ECRI Institute Provides Hospitals with Safety Roadmap

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A hospital's power to heal is often matched by its ability to injure. As a result, staffs of hospitals and healthcare systems should usher in the new year more with eyes peeled than corks popped.

Among the most prevalent mishaps for 2019 will include infections from decontaminated mattresses that aren't really clean, improperly disinfected endoscopes, and surgical sponges that have been accidentally retained despite staff tallying them before and after procedures. Of course, they should be ever vigilant for lifting devices that fail and send patients crashing. And while cleaning fluid is a godsend for sterile fields, all bets are off should it seep into certain electrical components.

All of these dangers are part of the **ECRI Institute's** "2019 top 10 health technology hazards" list. To round out the list, it cites multiple potential problems with devices' battery charging systems, and alarms on ventilators and physiologic monitors. But the number one hazard for 2019? It is cyber incursions and their potential to disrupt hospital devices and electronic records.

Hospitals increasingly have been relying on ECRI, a private non-profit patient safety organization in Plymouth Meeting, Pa. Founded in 1968 by **Joel Nobel**, M.D. a Philadelphia emergency medicine specialist, ECRI has grown from a simple testing and evaluation laboratory into a global institution with $59.8 million in revenue in 2016, according to its most recently available Form 990 filing with the **Internal Revenue Service**.

Nobel, who died in 2014, was practicing in the 1960s at what was then Pennsylvania Hospital in Philadelphia. He complained that certain makes of the resuscitation devices he was using often failed to work. Hospital administrators barred him from publishing any research that named names.

But when a resuscitation device failed while being used on a four-year-old, leading to the child's death, Nobel, then only in his mid-30s, was prompted to start ECRI. He is also credited with inventing the first "crash cart" – a portable piece of equipment to treat patients in cardiac and respiratory arrest.

One of Nobel's carts is on display in ECRI's entryway.

Hospital Safe Space

When an incident involving a medical device causes a death or serious injury, hospitals must report it to the **U.S. Food and Drug Administratio**n (FDA). But when a device malfunctions without causing an injury, reporting is voluntary and often that means contacting ECRI, which lets hospitals voluntarily share their near misses.

On a recent visit to ECRI's campus, *Health System Specialist* got a behind-the-scenes view of the company's operations.

In the years since the **Institute of Medicine's** groundbreaking 1999 report on medical errors, "we are looking at patient safety in a new way," says **Bill Marella**, ECRI's director of patient safety organizations operations. Due to providing confidentiality to hospitals, it is a "safe space for sharing," he adds.

"The FDA looks at what a manufacturer is claiming the device does," says ECRI's **Diane Robertson**, director of health technology assessment. "We look at the entire process, we do a systematic review."

For instance, Robertson notes, when lasers first came into use for surgical procedures, the devices did what the manufacturers said they would do, but also caused other problems. Those included a potential to accidentally burn a patient, or even set an operating room on fire.

That wasn't an intended outcome from the manufacturers of such devices, but once their product goes into use, they cannot fully account for human behaviors – and fallibility.

"We find workarounds and procedure drift," Marella says.

For instance, he says, nurses can become "alarm fatigued" and start turning off alarms if they continuously go off when patients are not in distress.

"There no one size or no single set of alarm settings, but they do have to be titrated to the acuity level of the patient," he says.

A Global Sentinel

In addition to investigating hospital accidents and tracking adverse events, ECRI monitors hospitals' prescribing practices, writes guidelines and best practices for dealing with hospital mishaps and infection control, and eliminating systems failures. The company regularly issues safety alerts and analyses that compare the prices and functions of various manufacturers' medical devices.

ECRI also takes on special assignments, contracting with governments, health systems, and other entities. One notable example was its design of a medical device safety system specifically for use in Hong Kong, where aestheticians are allowed to use certain surgical instruments without a medical license. They are permitted to use lasers, perform cryo-ablation, and hair restoration involving transplanting plugs of scalp. All this work in the U.S. is the sole domain of physicians.

"They asked us to do an inventory of devices in use by aestheticians and tell them which ones should only be used by doctors," says **Tom Skorup**, ECRI's vice president of applied solutions.

Hospital Mergers As Business Driver

Another area that has helped ECRI grow has been the ongoing wave of hospital and healthcare system mergers in the U.S. Such transactions usually involve performing an inventory of medical

equipment. That would include not only huge numbers of surgical instruments, but big-ticket items such as CT scanners.

Another new line for ECRI is examining the technology involved in remote patient monitoring, whose use has been picking up in rural parts of the country.

“Our legacy is acute care focused but we are doing more on ambulatory care,” Skorup notes.

Infusion pumps have proven to be particularly problematic devices in recent years, so much so that a hospital system approached ECRI earlier in 2018 to ascertain why its infusion pumps often stopped working.

Director of Operations **Jason Launders** and Senior Project Officer **Juuso Leinonen** scrutinized the problem at length in ECRI’s testing lab. The problem turned out to be corroded electrical connections. The culprit? The cleaning solution used by the healthcare system’s hospital.

Nor was that the only potential hazard associated with such devices.

Another manufacturer’s pump design contained a flaw in the keypad resulting in the zero digit being in the wrong place, according to Leinonen. The manufacturers moved that key from the center of the bottom row of icons to the top as part of a redesign to make the keypad smaller.

But in this case, smaller was not better – sleepy or distracted staff could easily make a mistake in entering dosage amounts. Leinonen confirms that such an incident occurred with at least one patient.

Other ECRI detective work involved an infusion device that had a poorly designed lock, meant to keep patients from upping their dosages of morphine. An ECRI investigation concluded that anyone with scissors could unlock the devices with the blade tips.

“It’s effectively a dummy lock,” Launders says.

The Price Vs. Value Equation

Hospitals aren’t just coming to ECRI to determine the safety of certain products. They also want to know whether they’re worth buying in the first place. Among ECRI’s products are a guide to help hospital administrations decide what to buy, particularly useful given that nearly a third of a hospital’s costs are tied to material acquisitions. Big ticket items such as robots often raise questions.

“Beware of technology in search of a patient,” Skorup warns.

An example of that was the use of lasers in performing gallbladder surgery. Although Skorup recalls there was a rush to buy the new technology, the required setup of protective goggles and screens were so time consuming that it was linked to a decline in daily surgical volumes.

In such cases, “we play a strong role,” Skorup says. “It’s hard for a CEO to say ‘I don’t know’” to a surgeon.

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