

Patient Safety Improvement: Prospective Analysis

Introduction

One of CCHSA's Patient Safety Goals is to create a culture of safety within health service organizations. An associated *Required Organizational Practice* is to **carry out one patient safety-related prospective analysis process per year, and to implement appropriate improvements/changes**. In other words, CCHSA is requiring all member organizations to select a high risk process or activity and to proactively analyze it to identify ways it could be improved and made safer. The intent is to encourage our members to review and improve processes to prevent the occurrence of an adverse event.

In choosing a high risk process or activity, one needs to consider processes in which a failure of some type would likely compromise client/patient safety. High risk processes include, but are not limited to, medication use, operative and other procedures, patient identification, use of restraints or seclusion, blood administration, care provided to high-risk populations, and emergency care. Even client/patient admission, discharge, and transfer processes can be complex and therefore high risk. All of these are examples of typical processes that may be the subject of prospective analysis.

Prospective analysis can also be linked to more modern, integrated approaches to risk management. Integrated risk management focuses on identifying new opportunities for improvement of risk practices, and prevention, in addition to minimizing losses, the traditional focus of risk management. Integrated approaches to risk management can help clinicians and administrators better understand, communicate, and manage risk and improve related decision-making.¹

There are a **variety of prospective analysis tools and techniques** that are available to organizations. These include:

- Failure Modes and Effects Analysis (FMEA)
- Errors of Omission (J. Reason)
- Simulation
- Fault Tree Analysis
- Hazard Analysis
- Worst-Case Analysis
- Hazard Analysis and Critical Control Point (HACCP)

An overview of each of these tools and techniques is presented below. This information is meant to provide a brief introduction to common prospective analysis tools. CCHSA encourages its members and surveyors to increase their awareness, and share their knowledge, of these tools.

Common Prospective Analysis Tools and Techniques

a) Failure Modes and Effects Analysis

FMEA is a team-based systematic and proactive approach to identify ways that a process or design can fail, why it might fail, the effects of that failure, and how it can be made safer. FMEA focuses on how and when a system will fail, not IF it will fail.ⁱⁱ By carrying out a FMEA, a team can assess the relative impact of different failures, in order to identify parts of the process that are in most need of change.

FMEA includes review of the following:ⁱⁱⁱ

- Steps in the process (diagramming/flowcharting the process is recommended)
- Failure modes (what could go wrong?)
- Failure causes (why would failure happen?)
- Failure effects (what would be the consequences of each failure?)

The FMEA team works together to assign a risk priority number (RPN) for each step in the process, each associated failure mode, and the entire process. Specifically, a number between 1-10 (other scales exist) is assigned for the likelihood of occurrence; a number from 1-10 is assigned for the likelihood of detection; and a number from 1-10 is assigned for severity. The total RPN is calculated by multiplying these three numbers together. Failure modes with the highest RPN are usually the best areas to target improvement.

In redesigning the process to make it safer, strategies need to be applied to decrease frequency, decrease severity, or increase detection. Strategies/solutions often involve simplification, automation, standardization, fail-safe mechanisms, forcing functions, and redundancy. Checklists, cognitive aids, and usability testing may also contribute to improvements.

Evaluation of the improved process or activity is also required. Teams may wish to consider conducting a FMEA of the re-designed process. Simulation (discussed later) can also be used to test changes. Pilot testing on a small scale is also recommended. Monitoring results over time is required.

Other than the demand on human resources and time, the main limitation of FMEA is that it deals with failure modes one at a time. In most cases, adverse events are typically the result of multiple failures and pre-existing hazardous conditions.^{iv}

b) Errors and Omissions Assessment

James Reason's Errors and Omission Model^v can be viewed as a simplified FMEA. Reason notes that leaving out necessary tasks/steps is the single most common human error type. Task characteristics most likely to allow omissions are termed "affordances." There are eight important affordances: high information (reliance on short-term memory); isolation; recursive (repeated procedural steps); following (necessary steps that follow the achievement of the main task); hidden (item to be acted on is not conspicuous); interrupt

(steps following unexpected interruptions); depart (planned departures from standard operating procedure or habit); poor signals (actions that are triggered by weak, noisy, or ambiguous signals).

There are four main steps to use this model:

1. Set up a team
2. Conduct a task analysis
3. Assess omission likelihood
4. Choose and attach a reminder.

In setting up **the team**, the right people need to be included. For example, if the process is medication-related, then a pharmacist should be present. Ask yourself if you need to include someone who is responsible for staff education, or whether you need the involvement of a physician, for example. Those asked to participate must understand why they were asked, and should be supported to take the time required to carry out the prospective analysis.

Conducting the **task analysis** involves decomposing an activity or procedure into a meaningful number of discrete steps. This is not particularly difficult, but it can be labor intensive. Therefore, it is important to be selective when choosing the activity or procedure. Determine whether safety is critical. Ask yourself, “Would the omission of particular steps in the task have an injurious effect upon the client?”

To **assess omission likelihood**, first review each task/step for its omission affordances. Use a grid with each task/step in the first column, and the eight important affordances along the top row. Mark the columns in which an omission provoking characteristic exists for each task step. Sum the ticked features across the columns. Any step that possesses two or more ticks is a candidate for a reminder.

| | High info | Isolation | Recursive | Following | Hidden | Interrupt | Depart | Poor signals |
|--------|-----------|-----------|-----------|-----------|--------|-----------|--------|--------------|
| Step 1 | | | | | | | | |
| Step 2 | | | | | | | | |
| Step 3 | | | | | | X | | X |

Reminders should then be developed to prevent omissions. The following table outlines criteria for good reminders.

| Universal Criteria for Good Reminders – The Five ‘Cs’ | |
|---|---|
| Conspicuous | A good reminder must be able to catch the actor’s attention at the critical time |
| Contiguous | A good reminder should be positioned as close as possible in time and space to the location of the necessary action |
| Context | A good reminder should provide information about the “when” and “where” of the item to be remembered |
| Content | A good reminder should provide sufficient information regarding what has to be done |
| Count | A good reminder should allow the actor to count off the number of discrete actions/tasks that need to be done |

Simulation

The term “simulation” in health care is commonly associated with the clinical education of health care professionals. At its basis, simulation is a technique to replace or amplify real life experiences with guided experiences that evoke or replicate substantial aspects of the real world in a fully interactive manner.^{vi} This technique is helpful in preparing people for error-prone, high risk, or unusual situations. By simulating possible adverse events, people learn to recognize problems and understand the effects of their responses in a safe environment.

Simulation forces people to review processes on a very detailed level, and this can help to improve patient safety. Additionally, its true power lies in the ability to explore “what if” scenarios and make decisions accordingly. For example, simulation can be used to help determine the appropriate resource requirements associated with a defined patient volume and provider practice patterns – such as the appropriate level and mix of nurse staffing.^{vii}

Simulation demands effective process analysis, which requires the participation of a representative from each part of the process. At least one external person should also be involved to ask critical questions, possibly draw flow diagrams, and help to guide the work of the team. The team would likely require more than one meeting to complete the process analysis and simulation. “On the positive side, it is quite common that the interaction and discussions lead very quickly to the detection of easily solvable problems and improve coordination.”^{viii}

Typical results of simulations include changing the process flow, reducing process times, changing material handling methods, re-assigning functions, bringing in new technologies, updating information processing methods, and adding or replacing resources. These changes, when appropriate, can help to improve patient safety.

Fault Tree Analysis

Fault Tree Analysis is a graphical technique that provides a systematic description of the combinations of possible occurrences in a system, which can result in an undesirable outcome.^{ix} This method can combine hardware failures and human failures. The team begins by identifying the most serious possible outcome (i.e. the Top Event) – such as a client/patient death - and a fault tree is then constructed by relating the sequences of events, which individually or in combination, could lead to the top event. The fault tree is constructed by deducing in turn the preconditions for the top event and then successively for the next levels of events, until the basic causes are identified.

By ascribing probabilities to each event, the probability of a Top Event can be calculated. This is a powerful technique for identifying the failures that have the greatest influence on bringing about the End Event.

Hazard Analysis

Hazard Analysis is a useful technique that can benefit patients/clients as well as the entire organization.^x This technique is known for its effectiveness in regards to improving health and safety in the workplace, and as such, can be used to identify and address areas for patient safety improvement. The key steps include:

- identifying health and safety hazards
- evaluating hazards associated with specific jobs, tasks, machines, and tools
- prioritizing hazards in terms of the risk posed
- describing methods to control the hazards and implement corrective actions
- explaining practical hazard controls that are applicable
- writing detailed, safe-work job practices and procedures, incorporating the hazard analysis into each

Using these steps, hazard analysis can be used by health service organizations to proactively assess high risk activities and processes, in order to make improvements to patient safety.

Worst Case Analysis

Worst Case Analysis is often used in the design and analysis of circuits, devices, and equipment. The worst case is simulated by taking all variables to their 2-sigma or 3-sigma worst case values. Since it is unlikely that several independent variables will attain their worst case values simultaneously, this technique tends to be overly pessimistic, and can lead to over-design. However, it is useful as a fast check.

Hazard Analysis and Critical Control Point

Hazard Analysis and Critical Control Point (HACCP) is based on a food safety program developed nearly thirty years ago in the United States. HACCP involves seven principles^{xi}:

1. Identify and analyze potential hazards. Using a food safety example in a long-term care organization (such as meals for residents in a long-term care organization), the hazard could be biological (a microbe); chemical (such as a toxin); or physical (such as a glass fragment).
2. Identify critical control points. These are points in the process at which the potential hazard can be controlled or eliminated. Using the food safety example, critical control points include storing food, cooking, cooling, portioning, and delivering food to residents.
3. Establish preventive measures with critical limits for each control point. For cooked food, this might include setting the minimum cooking temperature and time required to ensure the elimination of harmful microbes.
4. Establish procedures to monitor the critical control points. Such procedures might include determining how and by whom cooking time and temperature should be monitored.

5. Establishing corrective actions to be taken when monitoring shows that a critical limit has not been met. For example, reprocessing or disposing of food if the minimum cooking temperature is not met.
6. Establish procedures to verify that the system is working properly. For example, testing time- and temperature-recording devices to verify that a cooking unit is working properly.
7. Establish effective recordkeeping to document the HACCP system. This would include records of hazards and their control methods, the monitoring of safety requirements and action taken to correct potential problems. Each of these principles must be backed by evidence.

HACCP's advantages to patient safety include its focus on identifying and preventing hazards, as well as its basis in evidence. This model is most appropriate to help ensure safety of high risk activities and processes.

Conclusion

This document provides a brief overview of common prospective analysis tools that can be used to analyze high risk processes or activities in order to identify ways they may be improved and made safer. CCHSA's *Required Organizational Practice* on prospective analysis is meant to encourage our members to review and improve high risk activities and processes to prevent the occurrence of an adverse event.

CCHSA encourages its members and surveyors to seek out additional information and resources on prospective analysis tools and techniques. Information on education sessions and other resources can be obtained by contacting CCHSA's Education Team at 613- 738-3800 or 1-800-814-7769.

ⁱ Patrick L. Building an effective risk management program in a healthcare setting. *Healthcare Management Forum* 2004 17(3):27-9.

ⁱⁱ Institute for Safe Medication Practices Canada (ISMP). 2004.

ⁱⁱⁱ Institute for Healthcare Improvement: Failure Modes and Effects Analysis Tool Report. January 2005. <http://www.ihl.org/ihl/workspace/tools/fmea/ViewTool.aspx?ToolId=1>

^{iv} Croteau RJ, Schyve PM. Proactive error-proofing healthcare processes. Chapter 7. In: *Error Reduction in Healthcare: A systems approach to improving patient safety*. San Francisco, Jossey-Bass/AHA press, 2000.

^v Reason, J. Combating omission errors through task analysis and good reminders. *Quality & Safety in Health Care* 2002;11:40-44.

^{vi} Gaba, DM. The future vision of simulation in health care. *Quality & Safety in Health Care* 2004;13:i2-i10.

^{vii} Sanchez S, Ferrin D, Ogazon T, Sepulveda J. Emerging Issues in Healthcare Simulation. *Proceedings of the 2000 Winter Simulation Conference*. J.A. Joines, R.R. Barton, K. Kang, and P.A. Fishwick, eds.

^{viii} Ibid.

^{ix} Institute of Electrical Engineers, UK. September 2004. Health and Safety Briefing No 26c. www.iee.org

^x Hazard analysis. http://www.pragmatic-solutions.com/safe-t-link/hazard_analysis.htm

^{xi} FDA Backgrounder. HACCP: A state-of-the-art approach to food safety. <http://www.cfsan.fda.gov/lrd/bghaccp.html>