

# Medication Safety Alerts

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## APPLYING ENGINEERING PRINCIPLES TO MEDICATION SAFETY

Some readers may be familiar with the legend of the Iron ring that is worn by professional engineers. In 1900, construction began on a railway bridge near Quebec City that would be part of the National Trans-Continental Railway. On August 29, 1907, the nearly completed bridge collapsed under the weight of a train loaded with steel, killing 75 workers. The tragedy was determined to have been caused by human error. It is commonly believed that the iron rings awarded to graduating engineers are crafted from the steel of the collapsed bridge as a reminder that errors can have devastating consequences and as a reminder of the role of the professional engineer. In fact, this is a myth; the rings were never made from bridge materials and do not symbolize the failure of this or any other engineering project.<sup>1</sup> However, the story does provide a useful metaphor for health care. Similar to the way in which engineers have learned to design safe bridges, significant steps are being taken to apply engineering principles within our health care systems, to design processes with inherent safeguards, in the hope of replacing a culture of blame with a culture of safety.

In 2000, the US Institute of Medicine published a comprehensive report, *To Err is Human: Building a Safer Health System*,<sup>2</sup> which examined the current state of medical error and the need for major system changes. The report noted that “medical culture creates an expectation of perfection and attributes errors to carelessness or incompetence.” Leape has noted that “Errors must be accepted as evidence of system flaws, not character flaws.”<sup>3</sup> Despite this awareness, health

care workers, unlike engineers, are not taught the principles of creating systems to enhance safety and minimize opportunities for error. General knowledge about how to proactively design health care processes is limited, and a culture of blame remains prevalent. Furthermore, the “rate of failure in health care is unknown and may be unknowable.”<sup>4</sup> As health care processes become more complex and interdependent, opportunities for failure increase, as does the difficulty of recovering from such failure. Critical evaluation of processes through the use of failure mode and effects analysis and root cause analysis provides insights into proactive and reactive process corrections to prevent future errors. For these tools to be most effective, they must be undertaken with an understanding of the principles of human factors engineering. As noted by Gosbee and Anderson,<sup>5</sup> “without some appreciation of human factors engineering, the focus of adverse event analysis is often misguided towards policies or an individual’s shortcomings, leading to ineffective solutions.”

### Human Factors Engineering

Human factors engineering is defined as the “study of interrelationships between humans, the tools they use, and the environment in which they live and work.”<sup>2</sup> Consideration of human factors anticipates that people make errors, as illustrated by the 4 basic principles of human factors engineering<sup>6</sup>:

- All people are fallible.
- System design can reduce errors.
- System design can detect errors.



- System design can reduce the consequences of errors.

The increasing use of technology at all levels of health care makes consideration of human factors a requirement for error prevention. A recent United Kingdom study, reviewing 1495 incidents directly associated with infusion pumps, showed that in 53% of cases no fault was found with the device.<sup>7</sup> Technical excellence was not sufficient to prevent serious errors from occurring. In his book *The Human Factor*, Vicente has noted that “More and more, we’re being asked to live with technology that is technically reliable ... but that is so complex or counterintuitive that it’s actually unusable by most human beings.”<sup>8</sup>

Medication systems in health care are complex and require the interaction of multiple subsystems involving people, equipment, and organizational frameworks such as policies, procedures, and guidelines. An individual’s ability to complete work is influenced by many factors, some of which are not readily apparent. The principles of human factors engineering take into account human characteristics such as physical dimensions and human mental characteristics such as learning, remembering, and decision making. Other human factors such as group dynamics, task complexity, and concurrent tasks also affect job performance.<sup>9</sup>

Medication label design is an example of an area where the consideration of human factors principles is critical. Use of simple, sans serif fonts and of font size appropriate to reading distance and lighting levels substantially improves readability of labels. Use of “tall-man lettering” (i.e., combinations of uppercase and lowercase letters, instead of full uppercase or full lowercase lettering) is an effective method of differentiating look-alike drug names, because it recognizes and accommodates the human factors principle of confirmation bias.<sup>10</sup> Tall-man lettering creates a mental alert by changing the shape of words that look similar when seen in uppercase letters only. An example of tall-man lettering is shown below:

VINCRISTINE	VinCRIS <sup>t</sup> ine
VINBLASTINE	VinBLA <sup>s</sup> tine

## Failure Mode and Effects Analysis

Failure mode and effects analysis is a systematic, proactive evaluation method used to identify and prevent process and product problems before they can occur. The first such analyses were performed in the aerospace industry in the 1960s, focusing on safety improvements. Since then, they have been used

extensively in the aeronautical, nuclear, and automotive industries and more recently have been beneficial in the evaluation of health care procedures. Failure mode and effects analysis is effective in evaluating a new process before its implementation and in proactively appraising the consequences of proposed changes to current processes. The analysis includes review of:

- steps in the process
- failure modes (What could go wrong?)
- failure causes (Why would the failure happen?)
- failure effects (What would be the consequences of each failure?)

The first step in conducting a failure mode and effects analysis is the identification of the specific process to be reviewed. Complex processes must be broken down into subprocesses. For example, the medication ordering, dispensing, and administration components of the medication-use system require separate analyses, since the system as a whole is too complex. Failure mode and effects analysis should be a team responsibility and should include everyone who is involved in the process under review. The team’s first task is to identify and chart all the steps in the process. Once this has been completed, the team identifies the possible “failure modes”, i.e., opportunities for error.

A key feature of failure mode and effects analysis is the assessment of the risk associated with each failure mode. In some approaches a mathematical calculation is used to develop a risk priority number for each failure mode. This calculation is based on the likelihood of occurrence, the likelihood of detection, and the severity of harm resulting from a system failure. Use of the risk priority number allows an objective assessment of the identified failure mode and assists the team in prioritizing areas for improvement. Processes with a high likelihood of occurrence and a low likelihood of detection have a higher risk priority number; low risk priority numbers are less likely to be of clinical significance.<sup>11</sup> In 2001, the US Department of Veterans Affairs developed a streamlined version of failure mode and effects analysis specifically for use in health care. This process uses a decision tree algorithm and replaces the risk priority number with a hazard score.<sup>12</sup> Detailed information on failure mode and effects analysis in health care can be found at the Department of Veterans Affairs Web site,<sup>13</sup> as well as the Web site of the Joint Commission on Accreditation of Healthcare Organizations.<sup>14</sup>

For failure modes that are likely to occur and that have a high risk priority number or hazard score, causes should be eliminated, if possible, or safeguards implemented. Examples of safeguards are verification



steps, forcing functions, and constraints. Constraints and forcing functions are the most useful interventions in reducing error potential because they direct people to perform in a given way. They use human factors principles to avoid over-reliance on memory and problem-solving. For example, a failure mode and effects analysis might determine that for medication products that look and feel alike, such as potassium chloride concentrate and 0.9% sodium chloride for injection, a system safeguard must be implemented to prevent deadly substitution errors. Removing potassium chloride concentrate from nursing units provides a constraint safeguard, in that the product is not available and cannot be selected in error. Regular pharmacy rounds to remove discontinued medications from patient care units, to decrease the risk of unordered medications being administered, is another example of a constraint safeguard.

## Root Cause Analysis

Root cause analysis is used to determine the underlying causes of an event and to identify strategies for the prevention of error-induced injuries. It differs from failure mode and effects analysis in that it is conducted after an event has occurred. Root cause analysis is a systematic process of investigating a critical incident or an adverse outcome to determine the multiple, underlying contributing factors.<sup>15</sup> A cause may be identified as a set of actions, circumstances, or conditions. When performing a root cause analysis it is important to frame questions in a nonthreatening manner, for example, "What should be done to prevent this in the future?" rather than "What should have been done to prevent this occurrence?" It is important to believe that each human error has a preceding cause. Determining that a human error has been made without asking "why" does little to assist in the prevention of future errors. Root cause analysis is similar to failure mode and effects analysis in that it requires the involvement of a multidisciplinary team and an understanding of the processes involved in the event. The investigative phase focuses on a series of "why" and "how" questions to determine the underlying causes of an event, including a review of relevant human factors. Root cause analysis assists with differentiating the immediately obvious proximate causes from the underlying causes that led to the proximate causes. The true root causes are the earliest points where action could have been taken to enhance the support system such that the appropriate care could have been delivered, the incident prevented completely, or the effect on the patient substantially

decreased.<sup>16</sup> Consideration of human factors in root cause analysis provides real understanding of the reasons why an event occurs, rather than just creating a list of procedural violations.<sup>17</sup> Once the predominant underlying causes have been identified, human factors engineering principles assist in developing a workable action plan. An effective root cause analysis action plan includes responsibility for implementation, supervision, testing (if needed), timelines, and outcome measurement.

## Conclusions

Consideration of human factors engineering principles, failure mode and effects analysis, and root cause analysis provides for a combination of proactive and reactive system changes that will have a synergistic positive effect on patient safety and overall process improvement in health care. It is no longer sufficient to rely on staff "doing their best" to provide top-quality health care. Systems must be thoughtfully designed and systematically evaluated to support health care providers in their day-to-day efforts to care for patients. "We must never let 'good enough' be good enough. We must be relentless in our pursuit of finding ways to improve our systems."<sup>18</sup>

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### **CJHP Supplement for 35th Annual Professional Practice Conference (PPC): Correction**

The 35th Annual PPC Supplement, published in January 2004, did not include the volume and supplement number designation. The correct designation is as follows:

**Vol. 57, Supplement 1 (PPC) January 2004**

### **Hypoglycemia and Hyperglycemia Associated with Fluoroquinolones: Correction**

Because of a production error, an incorrect value appeared in Figure 1 of the recently published article on reports of hypoglycemia and hyperglycemia associated with systemic fluoroquinolones, by Sandra A.N. Tailor and others.<sup>1</sup>

Figure 1 (on page 15) illustrates the number of reports about this group of drugs made to the Adverse Drug Reaction Monitoring Program that were due to hypoglycemia, hyperglycemia, or both. Of the 27 reports of adverse reactions associated with gatifloxacin, a total of 25 (not 26) were related to these 2 problems. The percentage of the total number, 93%, is presented correctly in the figure.

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