



American Hospital
Association®

800 10th Street, NW
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100 Phone
www.aha.org

January 6, 2017

Submitted Electronically

Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

***Re: The Role of Hospitals in Modernizing Evidence Generation for Device Evaluation:
Harnessing the Digital Revolution for Surveillance [Docket No. FDA-2016-N-1380]***

Dear Dr. Califf:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) request for comment on *The Role of Hospitals in Modernizing Evidence Generation for Device Evaluation: Harnessing the Digital Revolution for Surveillance*, which was published in the Federal Register on Oct. 25, 2016.

Every day, hospitals across our nation work hard to improve care, prevent errors and provide the best care possible to patients and their families. Quality improvement is a never-ending journey, and the AHA is pleased that the FDA is looking to modernize medical device safety reporting and commits to serving as a partner in that process. **However, the AHA recommends that the FDA examine existing safety efforts, and particularly the role of patient safety organizations (PSOs), to determine the extent to which the agency can leverage current reporting streams to gather evidence and information about medical device safety rather than relying on a separate and potentially duplicative event reporting structure.**

PUTTING MEDICAL DEVICE EVALUATION IN CONTEXT

Hospitals approach patient safety in a holistic manner. When a safety event, adverse event or near miss happens, hospitals engage in determining all of the causes leading up to the event, including lapses with information systems, issues with workflow, clinical factors and the role of medical devices. In general, such events rarely have a single cause. As such, hospitals generally do not focus on medical device safety in isolation, but rather as one factor among many. Indeed, in investigating an adverse event, the role of medical devices may not be apparent until well after



Robert M Califf, M.D.

January 6, 2017

Page 2 of 5

the event occurred, particularly in the case of infection or other harm that takes time to manifest. And when the harm becomes apparent, the role of any of the devices in contributing to or causing the incident may not be apparent.

To further the collective knowledge and improvement in safety, hospitals participate in a plethora of reporting and improvement activities. For example, hospitals participate in PSOs, which provide “safe tables” through which health care providers candidly share experiences about adverse events and lessons learned. Currently, there are 86 PSOs registered with the Agency for Healthcare Research and Quality (AHRQ). The PSOs also are able to take the data reported and give feedback to participants in order to support provider improvement. In addition, hospitals participate in Hospital Improvement Innovation Networks (HIINs), sponsored by the Centers for Medicare & Medicaid Services (CMS), which work at the regional, state, national or hospital system level to accelerate progress and momentum toward continued harm reduction. Approximately 4,000 hospitals are engaged in the work of the HIINs. Finally, the Centers for Disease Control and Prevention, AHRQ, The Joint Commission, medical specialty societies, registries, state agencies and state hospital associations all have safety activities in which hospitals actively engage.

Furthermore, CMS and private safety experts are working to identify electronic surveillance methods. Working from electronic health records, these organizations hope to perfect ways to improve surveillance for adverse events and the associated data collection on what went wrong and why. Early indications are that this information can be generated electronically for many types of errors more reliably than by expecting individuals to file separate reports. The FDA should examine whether this is a more reliable method for detecting harm and generating information than its current required reporting. Rather than creating new reporting streams, the FDA may be able to leverage existing safety reporting efforts.

IMPROVING THE EXISTING MEDICAL DEVICE REPORTING SYSTEM

The FDA currently collects reports of suspected device-associated deaths, serious injuries and malfunctions through its Medical Device Reporting (MDR) system. The FDA requires “user facilities,” which include hospitals, to report a suspected medical device-related death to both the FDA and the device manufacturer within 10 work days of becoming aware. User facilities also must report any medical device-related serious injuries to the device manufacturer within 10 work days of becoming aware, or to the FDA if the manufacturer is unknown. In addition, user facilities must submit annual summary reports to the FDA.

The FDA has acknowledged that such “passive” surveillance has important limitations because it relies on individuals to identify that a harm has occurred or that a risk is present, as well as to recognize that the harm or risk is associated with the use of a particular device. We are pleased that the FDA is dedicated to improving the way in which the agency works with hospitals in order to address these limitations and to modernize and streamline data collection about medical devices. In particular, we are confident that hospitals will be able to participate effectively in the National Evaluation System for Health Technology (NEST) and that, ultimately, the effectiveness of NEST and/or other more modern software tools for conducting active

surveillance of electronic health information involving devices, will allow the current passive reporting requirements to be modified or even eliminated.

Based on conversations with our members and what we heard at the FDA's Dec. 5, 2016 public workshop, below we outline several key lessons learned that we hope will inform future efforts in modernizing medical device post-market surveillance:

- A paper-based reporting process is burdensome and inefficient. **We strongly support movement toward the use of electronic reporting using online forms, such as that used by the Medical Product Safety Network (MedSun) hospitals.** MedSun hospitals use an Internet-based system that is designed to be an easy and secure way to report adverse medical device events, and each hospital has online access to the reports they submit to MedSun so that they can be tracked and reviewed at any time.
- While hospitals are required by regulation to report medical device related deaths and serious injuries, as the FDA has found, some hospital staff may not be aware of nor trained to comply with all of the agency's medical device reporting requirements. Some of this may be due to the limited education provided by the FDA on these requirements and the lack of understanding of the possible benefits of reporting. Hospitals are subject to numerous regulations and reporting requirements and struggle to educate their staff about these constantly changing requirements. **The AHA would be pleased to help the FDA carry out education programs that spread the word about the MDR requirements and identify how reporting benefits hospitals and their patients.**
- **The FDA should work with hospitals to identify how it can best share important insights gleaned from hospital reports that have been filed.** Helping hospitals identify risks and act to prevent patient harm provides value for the time and effort invested in preparing and submitting the report.
- Hospitals care deeply about patient safety and would welcome the opportunity to participate in reporting that is simple and convenient, and easily linked to further improvements in care delivery.

Finally, manufacturers are a key source of safety information, including information originating from hospitals. Under the existing medical device reporting structure, the FDA requires hospitals to report to *either* the manufacturer *or* the agency, except in situations where a medical device has caused death. In many instances, it may make more sense for the hospital to report to the manufacturer, given that the manufacturer is generally the first point of hospital contact for maintenance and repair of devices. Therefore, it is important for the agency to be mindful that reports from manufacturers may well, and often do, originate with a hospital or other provider. Considering only direct reports from hospitals and other providers as a metric of how often they report will underestimate current efforts.

LOOKING TOWARD THE FUTURE

The NEST promises to gather important information for improving patient safety, and the AHA supports the vision the FDA has put forward. Given the many different safety efforts in which hospitals engage, and varying capacity to add new efforts, voluntary opportunities to participate in NEST will likely work best. Under a voluntary effort, those hospitals with the resources and interest in research can participate in the more in-depth, interactive activities that provide clear benefits for patient safety and the participating hospitals. The NEST will be of great benefit if the information collected is effectively shared with providers and patients, as well as the FDA. We encourage the FDA to consider how best to communicate its findings to a broad audience.

The AHA was a strong supporter of the statute that create the Unique Device Identifier (UDI) and we believe it will improve patient safety, management of recalls, supply chain management and post-market surveillance. The Association for Healthcare Resource and Materials Management (AHRMM), an affiliate of the AHA, also runs the Learning UDI Collaborative, which seeks to develop a common understanding and approach to UDI adoption for supply chain management and clinical care. We also have worked with the FDA and other stakeholders to find a way to include the UDI on the health care claim form in a way that meets the agency's needs without disrupting efficient automated claims analysis.

However, despite all its potential benefits, we caution that the UDI should not be seen as a silver bullet. Information technology (IT) systems will be key in supporting structured reporting on devices that include the UDI, and significant improvements will be required before data can be easily shared across platforms. **The AHA recommends that the FDA work directly with health IT vendors to ensure that their products not only have a field to house the UDI, but offer "smart" technology that can receive the UDI from barcode scanners or other automated technology and parse the UDI into its component parts.**

Sharing relevant clinical and other information about devices and patients will require consistent use of standards by both reporters of the data and recipients of the data, including registries. The certification program of the Office of the National Coordinator for Health IT (ONC) is an important first step to building consistent use of standards, but has yet to result in the kind of efficient and effective sharing of information that will be needed to support the goals of the NEST. **As another important step, the AHA recommends that FDA work directly with registries to encourage them to be certified by ONC, particularly with respect to receipt of a core clinical data set using national recognized standards, as provided for under the recently passed 21st Century Cures Act.**

Finally, the AHA recommends that the FDA clearly state its expectations of health insurers and other payers with regard to participating in medical device surveillance systems. In the coming years, hospitals and physicians will go to considerable effort and expense to include UDIs on health care claims for high-risk implantable devices. The FDA has argued that this work is needed to improve post-market surveillance of medical devices, and particularly to help provide longitudinal information across settings of care and information that provides a denominator of how many patients may use a specific device. However, the agency has not yet

Robert M Califf, M.D.

January 6, 2017

Page 5 of 5

made clear its expectations of insurers and other payers to provide it with de-identified claims data outside of the voluntary Sentinel systems, which have seen limited participation to date. It seems likely that achieving the kind of research base envisioned will require more routine participation by payers.

The AHA recommends that the FDA work with medical device manufacturers to ensure their products contribute data to the record about their performance. Almost all medical devices now have a software component. As such, they may be able to gather and share data about their performance on an ongoing basis. For example, if a device needs a steady current to function properly, the device could be programmed to track the current and note any anomalies. And, in this age of cyber attacks, devices could, and should, be programmed to provide software security errors or alerts. Such information could be used in ongoing maintenance. And, in the case of an adverse event, performance information gathered by the device could help inform investigations into what went wrong, just as an airplane's "black box recorder" provides information invaluable to investigating crashes.

Hospitals have an array of reporting requirements that they follow when a safety event occurs. We look forward to continuing to work with the agency to improve its own reporting process so that problems can be quickly addressed and information shared with device makers, the FDA, clinicians, and patients and their families to improve safety.

Thank you for the opportunity to comment. Please contact me if you have questions or feel free to have a member of your team contact Chantal Worzala, vice president, health information and policy operations, at cworzala@aha.org or Roslyn Schulman, director of policy, at rschulman@aha.org.

Sincerely,

/s/

Ashley Thompson
Senior Vice President
Public Policy Analysis and Development