Failure Mode and Effects Analysis Can Help Guide Error-Prevention Efforts

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Too often, marketing efforts, contractual agreements with purchasing groups or vendors, and costs serve as primary sources of information when decisions are being made about which medical products to purchase and use. Evaluation and input from users of the products are not always sought, and the potential for errors might not be considered ahead of time. Later, these omissions can lead to unforeseen problems in the hands of clinical users.

A process known as *failure mode and effects analysis* (FMEA) can be used to help avoid these pitfalls. FMEA provides a way to examine the use of new products and the design of new services and processes, so that points of potential failure and their effects can be determined—*before any error actually occurs.*

In this regard, FMEA differs from *root cause analysis* (RCA). Root cause analysis is a *reactive* process that is used *after* an error occurs in order to identify the error's underlying causes. In contrast to this method, FMEA is a *proactive* process that is used to examine vulnerable areas or practices more carefully and systematically. FMEA can be employed before new services, processes, or products are purchased or implemented, to identify potential failure modes, and so steps can be taken to avoid errors before they occur.

How can FMEA be used to reduce the risk of medication errors? To cite just one example, an interdisciplinary P&T committee might use FMEA to assess new drugs being considered for the formulary. Here's how the process would work:

Step 1. The P&T committee would explore how the intended product would be procured and used, from acquisition through administration. Who would prescribe the drug and for what type of patient? Where would the drug be stored? Who would prepare and dispense it? How would the drug be administered?

Step 2. The committee would identify potential failure modes (i.e., how and where systems and processes can fail) while considering how the product would be used. Can the drug be mistaken for another similarly packaged product? Does the label clearly express the strength or concentration? Does the drug name sound or look like another drug on the formulary? Are dosing parameters complex? Is the administration process prone to error?

Step 3. Once failure modes have been identified, the staff would determine the likelihood of making a mistake and the potential consequences of an error. What would happen to the patient if the drug were given in the wrong dose, at the wrong time, to the wrong patient, by the wrong route, at the wrong rate?

Step 4. The staff would identify any pre-existing processes in place that could help detect the error before the drug reaches the patient. In addition, the staff would evaluate the effectiveness of these processes based upon knowledge of human factors.

Step 5. If failure modes could cause errors with significant consequences, actions would be taken to prevent the error, to detect the error before the drug reached the patient, or to minimize the consequences of the error. For example, the staff might use an alternative product, prepare the drug in the pharmacy, standardize drug concentrations, order communication and dosing methods, use auxiliary warning labels or computer alerts, and require entry of specific data into computer systems before processing orders.

The new patient safety standards for hospitals, as outlined by The Joint Commission on Accreditation of Hospital Organizations (JCAHO), now require organizations to engage in proactive risk-management activities, including FMEA. Although industries outside of medicine have developed elaborate FMEA scoring systems to rank items for action, the simplified FMEA process, as described in this article, can be an efficient, proactive risk-management tool, especially when organizations consider what is already known about the potential for errors from past experiences or from information available in the media, such as the medication safety alerts announced by the Institute for Safe Medication Practices (ISMP).

SELECTED READINGS

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