It’s no mean feat to win over industry experts who live and breathe the regulations, science, and art of monitoring medical devices on the market. Safety, quality, and risk management veterans typically exude a healthy skepticism about any proposed adjustments to well-known and well-honed—but considerably challenging—postmarket surveillance activities.

Now, though, industry experts are expressing cautious optimism about the broad intent of a plan by the U.S. Food and Drug Administration (FDA) to leverage big data and broad partnerships to enhance postmarket activities and improve patient safety.

If the plan becomes a reality over the next decade, it would unleash an unprecedented era of research, discovery, and innovation that would benefit patients, clinicians, manufacturers, regulators, and payers with safer and more effective devices, according to its supporters.

Moreover, postmarket vigilance could become less of a burdensome chore focused on regulatory compliance and enforcement and more of an ecosystem that supports better, faster, cheaper—and value-added—practices for improving the full life cycle of medical devices.

“Big data is where you can...
really see signals in device use and performance. If companies are able to get to this data, it will provide a wealth of information,” said Lina Alzate, senior director of medical safety operations at Johnson & Johnson Medical Devices.

Patrick Caines, director of quality and postmarket surveillance at Baxter Healthcare, agreed.

“The initiative that the FDA has laid out and its partnership with industry are good things,” he said. “Compliance is a minimum entry point for being in this game. The next question is, how do you turn it into a competitive advantage? Progressive companies already view postmarket activities with a life cycle approach—a closed-loop system of feeding information back into risk management and design to improve the safety and effectiveness of the process and products. Once people really understand the benefits to business if it’s done in this fashion, I think you will see more ready adoption.”

Data are the linchpin of postmarket monitoring. Right now, though, getting high-quality, comprehensive, timely data about device use, safety, and performance in the field is a challenge.

In an interview at FDA headquarters outside Washington, DC, Greg Pappas, MD, associate director for national device surveillance at the FDA’s Center for Devices and Radiological Health (CDRH), shared key points about the plan’s potential.

Big data available in near real time would support faster detection of device-related issues in the market—and shift the focus from passive to active surveillance. “Big data is here,” Pappas said, and the time is right to “reap the benefits of real-world data for public health and specifically in the device space.” Data are the linchpin of postmarket monitoring. Right now, though, getting high-quality, comprehensive, timely data about device use, safety, and performance in the field is a challenge.

To overcome that challenge, the FDA intends to work with industry and other partners in the public and private sectors to enhance existing postmarket surveillance requirements (summarized on page 383) by tapping into new sources of information about medical devices on the market and integrating that information to enable data analysis. Those new sources of information include:

- **Unique device identification (UDI),** a label barcode that will allow tracking of most medical devices through their distribution and use. The FDA and industry are scheduled to complete the phased-in rollout of UDI, which began in 2014 with implantable, life-supporting, and life-sustaining devices, in 2020. Device labelers are required to submit information about each device to the FDA’s Global Unique Device Identification Database.
- **Payer systems,** such as the Centers for Medicaid & Medicare Services
- **Electronic health records (EHRs),** using deidentified patient health information that complies with the Health Insurance Portability and Accountability Act (HIPAA) privacy rule on protected health information
- **Medical device registries,** which are established or sponsored by states, indus-

Hallmarks of the Plan

The FDA plan, which has been in the works for at least three years, is laid out in a 141-page draft report, *Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge Clinical Care and Research.* The plan was released in August; public comments were solicited through Oct. 26.

Developed by the Medical Device Registry Task Force and the Medical Devices Epidemiology Network Public-Private Partnership, the plan for a National Medical Device Evaluation System has evolved from two earlier reports:

- **Strengthening Our National System for Medical Device Postmarket Surveillance,** a 2012 FDA report
- **Strengthening Patient Care: Building an Effective National Medical Device Surveillance System,** a February 2015 report by the Engelberg Center for Health Care Reform at the Brookings Institution

For a look at how the postmarket surveillance system is working now, see page 384.
try, associations of specialty or subspecialty clinicians, and healthcare delivery organizations to record and, for some, track and research device use. Typically, registries are set up around specific devices or types of devices, such as implantables, and can encompass regional, national, or global communities of stakeholders. For example, the American College of Cardiology’s National Cardiovascular Data Registry is a group of seven registries that include implantable cardioverter defibrillators and leads, diagnostic cardiac catheterization, and percutaneous coronary intervention.5

Together, these systems contain a wealth of information about how devices are used, how they perform, and how patients fare when using them. Their combined data sets will be a powerful resource for postmarket monitoring—and much more.

First off, these data, available in near real time, would enable industry and regulators to spot and address any device concerns much faster than they do now. “All of us—from a patient perspective, from a manufacturer perspective, from a clinical perspective, and from an FDA perspective—imagine a system in which, if a device is going to fail, we want it to fail fast, before it’s exposed to a huge number of people.”

—Greg Pappas, associate director for national device surveillance, FDA CDRH

Big data supports a learning healthcare system. Actively “dredging” databases to learn how devices are being used and how they’re performing would put both the industry and the FDA into a deeper learning mode, according to Pappas.

“This is not just an academic exercise involved with big data and cool technology,” he said. “It’s really about moving the device space forward and being able to address our mission more effectively. We’re all moving in this direction—harnessing this evolving electronic data world and using it in a whole variety of ways in which we can learn more rapidly and efficiently.”

A core strategy of the plan that is unique to the device space is linking high-quality device data in medical registries to longitudinal patient data in medical claims systems and EHRs. Pappas offered this example: “Patient X had a heart valve or pacemaker implanted. You could link the device with Patient X’s longitudinal claims data in Medicaid. Did the patient go to the emergency room, the doctor’s office, the hospital? For what? Follow that data over time and see what happens to that person.”

Analyzing data on many devices and patients can support expanded uses of devices and regulatory decision making, Pappas said. In fact, this scenario is no mere hypothetical. CDRH already has used this approach with at least a dozen studies that have met methodologically rigorous regulatory standards to make decisions about devices.

Approval of an expanded use of transcatheter valve therapy (TVT) is the best-documented proof of concept. In 2011, the FDA approved a transcatheter aortic valve for use in patients with severe aortic valve stenosis who needed aortic valve replacement but were not good candidates for traditional open heart surgery. The device was originally approved for implantation through transfemoral access only. Two years later, the manufacturer submitted real-world data from the Transcatheter Therapy Valve Registry (TVTR) that along with other clinical data, supported an FDA approval of the device for implantation through other alternative access
routes. This approval expanded access to this life-saving device to more patients. The TVTR was jointly developed and managed by the Society of Thoracic Surgeons and American College of Cardiology.

Notably, Pappas believes that one day, some original premarket approval submissions could be based entirely on these kind of data. This prospect aligns with a CDRH strategic priority of striking the right balance between pre- and postmarket data collection.6

Moreover, beyond its usefulness for regulatory processes, big data could support many different kinds of studies. “The FDA has a particular set of interests—there are 522s, PASs, IDEs that could be done in a more efficient, faster way,” Pappas said, referring, respectively, to 522 postmarket surveillance studies for Class II or Class III devices that meet certain criteria, postapproval studies (PASs) to help ensure continued safety and effectiveness of approved devices, and investigational device exemptions (IDEs) that allow investigational devices to be used in clinical studies to collect safety and effectiveness data. “But comparative effectiveness studies, cost-effectiveness studies, safety studies, quality studies—research that is done by payers and hospitals—can also use the same sort of data system,” he said.

Big, connected data also will make it possible to look at device safety and performance in completely new ways. For example, what happens to patients who have a pacemaker, a hip implant, and a disease such as diabetes? Big data will make it possible to examine patient outcomes at a much more granular level, taking into account patient conditions and other factors that might affect clinical decisions and patient outcomes.

“That’s exactly where we’re going in the future,” Pappas said. “We all understand that the body is an integrated reality. We can hypothesize about how all these things affect one another, but there’s never been a system to efficiently do that. Add in genetics—we have the genome system. We don’t think of genetic variations in the context of devices, but indeed there are some. That’s the promise of a learning health system.”

Big data can improve industry and health-care practices—and the bottom line. Medical device recalls have doubled between 2003 and 2012, Pappas said. According to a 2013 McKinsey report, “Non-routine quality events—such as major observations, recalls, warning letters, and consent decrees, along with associated warranties and lawsuits—cost the industry between $2.5 billion and $5 billion per year on average,” including lost sales of new and existing products.7 Quality issues also affect the share prices, bottom lines, and reputations of companies.

The McKinsey report also claimed that industry is approaching a “tipping point” that “will force companies to focus on quality and reliability throughout product design, manufacturing, and marketing.”

Companies with mature postmarket surveillance, quality, safety, and risk management processes already take a full life cycle approach to medical technology. But for the 6,500 U.S. device manufacturers—many of which are small and midsized companies—big data will help them do it better, Pappas said.

With new tools, product issues should be identified and addressed earlier. UDI is a
case in point. UDI labels will expedite the process of actually finding recalled devices. “Managing recalls is a nightmare,” Pappas said. “If you’ve got a UDI, it’s a much more efficient way to do it.”

The UDI system also will improve supply chain management and facilitate reimbursement. “Things expire, things get lost,” Pappas said. “You save money by having UDI in supply chain management. If you forget to bill for something, you lose money. Finance systems will benefit.”

Andrea Schwartz, manager II with the Medical Products Trending Team at Baxter Healthcare, is eagerly anticipating UDI. “I think the benefits will be coming in the next two to three years,” she said. “Traceability of products is one of the biggest challenges. You’ll be able to trace every device—you built it at this plant, you shipped it to this distribution center, it then got shipped to this hospital and placed in this patient. It will help to understand the longevity of the product kit, the shelf life, so many things you miss in terms of trending and understanding some factors that might have fed into complaints as well.”

Healthcare providers will benefit as well, Pappas noted. Right now, for example, to plan a hip resection surgery, clinicians need to know what kind of medical devices and equipment are already inside the patient. Finding out can take considerable legwork, including hours of phone calls to previous surgeons, hospitals, or payers. A UDI in a patient’s medical records would streamline that process. “I’m surprised hospitals haven’t gotten into a medical-legal discussion about this,” Pappas added. “‘You mean you put something in there and you don’t know what it is exactly? Really?’ It’s a safety issue that hasn’t come up yet.”

Challenges of the System

Pappas is frank about the work that will be required to create the system envisioned in the FDA plan. Among the challenges:

- **Interoperability:** Connecting complex systems that have different purposes
- **Data quality:** Populating systems with high-quality data sets that use standardized nomenclature and definitions
- **Privacy and security:** Keeping patient data safe and secure, as required by HIPAA
- **Partnerships and collaboration:** Engaging a complex set of stakeholders in the device space, including industry, healthcare providers, clinicians, academia, patients, payers, and other federal agencies

CDRH sees its role as a champion and coordinator of a national—not a federal—medical evaluation system.
The current scope of FDA postmarket surveillance

The FDA’s Center for Devices and Radiological Health (CDRH) traditionally has relied on several authorities and approaches in its postmarket surveillance program. Each of these activities represents a key piece of a larger postmarket surveillance system:

- **Medical Device Reporting (MDR).** Each year, the FDA receives several hundred thousand medical device reports of confirmed or possible device-associated serious injuries, deaths, and malfunctions. While MDRs are a valuable source of information, this passive surveillance system has notable limitations, including the potential submission of incomplete or inaccurate data, underreporting of events, lack of denominator (exposure) data, and the lack of report timeliness. MDRs are housed in the Manufacturer and User Facility Device Experience (MAUDE) database.

- **Medical Product Safety Network (MedSun).** MedSun is an enhanced surveillance network comprising approximately 280 hospitals nationwide that work interactively with the FDA to better understand and report on device use and adverse outcomes in the real-world clinical environment. Specialty networks within MedSun focus on device-specific areas such as cardiovascular devices (HeartNet) and pediatric intensive care unit devices (KidNet). In addition, the network is used for targeted surveys and focused clinical research.

- **Postapproval Studies.** The FDA may order a postapproval study as a condition of approval for a device heading to market. Typically, postapproval studies are used to assess device safety, effectiveness, and/or reliability, including long-term effects, in the real-world setting. Postapproval studies also can be used to assess the learning curve, effectiveness of training programs, and how well a device performs with certain groups of patients.

- **Postmarket Surveillance Studies.** The FDA may order a manufacturer of certain Class II or Class III devices to conduct postmarket surveillance studies (often referred to as “522 studies” for section 522 of the Food, Drug and Cosmetic Act). Study approaches vary widely and may include nonclinical device testing, analysis of existing clinical databases, observational studies, and, rarely, randomized controlled trials.

- **FDA Discretionary Studies.** In addition to medical device adverse event reports, postapproval and postmarket surveillance studies, the FDA also conducts its own research studies to assess device performance and clinical outcomes, investigate adverse event signals, and characterize device-associated benefits and risks for patient subpopulations. A variety of privacy-protected data sources are used including national registries, Medicare and Medicaid administrative and claims data, data from integrated health systems, electronic health records, and published scientific literature.

Source: FDA}
The FDA’s plan to enhance postmarket activities will supplement, not take away from, current regulatory requirements. So how is the current system working?

Industry experts interviewed for this article support the spirit of postmarket regulation as it exists today. “I don’t have any issues with the regulatory intent,” said Patrick Caines, director of quality and postmarket surveillance at Baxter Healthcare. “Both consumers and practitioners in this space have a vested interest in having safe and effective products in the marketplace.” (Caines’s comments represent his professional judgment, not Baxter positions.)

“It has the right intention,” agreed Lina Alzate, senior director of medical safety operations at Johnson & Johnson Medical Devices. “The regulation really wants industry to keep an eye on what’s going on in the market. And if we see something bad is happening to patients, don’t miss it, don’t let it slip.”

The devil is in the details, however. The current system is not perfect, and there are common pain points, which various stakeholders believe could be alleviated if the FDA plan goes forward and if industry and clinical stakeholders contribute to the solutions.

From an industry perspective, a mature postmarket surveillance program consists of four pillars:

1. **Data collection**: Gathering information about product safety and performance in the marketplace from all sources, including passive sources (complaints and reports) and active sources, such as literature reviews, market studies and surveys, and electronic portals.

2. **Data analysis**: Investigating collected information to identify signals or trends about product safety and performance.
3. **Action systems**: Reporting safety and performance issues to the FDA and global regulatory agencies, if necessary, and escalating issues to field actions, such as corrective and preventive actions (CAPAs) or recalls

4. **Dissemination**: Proactively connecting the insights from all postmarket activities to product design, development, and risk management

Challenges are associated with each of these pillars. “Making sure that information is collected in a timely and complete fashion is probably challenge number one,” Caines said. “The process is time bound in terms of regulatory reporting and the time frames around investigating patient issues.”

A second challenge is gathering enough data—and enough high-quality data—to conduct a meaningful analysis and tease out signals and trends. “Postmarket surveillance is all about signal detection and product performance,” Caines said. Getting customers to return actual devices relevant to complaints or incidents for companies to test and troubleshoot can be problematic as well. “Obviously, that gets more complicated in a global company, dealing with geographies, languages, shipping, all of that,” he said. “Depending on how companies are structured, some of these might be local or regional centers tied to manufacturing plants.”

A third challenge is familiarity with the global regulations. “If you’re just a U.S. company marketing U.S. products, you only have to worry about the FDA,” Caines said. “If you’re global company, you have to worry about all the regions or countries where a product is approved and marketed for sale.” Managing and integrating regulatory intelligence groups globally can be complicated. Inconsistent regulatory requirements, partially due to inadequate data, are a major issue for companies.

A fourth challenge is in disseminating lessons learned into risk management and design control processes. “Transfer of information in a timely fashion—and making sure that the message or information does not get diluted or distorted and that the appropriate people are engaged in the process—becomes complex in a global company,” Caines said. “Ultimately, the postmarket surveillance process should serve as a catalyst to drive and champion improvement activities that lead to safer, better, cheaper products to customers. It should be a closed-loop system.”

### How Would a National Medical Device Evaluation System Address Key Postmarket Challenges?

<table>
<thead>
<tr>
<th><strong>Data Collection</strong></th>
<th>Near real-time access to comprehensive data sets from UDI, payer systems, EHRs, and medical device registries would expedite and strengthen data collection and data quality.</th>
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</thead>
<tbody>
<tr>
<td><strong>Data Analysis</strong></td>
<td>High-quality, integrated data sets from UDI, payer systems, EHRs, and medical device registries would make detection of signals and trends in medical device safety and performance faster and easier. Comprehensive data sets would enable more robust data analysis—and, potentially, innovative ways of examining this data to better understand outcomes of device use for specific patient populations.</td>
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<tr>
<td><strong>Action Systems</strong></td>
<td>UDI and medical device registries would make it easier to locate devices and better manage field actions.</td>
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<tr>
<td><strong>Dissemination</strong></td>
<td>More efficient and robust data collection and data analysis would enable companies to disseminate insights from postmarket activities more quickly into product design, development, and risk management—and, potentially, accelerate innovation.</td>
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**Challenges and Opportunities**

Here’s a closer look at the postmarket challenges and opportunities:

**Underreporting, overreporting, and inadequate reporting.** Underreporting of device issues hampers postmarket surveillance, most industry experts say. Overreporting can be a problem as well, others say. They all agree that the quality of reports leaves much to be desired—and clinicians are a weak link in the process.

At Johnson & Johnson, Alzate understands both the industry and clinician perspectives on reporting. She directs the postmarket safety surveillance activities of some 25 companies in the corporation’s medical device sector portfolio. Before working in industry, she was a practicing physician. “As an industry person, the reports and complaints are what we have, so we try to make the most of them,” she said. “But as a
physician, the reports aren’t a priority.”

For example, if a tool breaks during surgery, “you just get another one and keep going,” Alzate said. “You take care of your patient. Maybe you will remember later that this happened, maybe not. If you remember, you will be annoyed, but that would be it. If it happens that the company rep is right there that day or the next day, you might mention it. If not, it’s over, it’s gone. You never report to the company.” Only when a device issue recurs multiple times do clinicians make it a priority to complain, she added.

That scenario is particularly the case with lower-risk, lower-cost, and higher-volume devices, Alzate said. “If a catheter used to deliver fluids breaks, you’re not going to tell the company about it, because you use, like, 20 of those a day,” she noted—and there are plenty of extras in stock.

“Now that I am in industry, I see each complaint as a gift,” Alzate added. “If you took the time to tell me about it, it’s because it’s important enough for you and you took time from something else you had to do to report it.” She believes that, as a rule of thumb, each complaint represents at least a few more similar issues the company never hears about.

Clinicians do complain with gusto about issues with life-supporting, expensive, complex devices with few backups on hand, she said. In fact, for some devices, the pendulum has shifted in recent years from underreporting to overreporting.

Adam Seiver, MD, senior director and chief of medical affairs at Philips Healthcare, sees that with ventilators. “About five years ago, there was a lot of interpretation of what the rules were for reporting medical device incidents,” he said. (His comments represent his professional judgment, not Philips positions.) “A lot of it hinges on interpretations of statements about probability and how likely, if something were to occur again, it would lead to serious injury. It all comes down to how you define ‘likely,’ how you define ‘serious.’ I suspect many in industry were very reasonably interpreting the rules as not requiring reporting for given situations.”

After the FDA faulted industry on inspections because the agency was not learning about ventilator-related problems, companies began reporting everything, Seiver noted. Plus, FDA and AAMI summits on ventilator technology left the impression that ventilator issues were on the rise. “And industry was saying, ‘No, there isn’t a sudden increase of problems, there’s just an increase in reporting.’ Ventilators are like airplanes—they’re just very, very safe. So the FDA suddenly got so many reports that the signal was lost in the noise. I don’t think they’ve got the filter quite right.”

Schwartz sees an industry-wide uptick in complaint volume in recent years for another reason—financial incentives. “Customers are more and more willing to submit requests for information about usage or issues with a product because they want to get credit or reimbursement for defective products,” she said. (Schwartz’s comments represent her professional judgment, not Baxter positions.)

“Ordinarily what clinicians do is put everything into a big bundle or box or container and then they have their shipping folks send all their products back with a note that says ‘broken,’ or “didn’t work,’” Schwartz said. “That way they get the credit, but they’re not providing us with any information. So we can’t really investigate what they’re reporting. We’re not getting the feedback we need to improve the products or address the issue—just processing the replacement.”

Baxter has implemented new processes in the past two years that have resulted in an increased complaint volume. “That doesn’t mean the information or content of those complaints is invalid or not valuable,” she said. “It just means we need to understand what our baselines are and be able to react to changes in that baseline when those shifts happen. That’s actually a significant issue. When we change our processes, we need to understand the changes—and measure against the change rather than measure against the history—so we don’t add in an unwarranted way something that is not an issue.”

Many complaints and reports fall into the “noise” category, most industry experts say. Information is incomplete or inadequate for investigative purposes.
detective purposes. “Reporting is not anybody’s particular responsibility or interest,” Seiver said. “You can’t automate it.”

Industry experts suggested potential solutions to reporting challenges:

- **“Canary” accounts:** Some companies pay select customers to fill out a form for every device issue they encounter, which provides an early harbinger of potential risks, like the canary in the coal mine. “I think it’s a fabulous idea,” Schwartz said. “Certainly, it’s a way to get a sampling of your customers to provide intimate details about how your product is being used. The intent certainly is to use that information to understand what the issues are, the circumstances when those issues were discovered, and how the devices were being used—and to have a point of contact, perhaps, for a follow-up conversation. This is a huge thing that we do not get frequently at this point.”

- **“There should be an app for that.”** “Maybe technology will bring us something easy,” Alzate said. “Maybe every time something happens, you just talk to the app. You don’t type anything, you say whatever you need to say, and send it. It would take you less than 30 seconds.”

- **An expanded role for HTM professionals.** For one product implementation Schwartz supported for Baxter outside of the United States, HTM professionals were responsible for filling out feedback forms for any issues encountered. “Biomeds were a fantastic source of information for us because they knew that product inside and out,” she said. “They knew how our customers or patients used it, what the nurses did. So they were intimately knowledgeable and able to provide us with the information we needed.”

**Detecting signals from the noise—systematically and consistently.** Medical device manufacturers have dedicated, multidisciplinary staff and whole infrastructures in place to meet both regulatory requirements and business needs for postmarket monitoring. Even so, given the reporting challenges, it’s not always easy to understand whether devices are performing safely and effectively in the field, or to determine the cause of any reported issues.

“What firms try to do is set up a systemic process that involves procedures, processes, systems, and tools that will facilitate that collection of information and assessing it in a way that makes it amenable for signal detection,” Caines said. “People study this for years and practice it for years before they get these systems working right. A big ‘watch out’ is consistency—a stable system in a supportive infrastructure with strong links among the procedures, processes, systems, and tools.”

Every complaint received is analyzed at Teleflex Medical, said Kathleen Whanger, senior quality assurance manager in the company’s vascular products business unit. Multiple complaints receive closer scrutiny to determine any trends in device safety and performance. A complaint team analyzes any sample devices returned to the company and determines potential root causes, which could be related to the device design, manufacturing, packaging, labeling, misuse, or misunderstanding of how to use the device properly.

“Obviously, that’s the last consideration in terms of your analysis, but all of these factors have to come into play,” Whanger said. “That’s really where risk management is so helpful. If you have the predictions in terms of what the failure modes might be, then you can draw a correlation between those failure modes and the information that’s received from customers. So then you can determine if your risk analysis was strong enough and try to improve it and make better correlations and predictions of the type of complaints that will come in. The biggest challenge you face is finding that correlation between complaints and risk management.”
Consistency is a singular focus at Johnson & Johnson. Three years ago, the corporation introduced harmonized objectives for postmarket surveillance, as well as for safety and quality, that all of its affiliate medical device companies are expected to meet. Individual companies have some flexibility now in how they meet the postmarket objectives, but Johnson & Johnson is moving toward similar standards and processes across the corporation, Alzate noted.

The regulatory environment, business efficiencies, and opportunities to benefit patients are driving this steady transformation. On the regulatory side, Johnson & Johnson’s two dozen medical device affiliates operate as independent companies, all with their own postmarket processes. But the FDA views them as part of the larger corporation. “The auditors are pushing us more and more,” Alzate said. “If they find something in one company, and then they find it again in another one, they’re asking us, ‘Why is this happening? We already told you about this issue.’ That brought into light that we really needed to start talking to one another and learning from one another.”

Making appropriate decisions and taking timely action. Reporting and analyzing issues with complex devices require both users and industry professionals to be “pretty sophisticated,” Seiver said. “It’s one thing when you’re complaining about a handle that fell off a device. It’s another thing when you try to understand how a device was used in a way that led to a systems error, where there are multiple faults, and getting to the root cause is not easy. You have to understand physiology, and how nurses and physicians interact—and, in the case of a ventilator, what the role of the respiratory therapist was—and how software works. It’s a multidisciplinary issue.”

Companies with mature postmarket systems bring that multidisciplinary lens to bear on device issues. For example, Johnson & Johnson risk managers, quality engineers, medical safety officers, and medical experts in the therapeutic specialty of any devices in question are involved in making decisions about collected data. Different experts would

Using ‘SMART’ Metrics to Mine and Leverage Postmarket Surveillance Data

To determine if there is a shift in predicted or expected rates of occurrence of a problem, and to prevent problems, measurement systems need to be evaluated continually. Any measurement or metric should be assessed against the “SMART” method, so you can look at the “right” data—and look at the data “right.”

**Specific**
Are your metrics specific and targeted to the area you are measuring? Do your metrics have clear ownership and accountability for the metric’s performance?

**Measurable**
Can you collect data that are accurate and complete for the process being measured?

**Actionable**
Are your metrics easy to understand? When you chart performance over time, is it clear which direction is “good” and which direction is “bad”? Do you know when to take action and what action to take?

**Relevant**
Also known as measuring the “vital few.” Are you measuring things that are not important? A common downfall is to measure everything (to make sure you don’t miss something important), which produces many meaningless measures without driving the desired outcome.

**Timely**
Can you get the data when you need them? Are the data time bound? Is there a specific beginning and end?

make different decisions on products—even given the same data sets and analysis. Together, they make better decisions.

“Medical experts will have very clinical, patient-oriented decisions,” Alzate said. “Medical safety officers who are trained in risk management will bring another way of thinking about risk. Quality engineers understand how the product is failing, when it would fail, and with what frequency it would fail. They all bring a richness to the discussion. These are the key people to make decisions when there is a risk-benefit safety issue to the patient.” Johnson & Johnson also carefully documents decisions and justifications to decisions.

Industry experts chafe at the tight, 30-day time frame for reporting device issues to the FDA. The clock starts ticking at the moment they hear about any issue, anywhere in the world. “If a patient suffers a serious injury related to your device, you have to report it,” Alzate said. “Or if your device could have caused a serious injury, you have to report it.”

It’s not always easy to determine that expeditiously—particularly if multiple devices are involved in patient care. It can be difficult to talk to clinicians involved to understand what happened, and to get devices shipped back to the company for investigation, within that time frame. Moreover, privacy laws in some countries prevent companies from asking questions about patient outcomes. But as Alzate noted, the FDA can fault companies that do not meet the 30-day reporting requirement if even one or two reports are late, out of thousands of complaints they might receive every year.

“I think there are two ways to look at what the FDA does,” Seiver said. “One way of looking at it is, they’re about enforcement. Then it’s just really a matter of figuring out whether a rule has been broken, and designing this system so that we optimize the signal so that we catch the rule breakers. Another way of looking at it is, the FDA is there to optimize public health. There are a whole bunch of different factors other than just the rules that come into play about whether public health has been adversely or positively impacted and, more important, what that means for what we should do. So the question is really not whether a rule has been broken, but what should we do to ensure that public health is optimized. Certainly enforcing the rules can be argued as helping to optimize public health, but you have to go beyond just the narrow interpretation of the rules because sometimes the rules don’t necessarily cover unique circumstances or very difficult circumstances.”

**Coming full circle**

**with postmarket activities.** Progressive companies find business value in postmarket monitoring when they plow the insights from data analysis and investigation back into device design, development, risk management, quality, and marketing.

That approach needs to be baked into the system. At Johnson & Johnson, the same multidisciplinary team involved in reviewing and making decisions on complaint data is also looped into product design and development. They’re the “gatekeepers” at key points in these processes whose approval is required to move forward, Alzate said.

“It’s just so critical to look at postmarket surveillance from a holistic view and a systematic approach,” Whanger said. Complaints should prompt companies to revisit and update their premarket predictions on device occurrences and severities, not just make “one-and-done” predictions. They should ensure that their postmarket analysis is tied to risk management, and vice versa. That should drive the change controls for the product development process.

That holistic, systemic process is “the only way to create better devices,” said Whanger. “It’s really one of the best ways to find even just a small tweak that can get a much better device for the field to use.”

“So the question is really not whether a rule has been broken, but what should we do to ensure that public health is optimized.”

—Adam Seiver, senior director and chief of medical affairs, Philips Healthcare
What is your role in collecting and reporting postmarket data on medical devices?
The University of Michigan Health System is one of the original MedSun member hospitals and is very active in voluntarily reporting issues with medical devices. Part of my role is to review and analyze the data and provide recommendations. Equally important is collaborating with internal staff and departments as well as external organizations such as the FDA, ECRI Institute, and manufacturers.

Who is involved in this effort?
The whole organization is engaged, starting from top leadership to frontline staff to nonclinical departments. When everyone is engaged in improving patient safety, the culture is much stronger—and patients and families are part of the team. We have a long-standing, interdisciplinary Safe Medical Device Committee that oversees the entire process and device experience issues. The committee consists of clinicians, such as physicians and nurses who represent various areas and specialties, and experts in support departments, including clinical engineering, information technology, value analysis, and safety management.

What role do HTM departments and professionals play in postmarket activities?
HTM departments and professionals play an integral role because they manage clinical technologies. One key point for HTM professionals is learning to identify threats related to the use of technology that cannot be resolved with a corrective or scheduled maintenance. So the detection of use-related problems can be beneficial in postmarket lifecycle surveillance work.

HTM community engagement in the following is equally important:
- Understanding device and patient safety
- Follow-up analysis and actions on technology issues
- Collaboration with IT professionals when perceived potential threats can compromise patient care
- Recreating reported issues that cannot be detected on the bench
- Providing insights on interoperability issues where it involved medical devices

The HTM community also should partner with risk managers to develop dashboards with metrics aimed at looking at trends in device experience data and trouble spots before harm occurs or as a way to monitor ongoing issues. The bottom line is that this is a window of opportunity to engage, show expertise, and learn from others.

Should close calls or near misses be reported? Why or why not?
Absolutely. Collecting these data is key to any safety culture trying to understand its vulnerabilities and on a journey for continuous quality improvement to deliver the ideal patient experience.
- One characteristic of a culture of safety is to learn and be in touch with frontline staff who use technology every day. A well-versed culture is one that collects, reviews, and analyzes data to make informed decisions with the aim to improve patient and staff safety. Therefore, collecting close-call and near-miss data can be very valuable and is logical.
- Reporting close calls shows that staff is engaged and that they take time to report events that did not lead to harm but require follow-up.
• Close-calls reports most often do not include harm and, as such, provide the engaged organization with opportunities to analyze what did not work or is not in sync throughout a system and try to make recommendations for improvements.

• Close calls when properly analyzed by a diverse interdisciplinary team may point to weaknesses or vulnerabilities within a system that can benefit from further improvement. For example, this can lead to improved staff education, revised policies and procedures, updates of aging and failing technology, and improved department and team communication.

• Data on near misses when reviewed in aggregate can potentially uncover a particular technology issue, especially if they are reported from various care areas throughout a health system or hospital and/or by multiple user types—nurses, medical technicians, HTM professionals, and so on.

However, a note of caution is that clinical technology safety should not be based solely on near-miss and close-call data. Instead, these data should be used in conjunction with other organizational strategies, such as incident report data analysis in aggregate, device maintenance service histories, FDA MAUDE data, ECRI Institute publications, listservs, and any other reliable sources that provide insight.

Can you provide an example of a close call or near miss in which staff would be engaged in follow-up and analysis with a diverse interdisciplinary team, and/or in collaboration with external stakeholders?

Single-use products such as IV tubing are used extensively in every hospital, are critical in the delivery of patient care, and are considered low risk based on their risk classification. They are marketed in the United States with minimal regulation. IV tubing is typically made up of multiple components glued together to produce the final product depending on the product design and indication for use.

On rare occasions the glue is missing. As a result, when the line is set, the IV tubing can become disconnected and leak fluids, nutritional formulas, or medications vital to patient recovery. Other times, a chemotherapy drug requires a specific procedure for cleanup. Furthermore, the tubing Luer lock connection can crack or become difficult to disconnect. Or, it can have a have a foreign material such as a piece of hair, a cut in the tubing, or other manufacturing defect.

When IV tubing leaks, there is no visible or immediate harm to the patient, but it can disrupt the care and compromise safety. Nursing staff may have to replace the line. Additional medication may have to be ordered from the pharmacy. If vital signs are affected, the provider is contacted for further management of the patient’s changing condition. Oftentimes, infection prevention professionals will get involved, as this would present a risk that may lead to a bloodstream infection.

HTM professionals collect the product and inspect for visual defects, perform the analysis, and provide a recommendation. Risk management is engaged to analyze the data in aggregate over time as part of the root cause analysis, in order to check for trends for a particular product. If the issue occurs multiple times and is traced to a particular lot number, supply chain professionals would be engaged to assist in removing the lot number off the shelves and coordinate with the vendor/supplier for product replacement. When a close call is reported to the FDA and manufacturer as a voluntary report, a certain follow-up is required by the manufacturer depending on frequency of occurrence or other variables.

In a hospital where a culture of safety exists, staff are encouraged to report such a close call. Sometimes a hospital can opt to change IV tubing type or vendor to minimize leaks or eliminate the problem.
References (for p. 378–89)


Resources


