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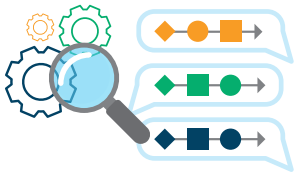
Understanding and Applying Proactive Risk Assessment Methodologies

The implementation of structured proactive risk assessment methodologies can help organizations identify and address vulnerabilities in a process, technology, product or service *before* a negative outcome occurs. This bulletin shares 3 approaches to proactive risk assessment that ISMP Canada has used in collaborative projects, specifically **cognitive walkthrough**, **failure mode and effects analysis (FMEA)**, and **usability testing**.

When planning a new program or change, there is often an informal process for considering risks; however, a structured process can improve the rigour and effectiveness of such an assessment. Key types of vulnerabilities to examine in a proactive risk assessment include process gaps, workarounds[1] (where team members have to overcome a system limitation), points of excessive cognitive burden, and inefficiencies. The results of such analysis can lead to insights for timely improvements or for further study.

In some projects, it can be beneficial to use complementary proactive risk assessment methodologies sequentially, with the findings from one analysis informing a later step in the project. The 3 described methodologies are presented in the order in which they would be suggested for a sequential project.

Cognitive Walkthrough



> *A **cognitive walkthrough** involves walking through the process or task of interest, examining the mental activities required at each step and the challenges experienced.*[2]

A cognitive walkthrough can be used for the following purposes:

- to gain an understanding of the process from the user's perspective[2]
- to develop a shared understanding of the points in the process where problems may occur[3]
- to suggest improvements for identified weaknesses in the process[3]

When to Use a Cognitive Walkthrough

In a health care setting, cognitive walkthrough can be helpful when planning a new process or considering potential changes to an existing process, or it can be used as a step in a detailed evaluation of a process (such as an FMEA, as described below). A cognitive walkthrough can be done quickly and does not require specialized equipment or resources. It provides a means of engaging the end-users of a process or product (e.g., patients and front-line providers) in a way that yields helpful feedback for process improvements.

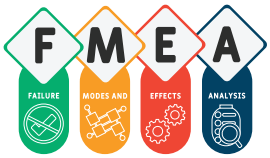
How to Conduct a Cognitive Walkthrough

Ideally, a cognitive walkthrough is conducted in the environment where the process occurs, using materials (e.g., medications, devices, software) that would typically be available.[2] When this is not possible, the walkthrough can take the form of a team meeting with individuals representing the disciplines and key stakeholders involved in the process under review.

During a cognitive walkthrough, each individual is asked to literally or figuratively "walk through" or describe each step. As they do so, they are asked to "think out loud", explaining what they are mentally considering while completing the step, as well as any difficulties that may occur.[2]

A key focus of cognitive walkthrough is the mental process and cognitive burden required to complete particular tasks or activities.[2] Understanding these as potential vulnerabilities can help in designing safeguards to support team members in consistent and accurate task completion.

Failure Mode and Effects Analysis



> ***Failure mode and effects analysis*** *(FMEA) is a step-by-step approach for identifying possible failures in a design, a process, or a product or service. It also captures the effects of each potential failure.*[4,5]
>
> *FMEA is based on the premise that all processes may contain embedded failures.*[4,5]

FMEA is a team-based, structured approach. The team typically includes representatives of all disciplines and key stakeholders involved in the process under review.

FMEA has the following goals:[5]

- to reduce the likelihood of failures
- to make failures visible (i.e., enable them to be corrected before they reach a patient)
- to reduce the impact of any failure that does occur

When to Use an FMEA

FMEA can be used to assess processes, technologies, products, and services. ISMP Canada's FMEA framework[5] describes the use of this methodology to evaluate health care processes. While FMEA shares similarities with other evaluation techniques that use process-mapping (e.g., LEAN),[6] it also includes structured risk assessment and prioritization components.

Although FMEA can be used to identify vulnerabilities in almost any situation, it can be resource-intensive and is typically reserved for the evaluation of processes that carry a higher risk for patients and/or staff.

How to Conduct an FMEA

Figure 1 outlines the steps in conducting an FMEA. Once a process has been selected for evaluation, the main process steps and sub-process steps need to be identified.[5] If a cognitive walkthrough has been completed, a flow chart of these steps, in addition to any areas of concern that have been identified, will already be available.

1	Select a process to analyze and assemble a team
2	Diagram the process and sub-processes chosen for analysis
3	Brainstorm potential failure modes within the process
4	Identify the effect(s) and cause(s) of the potential failure modes that impact patient safety
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)

FIGURE 1.
Steps in conducting a failure mode and effects analysis.[5]

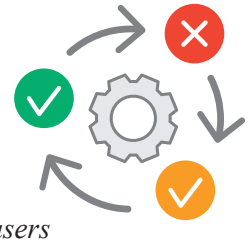
For each process step, the team brainstorms the potential failures that could occur, as well as the effect (i.e., consequence) and cause (i.e., contributing factor) of each.[5] As an example, for a process requiring a series of medications in syringes, a potential failure mode is a practitioner selecting the wrong syringe, and the effect of that failure mode could be that a patient receives an intended medication at the wrong time. A potential cause might be the use of labels that do not prominently display critical information.

The team then evaluates the severity, frequency, and detectability of each possible failure. A scoring process is used to prioritize the failure modes based on the highest potential risks.[5]

Once the potential failures have been prioritized, the team considers approaches to reduce the identified risks. Such reductions can be accomplished in any of several ways:[5]

- reducing the severity of the outcome, should the failure occur
- decreasing the frequency of the failure
- increasing the likelihood that the failure will be detected, should the failure occur

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.*[7]

Usability testing

- is conducted to determine the effectiveness of, efficiency of, and satisfaction with a product, with testing performed in the context the product was intended to support[8]
- provides quantitative data through observation and performance measures,[7] as well as qualitative findings

When to Use a Usability Test

Usability testing is resource-intensive and thus is typically used to test relatively complex or high-risk processes. It can be particularly helpful for testing new processes or new technologies.

How to Conduct a Usability Test

Begin by identifying the process or product to be assessed and determining the types of participants needed.

For a medication-related process, the test might include the following elements:

- the subject medication product(s)
- other, similar medications
- devices needed to administer the product
- other equipment that would be found in a typical practice environment

Suitable test participants would represent the disciplines typically handling the medication. The test begins with a brief orientation, during which participants are given background information similar to what is available in their work setting.[8] The test facilitator observes the participants as they complete the assigned task(s) to identify process challenges and actual or potential errors. The test concludes with a debrief interview.

Usability test findings demonstrate where end users experience difficulties in completing an assigned task.[7] These findings can be used to develop and implement safeguards in the process.

CONCLUSION

Structured proactive risk assessment methodologies can support health care providers and organizations in analyzing processes, products, and services to identify safety vulnerabilities, inefficiencies, and difficult user experiences. Readers are encouraged to consider how the described methodologies can be used in their own practice settings to enhance patient safety and improve the care experience for both patients and providers.

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CMIRPS SCDPIM

Canadian Medication Incident Reporting and Prevention System

Système canadien de déclaration et de prévention des incidents médicamenteux

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