br>• Human factors (slip/lapse)<br>• Poor usability of order set (paper or electronic). | 4 | 3 | 2 | 24 | Y | *Medium term*:<br>• Conduct usability testing on standard order sets with all disciplines using them (i.e., MDs, RNs, RPhs). |
| 1c3 | Incorrect drug/form of drug/route of administration | Inappropriate treatment prescribed; over/under-dose | • Slip/lapse<br>• Standardized order set not available | 4 | 2 | 3 | 24 | Y | See 1a 1 on interdisciplinary treatment guidelines. |
| 1c4 | Incorrect dose (e.g. daily dose, loading lose, maintenance infusion, titration) | Over/under-dose | • Unaware of patient factors (weight, age, renal function, platelet count) or not considered.<br>• Dose based on unverified weight.<br>• Unaware of treatment vs prophylaxis dosing. | 4 | 2 | 3 | 24 | Y | See 1a1 on interdisciplinary treatment guidelines. |

***Figure F: Completed FMEA spreadsheet for sub-process component 1c: Write / enter prescription***

## Component # 4: Monitor patient

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

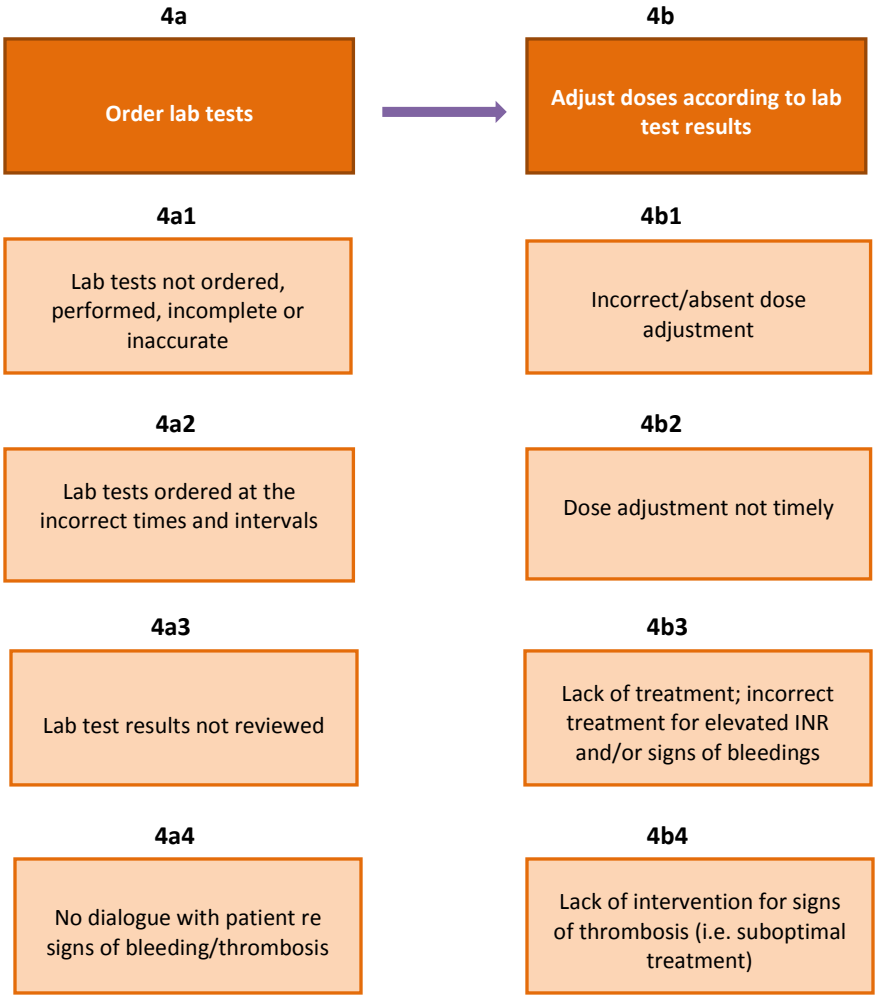


*Figure G: Potential failure modes for component # 4: Monitor patient*

### Step 4 – Identify the effects and causes of the failure modes
### Step 5 – Prioritize the potential failure modes
### Step 6 – Redesign the process

| **FMEA topic:** Anticoagulants | | | | | | | **Process component:** #4: Monitor patient | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 4a – Order Lab Tests | | | | | | | | | |
| **Failure Mode #** | **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** |
| 4a1 | Lab tests not performed, incomplete or inaccurate | Suboptimal treatment – over/under-dose. | • Failure to request prescribed lab tests<br>• Blood collection on the wrong patient.<br>• Incorrect test performed on blood specimen.<br>• Lab error (e.g. using incorrect reagent with testing equipment, mechanical failure, testing variability).<br>• Environmental factors.<br>• No standard protocol for monitoring, leading to variability. | 4 | 2 | 3 | 24 | Y | • See 1a1 on interdisciplinary treatment guidelines.<br>*Short term*:<br>Review lab processes to ensure:<br>• Use of two patient identifiers when drawing lab specimens<br>• Labelling of blood collection tubes while at the bedside<br>• Standard process for lab to investigate if INR values do not seem to correspond to clinical picture. |
| 4a2 | Lab tests ordered at incorrect times and intervals | Infrequent or inaccurate dose adjustments leading to over/under-doses. | • Failed or absent standard protocol for testing.<br>• Mental slip/lapse.<br>• Ineffective communication between practitioners. | 4 | 3 | 3 | 36 | Y | • See 1a1 on interdisciplinary treatment guidelines.<br>• Clinical pharmacy program to dose and monitor anti-coagulant therapy.<br>• Standard order sets/preprinted orders for warfarin and heparin, including monitoring requirements. |
| 4a3 | Lab test results not reviewed | Delayed opportunity to mitigate harm from over/under-doses. | • Lab values not available.<br>• Low perceived value of tests.<br>• Assume someone else is checking lab tests.<br>• Time constraints<br>• Wrong lab values checked. | 4 | 3 | 3 | 36 | Y | • See 1a1 on interdisciplinary treatment guidelines.<br>*Medium term*:<br>• Establish timeframe for test result turnaround.<br>*Short term*:<br>• Use of two patient identifiers when communicating diagnostic test results.<br>• Establish read-back process for test results communicated verbally. |
| 4a4 | No monitoring for sign of bleeding/ thrombosis | Delayed opportunity to mitigate harm/ treatment failure | • Lack of standardized anticoagulant protocol. | 5 | 2 | 3 | 30 | Y | • See la1 on interdisciplinary treatment guidelines. |

***Figure H: Completed FMEA spreadsheet for sub-process component 4a: Order Lab Tests***

| **FMEA topic:** Anticoagulants | | | | | | | **Process component:** #4: Monitor patient | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 4b – Adjust doses according to lab test results | | | | | | | | | |
| **Failure Mode #** | **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 | Failure to adjust dose in a timely manner | Labile anticoagulant levels leading to over/under-doses. | • Lab studies not performed or communicated.<br>• Failure to monitor patient lab values frequently enough.<br>• Critical lab values not flagged for reporting.<br>• Critical lab values/ assessment findings not communicated in a timely manner.<br>• Unable to reach physician with critical lab results/ assessment info.<br>• No protocols for dose adjustments.<br>• No protocols for treatment for dangerously elevated INR/aPTT<br>• Forgot to restart medication after holding.<br>• Interpreter biases.<br>• Patient-specific parameters unknown/ not considered (renal and hepatic function, allergies, platelet count).<br>• Making dose changes more or less frequently than necessary for the desired clinical outcomes. | 4 | 3 | 2 | 24 | Y | <u>*Short term*</u>:<br>• Develop a protocol to guide the treatment/ reversal of supra-therapeutic INR values for warfarin treatment.<br>• In treatment guidelines, include dose adjustment guidelines that will reduce large fluctuations in anticoagulation levels.<br>• In treatment guidelines, include directions for resumption of anticoagulant after reversal (e.g. for surgery). |
| 4b2 | Failure to treat patient / incorrect treatment when therapeutic levels are dangerously elevated | Bleeding leads to adverse event. | | 5 | 2 | 2 | 20 | Y | |

***Figure I: Completed FMEA spreadsheet for sub-process component 4b: Adjust Doses According to Lab Test Results***

| **FMEA topic:** Anticoagulant prescribing and monitoring | | **Process component #1:** Prescribe anticoagulant | | | |
|---|---|---|---|---|---|
| **Failure Mode #** | **Recommended action** | **Strength of action** | **Timeframe for implementation** | **Individual(s) responsible** | **Measurement plan** |
| 1a1<br>1a3 | Use of 2 identifiers when communicating diagnostic test results. | Medium (Reminders/ Double checks) | 3-6 months | Staff educators | Practice audits |
| | Use of "read back" for any test results delivered by phone. | Low (Education/ Information) | | | |
| | Review timelines for critical test results. | Medium (Simplification/ Standardization) | 3-6 months | Laboratory Manager | Timeline review completed and communicated; changes implemented as required. |
| | Develop standard testing protocols for patients who present with signs of thrombosis. | Medium (Simplification/ Standardization) | 6-12 months | P&T Committee/ Clinic task force | Protocols developed |
| 1a1<br>1a3<br>1b1<br>1c3<br>1c4 | Develop standardized Interdisciplinary guidelines for anticoagulant therapy that include prescribing guidelines (indications, contraindications, dosing), monitoring requirements and plan. | Medium (Simplification/ Standardization) | 6-12 months | P&T Committee/ Clinic task force | Protocols developed |
| 1a2 | Test alerts in medication order entry system for significant drug interactions/ incompatibilities (and disease interactions, if possible). | High (Automation/ Computerization) | 0-3 months | Designated pharmacist | Report of alerts tested and results |
| | Ensure medication reconciliation processes for patients prescribed anticoagulants. | Medium (Simplification/ Standardization) | 6-12 months | Organization task force | Health record audits |
| | Review data available to pharmacy (such as allergies, height, weight) as well as comorbid conditions and develop processes to collect missing info to support pharmacist review of anticoagulant orders. | Medium (Reminders/ Double checks) | 6-12 months | Designated pharmacists | Standard data collection/review forms for pharmacists |
| 1b1 | Provide point-of-care access to drug information. | High (Automation/ Computerization) | 6-12 months | Clinical Informatics Dept. | Audit of care unit computers |
| | Involve clinical pharmacists in dosing and monitoring of anticoagulants. | Medium (Simplification/ Standardization) | | Designated pharmacists | Practice audits |
| | Develop anticoagulant teams to manage patients with complicated thrombosis episodes. | Medium (Simplification/ Standardization) | | Organization task force | Team formed; case audits |
| | Implement CPOE with decision support | High (Automation/ Computerization) | More than 12 months | Clinical informatics | CPOE implemented |
| | Implement an interface between CPOE/ Pharmacy order entry and laboratory services to support immediate availability of laboratory results. | | | | Interface implemented |
| 1c1 | Gain consensus from the medical staff and establish standard order sets/preprinted orders or protocols for anticoagulants including monitoring requirements. | Medium (Simplification/ Standardization) | 6-12 months | P&T Committee/ Clinic task force | Order sets available |

| **FMEA topic:** Anticoagulant prescribing and monitoring | | **Process component #1:** Prescribe anticoagulant | | | |
|---|---|---|---|---|---|
| **Failure Mode #** | **Recommended action** | **Strength of action** | **Timeframe for implementation** | **Individual(s) responsible** | **Measurement plan** |
| 1c2 | Conduct usability testing on standard order sets with all disciplines using them (i.e., MDs, RNs, RPhs). | Medium (Simplification/ Standardization) | 6-12 months | P&T Committee/ Clinic task force | Testing completed; changes implemented |

***J: Completed action and measurement plan spreadsheet for component 1: Prescribe anticoagulant***

| **FMEA topic:** Anticoagulant prescribing and monitoring | | **Process: #4:** Monitor patient | | | |
|---|---|---|---|---|---|
| **Failure Mode #** | **Recommended action** | **Strength of action** | **Timeframe for implementation** | **Individual(s) responsible** | **Measurement plan** |
| 4a1<br>4a2<br>4a3<br>4a4 | Develop standardized Interdisciplinary guidelines for anticoagulant therapy that include prescribing guidelines (indications, contraindications, dosing), monitoring requirements and plan. | See: 1a1, 1a3, 1b1, 1c3, 1c4 | | | |
| 4a1 | Review lab processes to ensure:<br>• Use of two patient identifiers when drawing lab specimens<br>• Labelling of blood collection tubes while at the bedside<br>• Standard process for lab to investigate if INR values do not seem to correspond to clinical picture. | Medium (Simplification / standardization) | 3-6 months | Laboratory manager | Practice audits |
| 4a2 | Clinical pharmacy program to dose and monitor anticoagulant therapy. | See 1b1 | | | |
| | Standard order sets/preprinted orders for warfarin and heparin, including monitoring requirements. | See 1c1 | | | |
| 4a3 | Establish timeframe for test result turnaround. | See 1a1, 1a3 | | | |
| | Use of two patient identifiers when communicating diagnostic test results. | | | | |
| | Establish read-back process for test results communicated verbally. | | | | |
| 4b1<br>4b2 | Develop a protocol to guide the treatment / reversal of supra-therapeutic INR values for warfarin treatment. | Medium (Simplification / standardization) | 3-6 months | Unit team (physician/ pharmacist) | Availability of protocol. |
| | In treatment guidelines, include dose adjustment guidelines that will reduce fluctuations in anticoagulation levels. | Medium (Simplification / standardization) | 3-6 months | Unit team (physician/ pharmacist) | Periodic audits of health records for use of protocol. |
| | In treatment guidelines, include directions for resumption of anticoagulant after reversal (e.g. surgery). | Medium (Simplification / standardization) | 3-6 months | Unit team (physician/ pharmacist) | Periodic audits of health records for use of protocol. |

***Figure K: Completed action and measurement plan spreadsheet for component 4: Monitor patient***

# Appendix 4.6: Administration of parenteral analgesia in EMS*

**Case developed with assistance from the Regional Paramedic Program for Eastern Ontario*

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

The process selected for analysis is the administration of parenteral analgesia by Emergency Medical Services (EMS) personnel (i.e., paramedics). Drugs available for parenteral administration for analgesia in this EMS service are ketorolac (IV/IM) or morphine (IV/IM/SC).

The analysis team included the following team members:

- Base supervisor (team lead)
- Advanced care paramedic
- Primary care paramedic
- Base hospital physician
- Quality/safety lead

## Step 2: Diagram the process and sub-processes

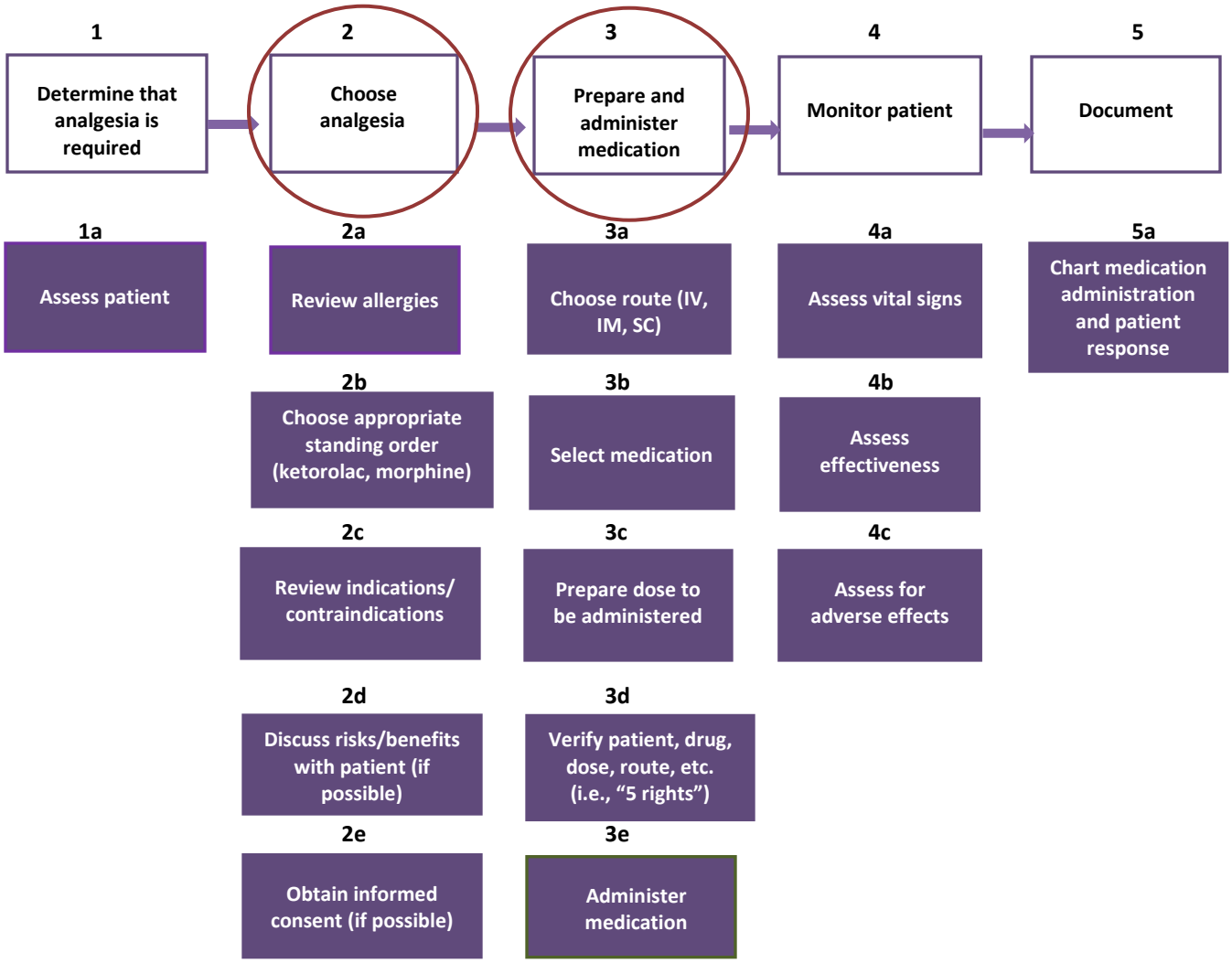


***Figure A: High level process and sub-process components for Administration of Parenteral Analgesia in EMS***

In this case example, Component 2 (Choose analgesia) and Component 3 (Prepare and administer medication) have been selected for detailed analysis.

## Component #2: Choose analgesia

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

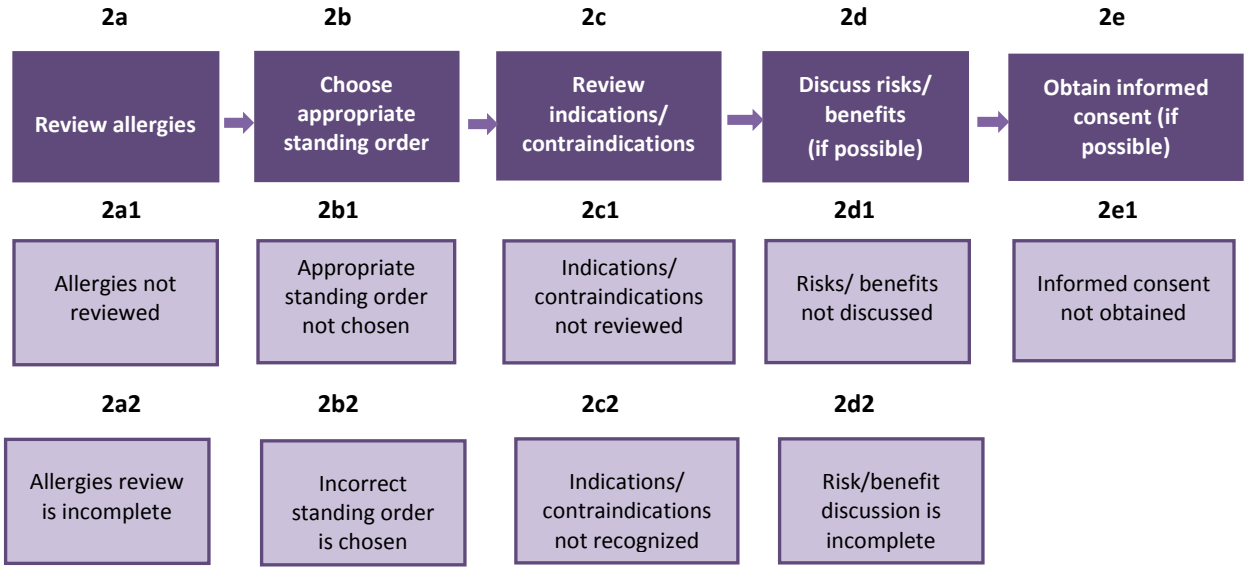


***Figure B: Potential failure modes for Step 2: Choose analgesia***

### Step 4 – Identify the effects and causes of the failure modes
### Step 5 – Prioritize the potential failure modes
### Step 6 – Redesign the process

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| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | | | | **Process component:** #2: Choose analgesia | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 2a - Review allergies | | | | | | | | | |
| **Failure Mode #** | **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** |
| 2a1 | Allergies not reviewed | Allergic reaction to medication | Knowledge gap; human/ environmental factors (e.g., distractions; forgot; language barrier; workload; workflow process) | 5 | 3 | 3 | 45 | Y | Short term<br>Reminder to staff about the importance of allergy review during history gathering |
| 2a2 | Allergy review is incomplete | Same as 2a1 | Same as 2a1 | 5 | 3 | 3 | 45 | Y | Same as 2a1 |

***Figure C: Completed FMEA spreadsheet for sub-process component 2a: Review allergies***

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | | | | **Process component:** #2: Choose analgesia | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 2b - Choose appropriate standing order (ketorolac, morphine) | | | | | | | | | |
| **Failure Mode #** | **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 | Appropriate standing order not chosen | Incorrect plan of action, including working diagnosis, lack of pain management | Knowledge deficit; assessment skills deficit | 3 | 1 | 3 | 9 | No | No action planned due to lower criticality score |
| 2b2 | Incorrect standing order is chosen | Same as 2b1 | Distractions; workload/ workflow | 3 | 2 | 3 | 18 | No | No action planned due to lower criticality score |

***Figure D: Completed FMEA spreadsheet for sub-process component 2b: Choose appropriate standing order***

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | | | | **Process component:** #2: Choose analgesia | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 2c - Review indications/ contraindications | | | | | | | | | |
| **Failure Mode #** | **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 | Indications and contraindications not reviewed | Contraindicated medication administered, possibly leading to an adverse event | Human factors/ environmental (e.g., distractions; forgot; workload; workflow process) | 3 | 3 | 3 | 27 | Y | <u>*Short term*</u><br>Education campaign about indications/ contraindications review during history gathering |
| 2c2 | Indications and contraindications not recognized | Contraindicated medication administered, leading to an adverse event | Knowledge gap | 4 | 3 | 3 | 42 | Y | Same as 2c1<br>Develop point of care references – quick, readable drug information reminders available at the point of care. |

***Figure E: Completed FMEA spreadsheet for sub-process component 2c: Review indications/ contraindications***

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | | | | | | **Process component:** #2: Choose analgesia |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 2d - Discuss risks and benefits | | | | | | | | | |
| **Failure Mode #** | **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 | Risks and benefits not discussed | Patient is not informed and may not have appropriately consented to treatment | Knowledge gap; forgot; time pressures; past experience; provider confidence | 3 | 4 | 3 | 36 | Y | *Short term*<br>Education campaign about importance of risks and benefits review prior to medication administration<br><br>*Medium term*<br>• Develop educational material for medications commonly administered, designed to address the gaps in paramedic knowledge<br>• Develop patient-friendly medication information |
| 2d2 | Risk/benefit discussion is incomplete | Patient is not fully informed and may not have appropriately consented to treatment. | Knowledge gap; forgot; time pressures; past experience; provider confidence | 3 | 2 | 3 | 18 | N | Addressed by actions for 2d1. |

***Figure F: Completed FMEA spreadsheet for sub-process component 2d: Discuss risks and benefits***

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | | | | | | **Process component:** #2: Choose analgesia |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 2e - Obtain informed consent (if possible) | | | | | | | | | |
| **Failure Mode #** | **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** |
| 2e1 | Informed consent not obtained | Patient rights are violated | Knowledge gap; forgot; time pressures; past experience; provider confidence; culture of expedient care | 4 | 1 | 3 | 12 | N | No action planned due to lower criticality score |

***Figure G: Completed FMEA spreadsheet for sub-process component 2e: Obtain informed consent***

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | **Process component:** Step #2: Choose analgesia | | | |
|---|---|---|---|---|---|---|---|
| **Failure mode number** | **Failure mode description** | **Criticality score** | **Recommended action** | **Strength of action** | **Timeframe** | **Individual(s) responsible** | **Measurement plan** |
| 2a1 | Allergies not reviewed | 45 | Reminder to staff about the importance of allergy review during history gathering | Low (Education/ Information) | Short term | Quality/ patient safety lead | - Check learning management system records of emails viewed<br>- Audit samples of patient care records to check for compliance |
| 2a2 | Allergy review is incomplete | 45 | Same as 2a1 | Low (Education/ Information) | Short term | Quality/ patient safety lead | Check learning management system records of emails viewed |
| 2b1 | Appropriate standing order not chosen | 18 | No action planned due to lower criticality score | -- | -- | -- | -- |
| 2b2 | Incorrect standing order chosen | 18 | No action planned due to lower criticality score | -- | -- | -- | -- |
| 2c1 | Indications and contraindications not reviewed | 27 | Education campaign about indications/contra-indications review during history gathering | Low (Education/ Information) | Short term | Quality/ patient safety lead | Check learning management system records |
| 2c2 | Indications and contraindications not recognized | 27 | Develop point of care references – quick, readable drug information reminders available at the point of care. | Medium (Reminders/ Double checks) | Medium term | Quality/ patient safety lead + team of frontline paramedics | Point of care references developed, approved and implemented |
| 2d1 | Risks and benefits not discussed | 36 | Education campaign about importance of risks and benefits review prior to medication administration<br><br>Develop educational material for medications commonly administered, designed to address the gaps in paramedic knowledge<br><br>Develop patient-friendly medication information | Low (Education/ Information)<br><br>Medium (Reminders/ Double checks)<br><br>Medium (Reminders/ Double checks) | Short term<br><br>Medium term<br><br>Medium term | Quality/ patient safety lead<br><br>Quality/ patient safety lead + team of frontline paramedics<br><br>Quality/ patient safety lead + team of frontline paramedics + patient representatives | Check learning management system records<br><br>Point of care references developed, approved and implemented<br><br>Patient information developed, approved and implemented |

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | **Process component:** Step #2: Choose analgesia | | | |
|---|---|---|---|---|---|---|---|
| **Failure mode number** | **Failure mode description** | **Criticality score** | **Recommended action** | **Strength of action** | **Timeframe** | **Individual(s) responsible** | **Measurement plan** |
| 2d2 | Risk/benefits discussion is incomplete | 18 | Covered by actions for 2d1. | -- | -- | -- | -- |
| 2e1 | Informed consent not obtained | 12 | No action planned due to lower criticality score | -- | -- | -- | -- |

***Figure H: Completed summary table process component 2: Choose analgesia***

## Component #3: Prepare and administer medication

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

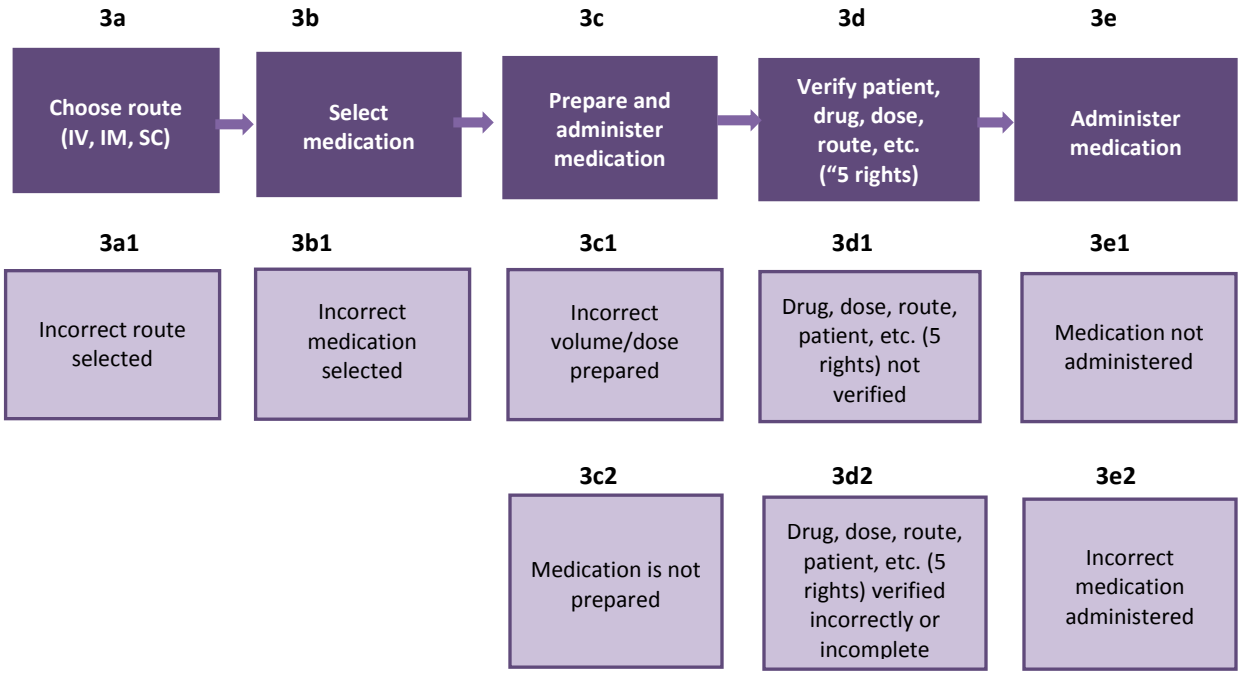


***Figure I: Potential failure modes for Step 2: Choose analgesia***

### Step 4 – Identify the effects and causes of the failure modes
### Step 5 – Prioritize the potential failure modes
### Step 6 – Redesign the process

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | | | | **Process component:** #3: Prepare and administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 3a - Choose route (IV, IM, SC) | | | | | | | | | |
| **Failure Mode #** | **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** |
| 3a1 | Incorrect route chosen | Absorption too rapid (e.g., IV chosen instead of IM/SC) leading to adverse effects | Slip/lapse, incomplete medical history, failure to use reference tools | 2 | 1 | 3 | 6 | No | Not at a priority at this time due to low criticality score |

***Figure J: Completed FMEA spreadsheet for sub-process component 3a: Choose route***

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | | | | **Process component:** #3: Prepare and administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 3b - Select medication | | | | | | | | | |
| **Failure Mode #** | **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** |
| 3b1 | Incorrect medication selected | Poor pain management; possibility of allergic reaction/other adverse event | Slip/lapse, medication not independently checked, medications restocked improperly | 4 | 3 | 2 | 24 | Y | <u>*Short Term*</u><br>Segregate look alike/sound alike drug names and packages<br><br><u>*Medium Term*</u><br>• Consider labelling safeguards (e.g., TALLman lettering)<br>• Implement independent double checks for high alert medications (e.g., opioids)<br><br><u>*Long term*</u><br>Research the possibility of implementing medication safety technology such bar code medication verification in the vehicles. |

***Figure K: Completed FMEA spreadsheet for sub-process component 3b: Select medication***

| **FMEA topic:** Administration of parenteral analgesia by EMS<br>**Sub-process component:**<br>3c - Prepare and administer medications | | | | | | | **Process component:**<br>#3: Prepare and administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Failure Mode #** | **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** |
| 3c1 | Incorrect volume/dose prepared | Poor pain management (too little), potential for adverse event (too much) | Slip/lapse, medical math error, failure to use reference tools, medication not independently checked | 5 | 2 | 3 | 30 | Y | *Short Term*<br>Provide training for staff on how to conduct independent checks<br>*Medium Term*<br>• Review concentration of medications supplied versus prescribed in standing orders<br>• Develop dosing charts |
| 3c2 | Medication is not prepared | Poor pain management | Slip/lapse, confounding factors at scene | 3 | 2 | 2 | 12 | N | No action planned due to lower criticality score |

***Figure L: Completed FMEA spreadsheet for sub-process component 3c: Prepare and administer medication***

| **FMEA topic:** Administration of parenteral analgesia by EMS<br>**Sub-process component:**<br>3d - Verify patient, drug, dose, route, etc. (5 rights) | | | | | | | **Process component:**<br>#3: Prepare and administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Failure Mode #** | **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** |
| 3d1 | Patient, drug, dose, route, etc. (5 rights) not verified | Incorrect medication administered; potential for allergic reaction/ other adverse event | Slip/lapse, knowledge gap, lack of resources (single provider) | 5 | 2 | 3 | 30 | Y | *Short term*<br>Reminder to staff regarding the importance of the 5 Rights<br>Medium term<br>Simulations of medication administration to assist staff with the "how to"; i.e., "5 rights" are the end goal, not the process<br><br>*Continued…* |

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | | | | **Process component:** #3: Prepare and administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 3d - Verify patient, drug, dose, route, etc. (5 rights) | | | | | | | | | |
| **Failure Mode #** | **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** |
| 3d2 | Patient, drug, dose, route, etc. verified incorrectly | Same as 3d1 | Same as 3d1 | 5 | 2 | 3 | 30 | Y | Same as 3d1 |
| 3d3 | Verification process is incomplete | Same as 3d1 | Same as 3d1 | 5 | 2 | 3 | 30 | Y | Same as 3d1 |

***Figure M: Completed FMEA spreadsheet for sub-process component 3d: Verify patient, drug, dose, route, etc. (5 rights)***

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| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | | | | **Process component:** #3: Prepare and administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 3e - Administer medication | | | | | | | | | |
| **Failure Mode #** | **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** |
| 3e1 | Medication not administered | Poor pain management | Slip/lapse, lack of resources (single provider), confounding factors at scene | 2 | 2 | 3 | 12 | N | No action planned due to lower criticality score |
| 3e2 | Incorrect medication administered | Poor pain management; potential for allergic reaction/ other adverse event | Slip/lapse; medication not independently checked; medications restocked improperly | 5 | 2 | 3 | 30 | Y | <u>*Short Term*</u><br>Segregate look alike/sound alike drug names and packages<br><u>*Medium Term*</u><br>• Consider labelling safeguards (e.g., TALLman lettering)<br>• Implement independent double checks for high alert medications (e.g., opioids)<br><br>*Continued…* |

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | | | | **Process component:** #3: Prepare and administer medication | | |
|---|---|---|---|---|---|---|---|---|---|
| **Sub-process component:** 3e - Administer medication | | | | | | | | | |
| **Failure Mode #** | **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** |
| | | | | | | | | | • Develop a targeted plan to review incidents related to incorrect medication administration to identify contributing factors and possible system-based solutions (related to severity of 5)<br><br><u>*Long term*</u><br>• Research the possibility of implementing medication safety technology such as bar code medication verification in the vehicles.<br>• Explore options for reporting of prehospital medication errors to organizations such as ISMP, CIHI, etc. for national trending and shared learning. |

***Figure N: Completed FMEA spreadsheet for sub-process component 3e: Administer medication***

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | **Process component:** Step 3: Prepare and administer medication | | | |
|---|---|---|---|---|---|---|---|
| **Failure mode number** | **Failure mode description** | **Criticality score** | **Recommended action** | **Strength of action** | **Timeframe** | **Individual(s) responsible** | **Measurement plan** |
| 3a1 | Incorrect route chosen | 6 | No action planned due to low criticality score | -- | -- | -- | -- |
| 3b1 | Incorrect medication selected | 24 | Segregate look alike/ sound alike drug names and packages<br><br>Consider labelling safeguards (e.g., TALLman lettering)<br><br>Implement independent double checks for high alert medications (e.g., opioids)<br><br>Research the possibility of implementing medication safety technology such as bar code medication verification in the vehicles. | Medium (Reminders/Double checks)<br><br>Medium (Reminders/Double checks)<br><br>Medium (Reminders/Double checks)<br><br>High (Automation) | Short term<br><br>Medium term<br><br>Medium term<br><br>Long term | Quality/ patient safety lead + Operations/ logistics<br><br>Medical leadership + Education team<br><br>Quality/ patient safety lead + Operations/ logistics | Ambulance audits<br><br>“<br><br>Practice audits<br><br>Project report, progressing to proposal/ business case/ strategic plan |
| 3c1 | Incorrect volume/dose prepared | 30 | Provide training for staff on how to conduct independent checks<br><br>Develop dosing charts<br><br>Review concentration of medications supplied versus prescribed in standing orders | Low (Education/ Information)<br><br>Medium (Simplification/ Standardization)<br><br>Medium (Simplification/ Standardization) | Short term<br><br>Medium term<br><br>Medium-long term | Education team<br><br>Quality/ patient safety lead<br><br>Quality/ patient safety lead + Operations/ logistics | Learning management system records<br><br>Charts developed, approved and implemented<br><br>Project report progressing to proposal/ business case |
| 3c2 | Medication is not prepared | 12 | No action planned due to lower criticality score | -- | -- | -- | -- |
| 3d1 | Patient, drug, dose, route, etc. (5 rights) not verified | 30 | Reminder to staff regarding the importance of the 5 Rights<br><br>Simulations of medication administration to assist staff with the “how to”; i.e., “5 | Low (Education/ Information)<br><br>Medium (Simulation) | Short term<br><br>Medium term | Quality/ patient safety lead<br><br>Education team | Learning management system reports<br><br>Learning management system reports |

| **FMEA topic:** Administration of parenteral analgesia by EMS | | | | **Process component:** Step 3: Prepare and administer medication | | | |
|---|---|---|---|---|---|---|---|
| **Failure mode number** | **Failure mode description** | **Criticality score** | **Recommended action** | **Strength of action** | **Timeframe** | **Individual(s) responsible** | **Measurement plan** |
| | | | Rights" are the end goal, not the process | | | | |
| 3d2 | Drug, dose, route, patient, etc. verified incorrectly | 30 | Same as 3d1 | -- | -- | -- | -- |
| 3d3 | Verification process is incomplete | 30 | Same as 3d1 | -- | -- | -- | -- |
| 3e1 | Medication not administered | 12 | No action planned due to lower criticality score | -- | -- | -- | -- |
| 3e2 | Incorrect medication administered | 30 | Same as 3b1<br><br>Develop a targeted plan to review incidents related to incorrect medication administration to identify contributing factors and possible system-based solutions (related to severity of 5)<br><br>Explore options for reporting of pre-hospital medication errors to organizations such as ISMP Canada, CIHI, etc. for national trending and shared learning | --<br><br>High (Safety culture)<br><br>High (Safety culture) | --<br><br>Long term<br><br>Long term | --<br><br>Quality/ patient safety leads +/- team<br><br>Organizational leadership | --<br><br>Process developed to flag selected incident types for priority review<br><br>Project report progressing to proposal/ business case/ strategic plan |

***Figure O: Completed summary table process component 3: Prepare and administer medication***

# 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;

**1. What are we trying to accomplish?**

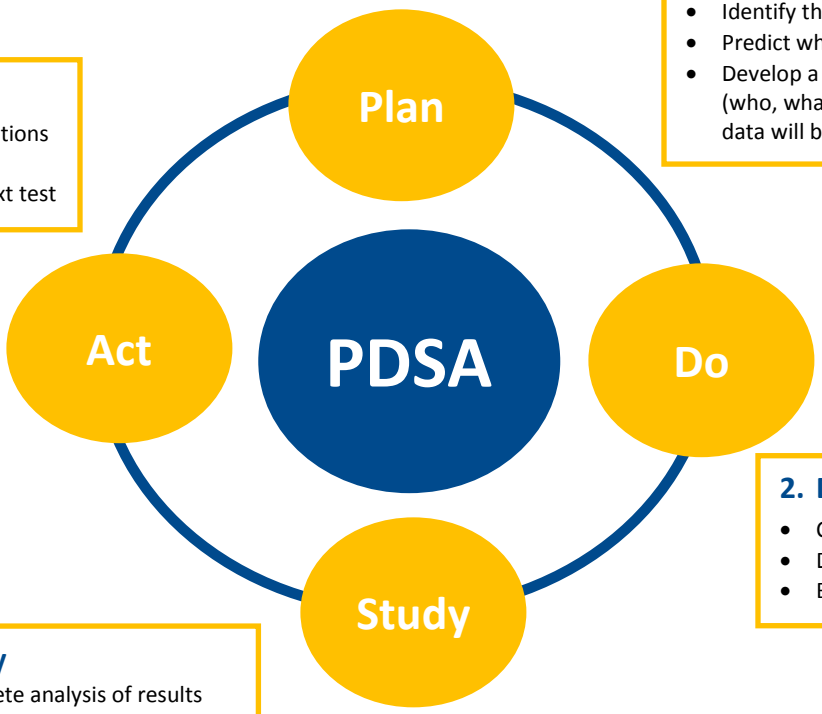
**2. How will we know that a change is an improvement?**

**3. What changes can we make that will result in 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.

**1. Plan a change**

- Identify the objective of the test
- Predict what will happen and why
- Develop a plan to test the change (who, what, when, where, what data will be collected)




**2. Do**

- Carry out the test of change
- Document observations
- Begin data analysis

**3. Study**

- Complete analysis of results
- Compare the results to your prediction
- What worked/didn't work?

**4. Act**

- Determine what modifications may be needed
- Prepare a plan for the next test

## Appendix 6: ISMP Canada Safety Bulletins related to FMEA

Ontario
CRITICAL Incident Learning
*Improving quality in patient safety*

**Issue 4**
**April 2013**

**Distributed to:**

- Chief executive officers
- Chiefs of staff
- Board chairs
- Quality/patient safety leads
- Directors of pharmacy

**Suggested action items:**

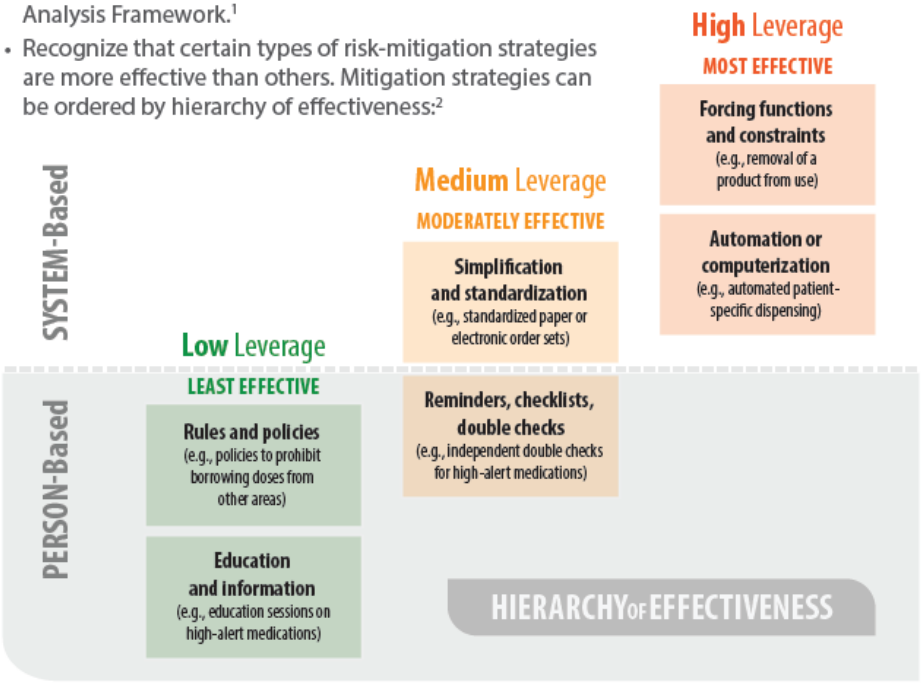
- Circulate bulletin to front-line staff and physicians
- Refer bulletin to quality and safety committees to encourage appraisal of effectiveness of hospital's recommendations and assessment of hospital's quality improvement initiatives
- Use bulletin as an educational resource in your hospital's safety huddles or rounds

# Designing Effective Recommendations

The reporting, investigation, and analysis of medication incidents are important elements in improving patient safety, but these efforts must be accompanied by effective strategies to mitigate the contributing factors leading to the incidents.

## Advice for Hospitals

- Review patient safety incidents using a systematic, team-oriented approach, as described in the Canadian Incident Analysis Framework.[1]
- Recognize that certain types of risk-mitigation strategies are more effective than others. Mitigation strategies can be ordered by hierarchy of effectiveness:[2]




- System-based recommendations have a higher likelihood of success because they do not rely on individual attention and vigilance.
- Appreciate that a small number of higher-leverage, more effective recommendations addressing the contributing factors determined from the incident analysis will be more likely to improve patient safety than a larger number of less effective strategies.
- Ensure that recommendations are specific, measurable, attainable, realistic, and timely (SMART).[3]
- Continuously monitor and assess the effectiveness of any recommendations arising from incident analyses.
- Provide feedback to staff about quality and safety improvement initiatives and achievements.

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## Background

A hospitalized patient received a fatal overdose of an opioid prepared from a high-concentration product. The facility conducted a full internal review of the incident and developed a series of strategies that were expected to reduce the likelihood of recurrence of this error, as well as to enhance the safety of other aspects of care within the facility. The recommendations included providing staff education, changing medication policies, reducing availability of the particular product, improving the labelling and delivery of all high-concentration products, and reinforcing independent double-check practices. Despite these measures, the facility has since experienced one near-miss incident and one harmful overdose of the same product.

## Learning from Analysis

Further analysis revealed that availability of the high-concentration product played a significant role in both of the subsequent errors, despite the institution's intent to develop and implement strategies specifically designed to address the identified contributing factors. For example, in areas where the product was still available, unused containers for discharged patients were being stored in drug carts until the next audit and collection opportunity. Doses of the high-concentration product were being borrowed for use in other areas of the facility, which led to opportunities for error. These actions reflected a desire for economy and efficiency on the part of staff members and were not performed out of carelessness or any intent to cause harm.

These findings emphasized that vulnerabilities in medication-use systems must be addressed with the most effective strategies that are reasonable and/or feasible to implement, given the particular circumstances. In this case, the facility ultimately opted to implement a *daily* audit of high-concentration opioids to ensure removal of items no longer required for admitted patients, effectively creating a high-leverage forcing function and constraint (i.e., the product would not be available for borrowing).

Organizations often respond to errors with policy and rule changes, but research and experience have clearly shown that such recommendations, implemented in isolation, are unlikely to provide any meaningful benefit to patient safety over the long term and that higher-leverage strategies are required. Hospital leaders are encouraged to analyze all recommendations proposed after review of a critical incident and to consider how effective they will be in preventing a future incident or mitigating harm from any incidents that do occur.

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*We gratefully acknowledge the review of this bulletin by the facility where the incident described took place.*



[1] Incident Analysis Collaborating Parties. Canadian Incident Analysis Framework. Edmonton (AB): Canadian Patient Safety Institute; 2012. Incident Analysis Collaborating Parties are Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices Canada, Saskatchewan Health, Patients for Patient Safety Canada (a patient-led program of CPSI), Paula Beard, Carolyn E. Hoffman, and Micheline Ste-Marie. Available from: http://www.patientsafetyinstitute.ca/English/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF

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[3] Doran GT. There's a S.M.A.R.T. way to write management objectives. Manag Rev. 1981;71(11,AMA Forum):35-36.

## Collaborating parties of the Ontario Critical Incident Reporting program

Canadian Institute for Health Information / Institut canadien d'information sur la santé · Ontario · Ontario Hospital Association · ismp Canada

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

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

Volume 12, Number 11 **ISMP Canada Safety Bulletin** November 22, 2012

# 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.[1] 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.[2] 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.[3]

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.[4]

### 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[5]), 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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Human factors specialists at HumanEra, Centre for Global eHealth Innovation, University Health Network, for expert review of this bulletin.

## 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

The full report is available from ISMP Canada in both English[1] and French[2]

[1] www.ismp-canada.org/download/MedRec/20121101MedRecCanadaENG.pdf
[2] www.ismp-canada.org/download/MedRec/20121101MedRecCanadaFRE.pdf

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The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

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

Volume 12, Number 1

# ISMP Canada Safety Bulletin

January 23, 2012

## 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).[1,2]

### 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).[3] 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.[2]

### 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

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* 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.[1]

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 walk-through 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.[3]

## 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.

*Acknowledgements*

ISMP Canada gratefully acknowledges:

Laura Lin Gosbee MASc, ISMP Canada's human factors engineering consultant, who not only provided input into this bulletin but also contributed her expertise during various FMEA projects, including the EMS project.

The Health Technology Safety Research Team, Centre for Global eHealth Innovation, University Health Network and University of Toronto, for their expert review of this bulletin.

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

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

Volume 6, Issue 8

# ISMP Canada Safety Bulletin

December 23, 2006

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

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

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

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

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

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

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

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

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

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

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

***Acknowledgement***

*ISMP Canada gratefully acknowledges the input provided by John Senders, PhD, Professor Emeritus, Faculty of Applied Sciences, University of Toronto.*

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

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9. Utah Hospitals and Health Systems Association Adverse Drug Effects User Group. FMEA Project on High Risk Drugs - Inpatient Anticoagulant Agents — January 2005. Accessed on 2006 December 20 at http://www.uha-utah.org/ADEpublications.htm.
10. Example of a Health Care Failure Mode and Effects Analysis for IV Patient Controlled Analgesia (PCA). Accessed on 2006 December 21 at http://www.ismp.org/Tools/FMEAofPCA.pdf.

## Medication Safety Self-Assessment® (MSSA)

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

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

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

Completion of the MSSA will assist health service organizations in:

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

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

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



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

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

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

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

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

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

ISMP Canada is an independent Canadian nonprofit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

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

# ISMP Canada Safety Bulletin

Volume 2, Issue 5 May, 2002

## 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.[1-5] 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 [6]. 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 #1and #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 [3,7,8] 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. 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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9. Brown, Nancy. A Mother's Plea: KCl Accidents and Deaths are Preventable. *Pharmacy Connection*. The Ontario College of Pharmacists. 8(4):19, July/August 2001.
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# Appendix 7: Additional selected resources

## Selected published examples of FMEAs


Daniels LM, Barreto JN, Kuth JC et al. Failure mode and effects analysis to reduce risk of anticoagulation levels above the target range during concurrent antimicrobial therapy. Am J Health Syst Pharm. 2015 Jul 15;72(14):1195-1203

Esmail, R., Cummings, C., Dersch, D. et al. "Using healthcare failure mode and effects analysis tool to review the process of ordering and administrating potassium chloride and potassium phosphate." *Healthcare Quarterly* 8 (2005): 73-80. Longwoods Publishing. [Cited 2016Aug10] Available from: http://longwoods.com/view.php?aid=17668&cat=399.

Mayadev J, Dieterich S, Harse R et al. A failure modes and effects analysis study for gynecologic high-dose-rate brachytherapy. Brachytherapy. 2015 Nov-Dec; 14(6):866-875.

Manger RP, Paxton AB, Pawlicki T et al. Failure mode and effects analysis and fault tree analysis of surface image guided cranial radiosurgery. Med Phys. 2015 May; 42(5): 2449-2461.

Nickerson T, Jenkins M, and Greenall J. Using ISMP Canada's Framework for Failure Mode and Effects Analysis: A Tale of Two FMEAs. Healthcare Quarterly. 2008; 11: 40-46 [Cited 2016Aug10] Available from: https://www.ismp-canada.org/download/HQ2008V11SP40.pdf


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Wetterneck, T.B., Schoofs,, Hundt A., and P. Carayon. "FMEA Team Performance in Health Care: A Qualitative Analysis of Team Member Performance." *J Patient Saf* 5.2 (2009): 102-108. Print.


## Websites


Associates in Process Improvement.
http://www.apiweb.org/ [2016Aug10]

Institute for Healthcare Improvement (IHI).
http://www.ihi.org/resources/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx [2016Aug10]

Institute for Safe Medication Practices Canada.
https://www.ismp-canada.org/fmea.htm. [2016Aug10]

United States Department of Veterans Affairs, National Center for Patient Safety. Healthcare Failure Mode and Effects Analysis (HFMEA™).
http://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp [2016Aug10]

# Appendix 8: Glossary[23]

## 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 JM, Hebert P, Hoffman C. Canadian Patient Safety Dictionary. Royal College of Physicians and Surgeons of Canada, 2003. [Cited 2016Aug10] Available from: http://www.royalcollege.ca/portal/page/portal/rc/common/documents/publications/patient_safety_dictionary_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, H.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[24]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 the 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 Assessment." *ISMP Canada Safety Bulletin.* 2009. [Cited 2016Aug10] Available from: https://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 JM, Hebert P, Hoffman C. Canadian Patient Safety Dictionary. Royal College of Physicians and Surgeons of Canada, 2003. [Cited 2016Aug10] Available from: http://www.royalcollege.ca/portal/page/portal/rc/common/documents/publications/patient_safety_dictionary_e.pdf.

## 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[23] 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 in Acute Care Settings. [Cited 2016Aug10] Available from: http://www.ismp.org/Tools/institutionalhighAlert.asp.

## Human factors engineering

Human factor 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. [Cited 2016Aug10] Available from: http://www.nccmerp.org/about-medication-errors.

Developed by the collaborating parties[23] of the Canadian Medication Incident Reporting and Prevention System, 2005.

**Similar term:** *Medication error*

## Medication Safety

Freedom from preventable harm with medication use.

**From:**
Institute for Safe Medication Practices Canada. "Definition of Terms." ISMP Canada: 2007. [Cited 2016Aug10] Available from: 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.
(Similar Terms: Near Hit or Good Catch)

Developed by the collaborating parties[22] of the Canadian Medication Incident Reporting and Prevention System, 2005.

## 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[23] 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:**

Kohn, 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:**

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