

Safer Management of Alerts and Recalls: Applying FMEA for Positive Change

Background

The Canadian Council on Health Services Accreditation Program requires that health organizations conduct at least one prospective analysis per year. Failure Modes and Effects Analysis is one example of a proactive risk assessment tool that can improve patient safety by helping us to:

1. understand how errors occur, and
2. drive change by forecasting potential failures and applying loss controls before harm occurs.

Managing hazard alerts and device recalls is a key patient safety process which can result in risk of injury or death if alerts/recalls are not promptly detected and resolved. There are also financial risks associated with equipment damage and loss.

As a large new regional health authority, Eastern Health was ready to rollout an internet based alerts tracker system that was in use primarily in the acute care tertiary centres. As the current process was not working optimally nor was it widespread throughout the organization, it was an excellent opportunity to conduct a failure modes and effects analysis.

This analysis allowed us to systematically identify several potential risks to the current process. For example:

- ❖ varied practices of managing alerts/recalls in legacy boards
- ❖ varied information systems in place
- ❖ not all equipment/devices are tracked through a central inventory
- ❖ evolving management structure in a new health authority
- ❖ little or no historical data on equipment
- ❖ alerts and recalls are received by many individuals
- ❖ alerts and recalls are received from many different sources
- ❖ alerts and recalls are received in paper and electronic formats
- ❖ no standardized process exists
- ❖ action is dependent on many individuals
- ❖ accountability for action is unclear

Process

Applying the steps of FMEA, we diagrammed all of the 10 steps for the management of alerts/recalls and plotted how the process is intended to work. We then critically evaluated what could fail at each step; why this failure would occur and what could happen as a result. Each failure was assessed using a risk assessment tool and rated for degree of probability and severity.

We examined specific incidents/occurrences of failures and also reviewed root cause analyses of events that occurred in other health care organizations relating to alerts

management. This helped us to evaluate the lessons learned and identify opportunities for improvement within our own system.

We thoroughly researched better practices for the management of alerts and recalls in health care organizations and identified alternate products and vendors. We then identified the key elements of a safer process for alerts/recalls management and outlined a redesign with options to improve the existing process.

Outcome

As a result of conducting a FMEA, a new process for the management of hazards, alerts and device recalls has been implemented throughout our organization. The system is now much more comprehensive and includes management of alerts and recalls for a broader range of domains, i.e. equipment, biomedical devices, medical supplies, blood products, pharmaceuticals, food, biologics, software, building systems and consumer products. The new process has defined requirements for notification and distribution, real time tracking and automatic time sensitive actions. It is easy to view and compile reports that track any responses and follow-up on a particular alert; and the automated notification and escalation features have enhanced accountability for action and a faster turn around time for response.

Results are regularly reviewed by domain managers and reported to the organization's alerts management steering committee and Quality Council.

The organization now has greater confidence that we receive, act on and resolve alerts and recalls more efficiently and effectively thereby providing a safer system for patients, residents and clients of our many programs and services.