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What We Have Here Is A Failure To Communicate

Patients Not Hearing About Recalls Is ECRI's No. 1 Technology Hazard

by Brian Bossetta

ECRI says gaps in communication about recalls of medical devices used at homes pose a significant risk to patients. The nonprofit safety organization's list of the top ten technology hazards for 2023 put lack of communication at the top.

More patients today are receiving care in their homes; and thanks to advancements in medical device technology, the quality of that care and access to it is greater than ever.

But there's a downside.

When at-home devices are recalled, patients reliant on those devices are often not notified in time, resulting in injury to many. This gap in communication between the device manufacturer and the patient is the top safety risk posed by health technology for 2023, according to a new report from the Emergency Care Research Institute, or ECRI.

In its report, "*Top 10 Health Technology Hazards for 2023: Expert Insight's from ECRI's Device Evaluation Program*," the nonprofit safety group says device manufacturers seldom have direct communication with home care patients, and health care providers may not proactively contact patients about recalls. All of this means that patients often do not learn about an issue with their device until long after the recall was initiated.

"Even if patients do receive notifications, the language may be jargon-heavy and perplexing, and patients may have difficulty determining whether their device is affected or what to do about it,"

ECRI president and CEO Dr. Marcus Schabacker told *Medtech Insight*.

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MARCUS SCHABACKER

Schabacker, an anesthesiologist and intensive care specialist, said device manufacturers are not set up to communicate directly with customers about product issues in the same way other industries are, such as automobile makers who can immediately notify customers about a car or tire recall.

But keeping patients informed about recalls is not the only gap in communication, Schabacker said.

As more technically advanced devices designed for in-home care hit the market, they will certainly bring the potential of better health outcomes but also risk, especially if how to use and maintain those devices is not fully explained to the user.

And closing these gaps, according to Schabacker, starts with the manufacturers. “They don't know how to reach the patient or the provider who prescribed or recommended the device,” he said, “and they don't know which device the patient ended up with.”

> *“Reaching out to the patient is often very difficult. And the providers don't have the setup, nor the will, to do that.” – Marcus Schabacker*

ECRI’s report cites the Philips recall of its continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP) machines as an example. Though the recall was initiated in June 2021, several months went by before some patients became aware of the recall. And as Schabacker noted, because of the language used in the recall notice, many patients were confused about whether to continue to use the device or what action they needed to take.

This illustrates, in Schabacker’s view, how the communication chain is broken. “Nobody in the system has made provisions for getting in touch with the patients,” he said, adding that in the case of the Philips recall that’s more than 5 million customers using the breathing machines. (Also see "*Philips Implements Plan To Address FDA Concerns Following Harsh Inspection Report*" - Medtech Insight, 27 Jan, 2023.)

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But on top of that, there are still patients at risk. According to Philips, 90% of the affected devices have been collected, which leaves some 500,000 still in use – or, as Schabacker noted, 500,000 patients still using potentially harmful devices.

“That’s nearly two years after the fact. And that’s simply unacceptable,” he said, adding that ECRI is calling on all stakeholders involved – industry, regulators, providers and those in home health – to sit down and come up with a solution.

In the report, ECRI challenges manufacturers of at-home medical devices to implement measures such as “providing users with easy-to-follow device registration instructions, writing simply worded recall notices, maintaining up-to-date databases of device distribution, and designating staff to ensure that recalls reach home users.”

And while Schabacker said he’s not opposed to regulation to fix the problem, he views that as a last resort and prefers instead a common agreement among all parties involved.

“Let's show some goodwill and assume that a manufacturer wasn’t aware of the problem. But now they do know and now we need to do something about it,” he said. “So let’s get everyone together and figure out how to make this work.”

But Philips isn’t the only example. Schabacker said there have been lags in communication with various implant devices, most notably ventricular assist devices in cardiac patients that have had issues with pumping power. Schabacker cited Medtronic, which has issued several recalls of its ventricular assist device system. (Also see "*Medtronic Issues Another Recall For The HeartWare VAD System*" - Medtech Insight, 1 Dec, 2022.)

“The initial communications from the company were written for healthcare providers and not in the language of a layperson,” Schabacker said, “so patients didn’t know what to do.”

> ***“Somebody who has a home device and is connected to the internet and has a cell phone is more likely to learn about a recall than someone who lives in a socioeconomically challenged environment.” – Marcus Schabacker***

Even for devices that are implanted in hospitals and formally recorded, such as cardiac devices, there are often still gaps in communication once the patient is released.

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“Reaching out to the patient is often very difficult. And the providers don't have the setup, nor the will, to do that,” Schabacker said. “So, again, we are saying it is upon the manufacturer to come up with more effective systems on how to make sure that they can keep track of where that implant is going.”

Cybersecurity

Another top-ten concern for ECRI is cybersecurity, especially for connected devices that download and send patient data.

As the report points out, accessing an electronic health record or a radiology system through the cloud can offer significant benefits compared with more traditional systems. However, that benefit comes with significant security considerations that organizations need to understand and address.

“In a cloud deployment, much of the workload and control shifts to the cloud provider,” the report explains. “Consequences of this shift are that the healthcare delivery organization must rely on the cloud company to ensure the security and reliability of its online operations and to remediate any security event and promptly restore service. Nevertheless, in most cases the liability for any failure remains with the healthcare delivery organization.”

Schabacker, who was the corporate vice president and chief scientific officer at Baxter before joining ECRI, said device cybersecurity was a top priority during his tenure in private industry.

In the report’s section on cybersecurity, the focus is on hospitals, Schabacker said, because more hospitals today are relying on the cloud instead of servers to store data as they did in the past.

“You need to have a security system in the hospital to make sure your Wi-Fi system is secure enough that nobody can hack into it,” he said.

And while that shift means more of the responsibility for cybersecurity is now on cloud providers, Schabacker said hospitals aren’t off the hook.

“They still have the responsibility to ensure that their providers are up to speed and that they are able to secure the data which is going back and forth and being stored,” he said. “There's a lot of shady providers out there in what we would consider insecure locations, like China or Southeast Asia or Eastern Europe.”

These cyber risks, as the report highlights, can also lead to significant disruption in care.

As the report notes, breaches in the cloud can lead to lengthy delays in care and adverse patient outcomes. To mitigate these concerns, ECRI says hospitals need to evaluate how a cloud provider

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safeguards both the functionality of its system and the confidentiality and availability of patient data.

“In addition, the organization should implement appropriate internal security controls to reduce the risks,” the report states.

Cardiac Telemetry

Though ranked No. 9 in the report, Schabacker said the overuse of cardiac telemetry monitoring, especially on noncardiac patients, is a major concern. Specifically, over reliance on this technology can lead to “alarm fatigue” as well as clinician cognitive overload and unrecognized critical events.

Telemetry monitors, as the report explains, are devices patients wear to detect heart rate and rhythm and other physiologic conditions so they can be assessed without restricting the patient to a bed. They are best suited, in ECRI’s view, for cardiac patients who are well enough to move around the facility, but who nevertheless need constant monitoring. However, there has been a trend toward using telemetry monitoring as a safety net for patients who do not have cardiac issues.

And this, Schabacker said, is the crux of the problem.

More telemetry monitoring means an increase in alarms, many of which will be false alarms. And this is heightened in light of nursing shortages in which there is often only one nurse for as many as six patients on a given shift.

“So our concern is that with these increased alarms – real or false – there is a higher likelihood that a critical event will be missed and that the nurse does not react in time,” Schabacker said.

Paradoxically, the report says increasing cardiac telemetry monitoring can actually lead to patients being less effectively monitored overall. To reduce this risk, ECRI suggests providers establish clear criteria defining when telemetry monitoring should be used, as well as when it should be discontinued.

Essentially, this means verifying that telemetry is being prescribed appropriately while regularly assessing each patient’s need for continued telemetry monitoring.

Health Inequity

Generally speaking, Schabacker said he continues to be troubled by inequities in healthcare across the board, especially in terms of technology and medtech.

“There needs to be more effort in acknowledging that there are differences in patients and that

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devices can't just be designed for white males," he said, adding ECRI is also bothered by the reality that one's socioeconomic status is often a determinant of one's health.

"Somebody who has a home device and is connected to the internet and has a cell phone is more likely to learn about a recall than someone who lives in a socioeconomically challenged environment who doesn't have internet or a cellphone," he said. "All those things factor into health inequities and continue to play a major role when it comes to patient safety."

ECRI's top ten concerns for 2023 in ranking order are:

- Gaps in Recalls for At-Home Medical Devices
- Growing Number of Defective Single-Use Medical Devices
- Inappropriate Use of Automated Dispensing Cabinet Overrides
- Undetected Venous Needle Dislodgement or Access-Bloodline Separation During Hemodialysis
- Failure to Manage Cybersecurity Risks Associated with Cloud-Based Clinical Systems
- Inflatable Pressure Infusers Can Deliver Fatal Air Emboli From IV Solution Bags
- Confusion Surrounding Ventilator Cleaning and Disinfection Requirements Can Lead to Cross-Contamination
- Common Misconceptions About Electrosurgery
- Overuse of Cardiac Telemetry
- Underreporting Device-Related Issues

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