Mrs. Jones? This is your hospital calling. We are very sorry to ask this, but we would like you to come in and get tested for hepatitis and HIV. We have had a bit of an issue with the colonoscope used during your recent colonoscopy. Well, it turns out that it had been the subject of a safety notice and we did not quite realize it in time and it may not have been appropriately disinfected. So, we need you to come back so we can make sure you do not have hepatitis or HIV. No, please don’t worry too much, it’s not likely you actually do have either of those, but we can’t rule them out without a test. We are very sorry. Patient safety is our No. 1 priority.”

Although the dialogue is fictitious, this situation happened. A device safety notice issued to providers was missed and patients had to be called back in for testing. In fact, there have been at least two situations in which a device safety notice related to endoscopes was missed, requiring patient callbacks for tests. In one case, the health care provider, a world-renowned academic institution, publicly acknowledged the mistake and suggested it may have contributed to two deaths.

**Manual Processes Fail**

While health care seems to be getting safer, products are being recalled at an alarming rate. ECRI Institute’s calculations show that medical device safety notices and product recalls have risen sharply from a couple hundred per year in 2002 to more than 2,200 per year in 2012. It’s both astonishing and worrisome.

Medical devices, however, are not becoming more dangerous. In ECRI Institute’s view, it seems that the increase is a combination of many factors — more products available, more regulatory scrutiny, more device complexity, better monitoring by manufacturers — all likely to contribute to this
trend. But regardless of why, these recalls present a growing challenge for hospitals to manage.

In most hospitals, product recalls traditionally were handled by manual systems of passing along paper documents to selected staff in relevant departments and trusting they took necessary corrective action. This system was never ideal, but it is incapable of managing the volume of recalls now hitting providers. And while not all recalls and safety notices are life-threatening, some are very serious.

In recent years, there have been several high-profile recalls of hip implants, pacemakers and pacemaker/defibrillator leads. In the case of the hip implants, premature device failures in some designs have led to elevated rates of patients requiring “revision” surgeries.

With pacemaker/defibrillator leads, a product line that had been on the market for more than a decade was recalled in December 2011 due to risk of the insulation breaking down and leading to possible loss of pacemaker therapy. At the time of the recall, 79,000 leads were reported to have been implanted.

Then, in August 2012, the Food and Drug Administration recommended that patients with the recalled leads be imaged to check for the insulation breakdown often happens. It also illustrates a common challenge with recalls and safety notices: They don’t always explain the necessary corrective action.

For many years, ECRI Institute has acted as a clearinghouse and disseminator of medical product recalls and safety notices, and through this function we have seen countless examples of poor transmission of information to the proper parties and confusing language in the recall notices themselves. In these cases, either the explanation was written poorly or the issue was too complex to be whittled down to an easily understood one-page notice. Unfortunately, poor writing may lead to unintended patient harm.

Further, product recalls do not represent the only time a hazard may exist in association with a device. And while these general hazards often are known in advance by some, they are not always communicated clearly to everyone who needs to know.

One issue continues to trouble me. In 2004, ECRI Institute investigated several incidents in which hoses from noninvasive blood pressure, or NIBP, monitors and sequential compression devices were inadvertently connected to needleless Luer ports on intravenous IV administration sets. (Luer is the connection system by which IVs, catheters, syringes and other medical equipment are attached to each other.) In one of the reports, a patient died from an air embolism when an NIBP monitor cycled and injected air through the patient’s IV line. In each of these incidents, the hoses used a Luer connector, allowing them to be mistakenly attached to mating connectors on the IV lines.

In this case, the hazard is not specific to one brand and model; it is possible to make this mistake with many different brands and models. To avoid the problem, the provider must pursue a more sophisticated solution than simply pulling a defective product off the shelf and replacing it with a better one. This was a simple misconnection, but one that led to patient deaths.

Board Responsibility
Providers face numerous patient safety challenges, and product recalls may fall through the cracks if not given leadership attention. The challenge has multiplied because of the growing number of notices now being sent.

Simple solutions exist to reduce this burden and improve safety at the same time. First, the board should make sure someone is overseeing the recall process at the enterprise level. In too many hospitals, recall management is treated as an administrative task rather than as a major patient safety initiative. If the staff responsible for related supply chain, maintenance and clerical tasks are not given a mandate from the top of the organization to collaborate with clinical experts in each patient care department, the likelihood of mishaps increases.

Second, in addition to raising accountability and awareness, providers must adopt a systems approach using digital tools and technology to improve communication and oversight of product recalls and safety notices. Ad hoc spreadsheets and paper files create too many safety gaps.

Third, trustees must ensure that their institutions have ongoing and mandatory product safety training to support clinical staff who use high-risk technologies and products. Ultimately, managing recalls effectively requires acknowledging that what worked well for many years simply won’t work now. Virtually any system will crack when exposed to a tenfold increase in volume. Simply stated, product recalls must move from clerical to critical. Lives depend on it. T

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