System Safety in Healthcare

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Software, Technology and Humans — A Safe Team Sport?

The medical industry is faced with new devices and technology on a regular basis. The multiple goals of these devices and technologies vary, depending on the user's angle. Ultimately, they hopefully provide the best care for patients in the most efficient way possible, while containing costs and maintaining patient safety. Recent studies have found that rapid implementation of new medical technology — surgical devices, electronic health records, monitoring systems and other tools — can lead to adverse patient events when implementation is not thoughtfully and carefully integrated into the workflow. This integration requires not only a thorough understanding of how the new tools work, but also of how they can be safely integrated into the system — including an analysis of human factors, such as in environments where people interact with these devices repetitively or in high-pressure situations.

From 2011 to 2013, human factor issues were the most frequently identified root cause of "never-events," such as medication errors and treatment delays, according to a Joint Commission report. "It's the interface of the human with the technology that creates a problem," said Ana Pujols-McKee, M.D., the commission's chief medical officer. This was highlighted in an unfortunate event at a MedStar Health hospital. In 2011, a clinical staff member misunderstood a confusing pop-up box on a digital blood-sugar reader and mistakenly administered insulin to a patient with low blood sugar, which caused her to go into a diabetic coma. Hospital staff had earlier made a seemingly minor customization to the glucometer, leading to this error [Ref. 1].

Technology is supposed to enhance workflow and decrease errors. However, software technology may sometimes *hamper* workflow, such as having repetitive pop-ups for every step of the procedure, which can lead to hospital staff members ignoring or speeding through them to get the work done. If the pop-ups "cry wolf" at every step, it can be predicted that at some point, when a critical pop-up appears, it will be mistakenly ignored. Another component that can be included in some of these programs is automation. Automation can include information linkage to improve medical history retrieval and medication reconciliation. This technology can be programmed to discontinue certain drugs at predetermined dates, such as antibiotics and narcotics. In 2013, a patient admitted to Northwest Community Hospital in Arlington Heights, Illinois, did not receive his previously prescribed psychiatric medicine for nearly three weeks during a hospital stay because the pharmacy's computer system was programmed to automatically discontinue orders for certain types of drugs after a predetermined time. The news report stated that there was no alert programmed into the system to let the patient's care team know that the drug order had been automatically suspended [Ref. 1]. As we have all learned, finding the critical balance where technology enhances workflow while decreasing errors and mishaps remains a challenge.

This challenge has been met with variable response. Although some report that these types of adverse events and near-misses are common when new technology is introduced without adequate analysis of how staff will interact with new devices, reporting of such events is sporadic, and there are few measures in place to help healthcare providers learn from others' mistakes. Also, it's not always the technology that is problematic, safety leaders say, but how thoroughly new tools are tested, understood by users and integrated into the care-delivery process [Refs. 1 & 3].

The Joint Commission reports sentinel events and root causes by event type. This includes the fundamental reason(s) for the failure or inefficiency of one or more processes and the point(s) in the process where an intervention could reasonably be implemented to change performance and prevent an undesirable outcome. It has

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found that a majority of events have multiple root causes. Between 2012 and 2014, human factors remains the most frequently identified root cause of sentinel events as reviewed by the Joint Commission each year [Ref. 2]. In 2014, the root cause for medical equipment-related events resulting in death or permanent loss of function was identified in 218 events in the second quarter alone. Human factors was the leading cause, followed by problems in leadership, physical environment, communication, assessment, information management, care planning, operative care, medication use and continuum of care. Introducing yet another variable in healthcare, such as new technology, requires a thorough consideration and assessment of how all these factors interact in the actual provision of medical care.

Possible Solutions

In such a complex environment, there are some possible approaches to assist in the decision-making process. The following solutions may be used:

- Conduct a hazard analysis before purchasing the system or technology
- Conduct a separate human factors analysis on use and misuse
- Conduct usability testing for human/device interface errors
- Conduct simulations, such as those in which mannequins with automated voices serve as patients and are outfitted with sensors that send cues to staff monitors indicating the success or failure of a process.

Some experts recommend mandatory training for newly introduced devices or technology, while others call for more transparency to allow hospitals to quickly share usability issues and solutions. Simulation is recommended by some. The Society for Simulation in Healthcare, which encourages the use of simulation to improve performance and reduce errors, supports simulation centers in the U.S. by focusing on training clinical staff in new procedures and devices.

Software, just like any new technology, plays a role in moving healthcare delivery toward new heights. But inherent in any ascent is a potential fall. Software, technology and the humans who use them are all players in the same game. After all, this is a team sport and everyone wants to win. The guiding principle from decades ago remains: First, do no harm. This applies to technology just as well.

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