Improving Patient Safety Through Collaboration Between Clinical Staff and Engineering Staff in Hospitals

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Clinicians and biomedical engineers each provide their unique skill sets to the common goal of improving patient safety. Increased communication between the two can improve the medical device experience of caregivers and patients at many points in the lifespan of a medical device. This includes purchasing, training, using, and adverse event reporting and investigation. The Food and Drug Administration's (FDA's) Medical Product Safety Network (MedSun), a network of 250 US hospitals trained to partner with FDA and device manufacturers to report and resolve problems with medical devices, works with participating hospitals to encourage communication and collaboration to improve adverse event reporting and promote patient safety. A cursory look at reports submitted through MedSun shows that hospitals with strong collaborations between engineering and clinical staff are more likely to submit higher-quality reports to FDA with both the clinical scenario and engineering evaluation necessary to appropriately identify and act on medical device issues. The purpose of this article was to discuss the various ways strong collaboration between clinicians and engineers can benefit hospitals and share collaboration strategies as reported by hospitals participating in MedSun.

When implemented effectively, new technology can improve patient care, provide previously unavailable diagnostic capabilities or treatment options, or help caregivers track critical patient information. However, new technology or devices can also complicate workflows, overwhelm caregivers, or result in adverse events. As medical devices become increasingly prominent in the patient care arena, ensuring the safety of both patients and caregivers, as well as the effective use and implementation of new devices and technology, is more and more dependent on collaboration between the clinicians and biomedical engineers at hospitals.

The Food and Drug Administration (FDA) Medical Product Safety Network (MedSun) works with its cohort of 250 US hospitals to report near-misses and noninjury reports and design issues for medical devices in addition to adverse events that result in patient injury or death as required by the Safe Medical Devices Act of 1990. Through this program, hospitals can identify actual or potential issues surrounding medical devices, including use errors, complicated workflows, and confusion associated with new technologies. It has been observed through reports submitted through the MedSun program that hospitals with high levels of communication between clinical and biomedical engineering staff more often submit high-quality reports.

These reports typically provide a complete picture of the event surrounding a near-miss or medical device failure and include details such as a timeline or sequence of events, the level of patient harm sustained, any related medical devices that may have also contributed to the event, and the frequency of occurrence. This is in contrast to reports that consist only of a set of identifiers and observations of the broken device by the reporting staff, which is not always someone with a clinical or technical background.

The details surrounding a device problem need to be gathered by the device user quickly after the problem occurs. Hospitals with strong communication between engineering and clinicians are primed to gather the additional details from the clinical staff that the technical staff needs to appropriately evaluate the device. Including this information in the medical device report can lead to increased patient safety by improving the ability for the hospital, FDA, and device manufacturer to work together to completely understand the problem reported and develop appropriate mitigation strategies.

One goal of FDA's MedSun program is to cultivate and encourage this level of communication and collaboration through education and outreach initiatives. However, improving reporting is not the only benefit of collaboration between technical and clinical staff. In fact, hospitals with increased communication between clinicians and engineers

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can reap benefits beyond effective medical device reporting. The purpose of this article was to discuss the various ways collaboration between these 2 groups can benefit hospitals and to share collaboration strategies as reported by hospitals participating in MedSun.

Choosing a Device

Benefits of collaboration can be observed at the earliest point for a medical device: the decision to purchase a particular device over the many competitors available. An understanding of the clinical environment in which a medical device will be used can be critical to choosing a device that can be utilized safely and effectively. Feedback on design features, usability, and intuitiveness can all be pieces of information provided by clinical staff and utilized by purchasing staff in choosing a device. Likewise, clinical engineering staff can provide insight on a device's total, long-term cost by factoring in maintenance and repair fees.[1] When clinical and engineering staffs discuss these factors together, purchasing staff has a clearer picture of the best devices for their facility.

Training for Device Use

Once a device is purchased, its introduction to the field can be aided by effective training by engineering staff. According to Keil,[2] the training and education that can be provided by biomedical engineering staff are invaluable to the hospital. This training can be tailored to the device and its intended clinical use. When purchasing updated devices, awareness of changes prior to use will decrease the amount of adverse events or near-misses associated with new technology rollout and increase patient safety. Changes can include updated software versions, newly added features, or slight variations of newer models. This is especially important for complex or high-risk devices that may be used in conjunction with various other technologies.

Adverse Event Reporting and Investigation

While collaborative and multidisciplinary purchasing and training processes can decrease the incidence of adverse events, they will not necessarily eliminate them. Communication and collaboration between clinical and engineering staff can directly improve patient safety in subsequent uses of the device following an adverse event. Failed devices are often left in the field as a result of poor communication between nursing and engineering staffs.[3]

At a bare minimum, a broken or failed device can be tagged as such by clinical staff and sent to engineering staff, preventing its further use on other patients and communicating the problem experienced to the engineering staff who can evaluate the product. Biomedical engineers need to know where to start investigations for root-cause analyses, and having this information from clinical staff is critical. Without the information needed to recreate the clinical scenario, biomedical engineers may not be able to replicate and diagnose the device issue. In this case, the device may be returned to the field, only to fail again the next time these clinical circumstances are repeated.

In contrast, improved communication between clinicians and biomedical engineering staff can aid in root-cause analyses. Clinicians have a wealth of information to provide that can lead to improved patient safety in their hospital and nationwide. Details regarding the device failure beyond a statement such as "device broke" or "device failed to operate" can provide critical pieces of the puzzle. Including any alarms that may have (or should have) sounded, what specific part of the device broke, contributing patient factors, the presence of smoke, or a timeline of patient care may all help biomedical staff isolate the cause of the failure. This level of communication between clinicians and engineering staff following an adverse event can make the difference between a correctly identified root cause and repaired device, rather than a device returned to the field incorrectly labeled "use error."

Fostering Communication

While clinical staff and engineering staff may both work to provide patient care and safety, communication is not always well established. One way of fostering communication and collaboration between clinical and engineering staff is through regular safety meetings in which both groups work together to share device-related information. Another way is to put a full-time clinician in the engineering department, or vice versa. As reported by MedSun hospitals who have successfully implemented this strategy, this conveniently provides a liaison that can work with both groups to facilitate discussion.

A more direct way to foster this communication is through a simulation laboratory. By providing an environment that replicates the clinical scenario in which a device will be or has been used, a simulation laboratory can provide a safe learning environment for clinical and biomedical staff alike. Different devices can be used and evaluated prior to purchase, and potential human factors issues can be noted. Likewise, simulation laboratories can provide an environment for biomedical engineering staff to collaborate with the clinicians involved in an adverse event to recreate the conditions surrounding the device failure in an effort to determine the root cause and avoid an incorrect "use error" determination. MedSun hospitals with proven high-level communication between clinical and biomedical staff have also mentioned joint projects with well-defined goals aimed at improving patient safety or having biomedical engineering staff participate in clinical rounds as ways of starting and fostering a collaborative environment. This is

promoted by others, in addition to in-person interactions, surveys, follow-up after service visits, and attendance at clinical meetings.[4,5]

Conclusion

Medical devices are critical to patient care and safety, but new technology can sometimes complicate workflows, lead to use errors, and put patients and caregivers at risk for adverse events. Effective communication between clinicians and biomedical engineering staff throughout the lifespan of a medical device can help mitigate device issues and hazards. Collaboration during the purchasing process can ensure that an appropriate device and training for the specific clinical care scenario are provided. Similarly, adverse event reporting and investigations are aided by improved flow of critical information. Hospitals participating in MedSun have noted various ways of promoting communication to increase patient safety, including simulation laboratories, inclusion of engineers on rounds, and joint patient safety projects. Regardless of the method of collaboration chosen, clinicians and engineers can impact patient safety by working together throughout the life cycle of a medical device.

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