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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
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Submitted electronically via regulations.gov

Re: Docket ID: FDA-2012-N-0359: National Medical Device Postmarket Surveillance System Planning Board Report entitled "Strengthening Patient Care: Building an Effective National Medical Device Surveillance System."

Thank you for the opportunity to submit comments on the recently published report by the National Medical Device Postmarket Surveillance System Planning Board. While the Planning Board offers several essential recommendations to strengthen the postmarket surveillance system for medical devices, all stakeholders—including FDA, manufacturers, hospitals, health plans and Congress—must now establish the proper infrastructure to rapidly identify safety risks and collect long-term outcomes information after products reach patients.

The Pew Charitable Trusts is an independent, non-profit research and public policy organization. Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

The importance of data on medical device performance extends throughout the entire product life cycle—from premarket trials to well after new products are regularly used in care and monitored for safety flaws.

A robust postmarket surveillance system will quickly detect unexpected adverse events and answer unresolved questions about long-term performance. Manufacturers use postmarket information to inform the next generation of products. Patients, providers and insurers utilize postmarket information to make clinical and patient care decisions. FDA needs these data to quickly identify safety risks, require changes to product labels and remove faulty products from the market. Recent high-profile performance issues with metal-on-metal hips and implantable cardioverter defibrillator leads show the importance of more quickly obtaining data on device performance after approval to prevent more patient harm when problems occur.

Achieving the Planning Board's vision requires action from FDA, manufacturers, hospitals, health plans and—if necessary—Congress in several areas, including:

- Adopting unique device identifiers into electronic health information, including patients' health records and insurance claims;
- Expanding the use and role of medical device registries; and

- Improving postmarket surveillance coordination across the health care system.

Full adoption of unique device identifiers

A national medical device postmarket surveillance system requires a standard method to identify the medical devices used in care and link those products to the patients who receive them. The Food and Drug Administration (FDA) finalized regulations in September 2013 establishing the unique device identifier system (UDI) to provide each medical device with a code corresponding to its manufacturer, model type and other critically relevant information, such as expiration date. Currently, the highest risk medical devices are required to have UDIs and all devices will have these identifiers by 2018.[1]

The UDI system—which FDA developed at the direction of Congress—will increase supply chain efficiencies, assist in recall resolution, enhance care coordination among clinicians and aid postmarket surveillance activities. As FDA outlined in its National Medical Device Postmarket Surveillance Plan, achieving the full benefits of UDI requires its adoption into electronic health data sources, including patients' health records and claims forms.[2,3]

The Planning Board also recognized the importance of UDI incorporation into these data sources. In fact, the Planning Board states that it "assumes" UDI incorporation throughout the health care system as the foundation to improved postmarket surveillance. Action is needed to achieve both the Planning Board's and FDA's goals.

UDI incorporation into patients' health records

Documenting the UDIs of implanted devices in electronic health records (EHRs) will provide several postmarket benefits to patients, clinicians, researchers and manufacturers. Those benefits include:

- *Enhanced recall resolution*: A list of implanted devices in EHRs will help identify patients that received recalled products and deliver appropriate follow-up care.
- *Improved adverse event reports*: Inclusion of UDI in EHRs will enable patients and providers to submit more precise adverse event reports that identify the make and model—and in some cases the lot number—of a potentially malfunctioning device.
- *Better clinical decision support and care coordination*: The inclusion of UDIs in EHRs will allow providers to make more informed decisions on patient care. This information is critical when patients switch providers or see multiple physicians, all of whom may need information on the specific device.
- *Patient engagement*: UDIs will provide a clear, accessible source of data on the devices implanted in patients' bodies, enabling individuals to take more active roles in their care.
- *Analyses of device performance*: Through UDI data from EHRs, hospitals, manufacturers, and other researchers could examine outcomes associated with different devices, identify patient subpopulations that respond differently to certain technologies, and better understand data on how physicians use certain products.

There is already significant momentum toward the incorporation of UDI in EHRs with the release of two recent federal regulations.

Specifically, the Office of the National Coordinator for Health Information Technology (ONC) has proposed to require that EHRs: 1) include a dedicated field for the UDIs of implanted devices; 2) link with the FDA's Global Unique Device Identification Database (GUDID) to extract human-readable information about the device into the EHR; and 3) incorporate the UDIs of implanted devices into summary of care documents, known as the common clinical data set (CCDS).

The other proposed rule, from the Centers for Medicare & Medicaid Services (CMS), would provide financial incentives for clinicians and hospitals to send and receive the summary of care information from the EHR. Through this program, known as Meaningful Use Stage 3, providers would exchange the CCDS, including UDI, with each other as a routine part of patient care. ONC and CMS must now finalize these rules to support the documentation and exchange of UDI.

Once finalized, these rules will help implement part of the Planning Board's visions for UDI information to be associated with patients by ensuing that EHRs can document and exchange the identifiers of implanted medical devices. Along with support from federal agencies, many clinician, patient and public health groups have supported the documentation of UDI in EHRs. Those organizations include: the American Association of Orthopaedic Surgeons, the American Joint Replacement Registry, Geisinger Health System, Intermountain Healthcare, Mercy, Pacific Business Group on Health, The Leapfrog Group, The Society of Thoracic Surgeons, and Trust for America's Health.[4]

Documenting UDI in claims is essential to improved postmarket surveillance

The Planning Board also recommended that UDIs be integrated into insurance claims submitted by hospitals to health plans and cited a number of benefits to doing so. The current utility of claims data for medical device surveillance is limited because claims only contain information on procedures, but not the specific product used. For example, claims can indicate that patients undergo hip replacement surgery, but can't document the brand or model of the product implanted.

Adding a field for UDI to insurance claims would enable:

- *Evaluations of device performance*: FDA, health plans and researchers could use claims data to conduct robust, longitudinal analyses of device safety and effectiveness. This is already regularly done by these groups to assess outcomes associated with drugs and procedures; adding UDI to claims data would enable these analyses for medical devices.
- *Expansion of FDA's Sentinel Initiative*: Once claims data contain UDI information, the FDA's postmarket surveillance Sentinel Initiative could also support evaluations of specific medical devices. The Sentinel Initiative—which relies predominately on claims data—has already successfully been used to evaluate the safety of drugs and vaccines. Congress, in the Food and Drug Administration Safety and Innovation Act of 2012, required FDA to expand the system to medical devices.[5]

- *Health plans to quickly resolve recalls*: Health plans can use UDI data in their claims forms to help identify members who received recalled devices and ensure appropriate follow-up care.
- *Registries to conduct long-term outcomes research*: Registries rely on data from multiple sources to better understand the long-term performance of medical products. Incorporating UDI information into claims will help registries evaluate product safety and quality over long periods of time, including through better identification of outcomes associated with specific products across data sets.

A wide range of provider, health plan, government and public health groups support including UDI in claims. Supporters include Aetna, Geisinger Health System, National Association of Accountable Care Organizations, Mercy, America's Health Insurance Plans, Society of Thoracic Surgeons, American College of Cardiology, American Joint Replacement Registry, Pacific Business Group on Health, AARP, Trust for America's Health, and The Leapfrog Group.[6-12]

Given the significant patient safety and public health benefits of including UDI in claims, the Planning Board rightly joined the chorus of supporters advocating for this change.

Expanding the role of medical device registries

In addition to device identification in electronic health data, the Planning Board also recognized the value of registries to develop better data on medical device performance.

Registries assess the real-world performance and long-term outcomes of medical devices that may not be detected in the clinical trial setting. Hip implants, for example, are expected to last 15-20 years, but typically require only two years of clinical data for FDA approval. Demonstrating the ability of registries to detect problems, the Australian Orthopaedic Association National Joint Replacement Registry first showed in its 2007 Annual Report that metal-on-metal hips failed at a rate more than two times higher than conventional hips, leading to a worldwide recall.[13]

Active surveillance using registry data

Expanding the role of registries in the United States offers a unique opportunity to conduct active postmarket surveillance for medical devices. Active surveillance, as defined by the Planning Board, involves using "routinely collected electronic health information to identify potential safety concerns rather than passively waiting for reports of potential adverse events." At this time, FDA largely relies on passive surveillance methods, such as adverse event reporting from clinicians, patients and manufacturers, and lacks a system to actively assess correlations between particular products and specific outcomes.

FDA's Sentinel Initiative, though an increasingly robust data source for drugs and biologics, still requires direct querying to receive results. The Sentinel Initiative also mainly relies on claims data, which lack UDIs, and thus is currently unable to evaluate the safety of specific medical devices. An active surveillance system based on the use of registry data could allow for near real-time assessments of the safety of medical devices.

The National Cardiovascular Data Registry (NCDR) has already been used in a proof of concept study for a proactive surveillance system that was able to trigger safety alerts for several cardiovascular devices—including drug eluting stents and vascular closure devices—in real time. The Data Extraction and Longitudinal Trend Analysis (DELTA) network study utilized information collected in the NCDR to show that the data in the registry could signal potential problems with a particular device.[14]

The Planning Board recognized that the DELTA and Sentinel models could serve as building blocks for the future development of medical device surveillance. FDA, researchers, registries and other stakeholders should evaluate how to more quickly advance active surveillance models.

Registries and innovation

In addition to active surveillance, registries have great potential to facilitate innovation and enable the shift of evidence collection from pre- to postmarket. Registries can be used to collect data to bolster product approvals as they support analyses of detailed clinical information. For example, FDA approved a new indication for a transcatheter heart valve based on information contained in a registry instead of requiring the manufacturer to create and conduct a new clinical study.[15]

Registries can also support clinical trials in a more cost effective and efficient manner, as demonstrated by the Thrombus Aspiration during ST-Segment Elevation Myocardial Infarction (TASTE) trial. In this study, Scandinavian researchers examined whether a particular cardiovascular intervention reduced mortality, enrolling over 7,000 patients in a national cardiovascular registry for about $50 per patient, with none lost to follow-up.[16]

While registries are a powerful tool that can be used for postmarket surveillance and enabling medical device innovation, several registry enhancements are needed for them to become a reliable part of the device surveillance infrastructure.

Improving existing registries

To advance the efficient use of registries, The Pew Charitable Trusts—along with the Blue Cross Blue Shield Association and the Medical Device Epidemiology Network Initiative (MDEpiNet) Science and Infrastructure Center at Weill Cornell Medical College—released a report in 2014 outlining best practices for the use of registries and how to overcome barriers to their use.[17]

The report includes recommendations on:

- Streamlining data collection by limiting data fields, using standardized definitions, and integrating information from other sources, such as EHRs and claims forms, to reduce time and cost of reporting;
- Public disclosure of information about registry governance, operation and financing;
- Dissemination of registry findings to the public, FDA, providers, patients and manufacturers;

- Clarifications needed from federal agencies on the interpretation of privacy and human subject protection laws for registries;
- Development of viable funding models to ensure registry sustainability; and
- Incorporation of UDI into electronic health information, including registries.

The Planning Board, consistent with our recommendations, highlighted the importance of capturing UDI of implanted devices at health care delivery sites and allowing that data to be transferred to registries in a designated field that stores this important information.

In addition, FDA has tasked MDEpiNet to issue a report on outlining strategies to accelerate the use and adoption of registries as part of both postmarket surveillance and innovation. The findings from this report are expected soon and may be useful in identifying and prioritizing short and long-term actions that are needed.

While some registries collect information on medical devices, many registries are designed as part of broader efforts to help evaluate provider and hospital performance. For example, CMS has used registry participation as a condition for provider reimbursement through the Coverage with Evidence Development program, and uses its qualified clinical data registry program as part of the physician quality reporting tool. Because registries are increasingly used throughout the health care system and by many federal agencies, the Department of Health and Human Services (HHS) should coordinate efforts to maximize the efficiencies and benefits of these important data collection systems.

Improving coordination of efforts

Along with better infrastructure to quickly collect robust data on the postmarket performance of medical devices, new efforts must include coordination among the many different entities collecting information on product safety and effectiveness. As mentioned in the Planning Board report, FDA, manufacturers, health care providers, health plans, registries and other organizations are often operating independently and without input from the other groups on postmarket activities.

To avoid the duplication of efforts, identify information gaps, and leverage data generated throughout the healthcare system, better coordination of activities is essential to more quickly discover problems with devices and reduce the costs of postmarket surveillance. Recognizing the need for a coordinating entity, the Planning Board recommends the development of a new postmarket surveillance center.

While this new center would not conduct postmarket surveillance itself, it would take the lead in developing the needed standards and infrastructure to efficiently collect data. Among its first priorities, the coordinating center should: 1) help develop or adopt common data standards—such as core pieces of information that need to be recorded for specific conditions or devices; 2) ensure that data from EHRs, claims and registries are easily shared across the health care system; and 3) support standards for the capture and exchange of UDI in various clinical, administrative and financial systems.

While pilot programs envisioned in the Planning Board report will evaluate the viability and effectiveness of alternative approaches to postmarket surveillance, temporary demonstrations are insufficient to establish the robust, sustainable data collection system that all stakeholders need. FDA, health plans, registries, manufacturers, hospitals, Congress and other stakeholders must implement needed reforms and develop the necessary infrastructure—including seed funding and a sustainable financial model for these projects—to more quickly identify problems with marketed devices and better assess product performance over time.

Conclusion

The Planning Board outlines several key steps to improve postmarket surveillance. A series of concrete steps, outlined above, will ensure that the necessary infrastructure exists to quickly and efficiently collect data on medical devices after approval. Key to fulfilling the Planning Board's vision—as well as meeting the recommendations from FDA and many other stakeholders—is UDI adoption into EHRs and claims forms, the expansion of medical device registries and coordination across the healthcare system.

Through the development of a robust postmarket surveillance system, all stakeholders—including FDA, manufacturers, physicians, patients and health plans—will have the needed data to quickly identify problems, withdraw faulty products from the market and better understand the long-term performance of new products. Action from these groups, including Congress when necessary, is essential to achieving this potential.

Thank you for your consideration of our comments. Should you have any questions or if we can be of assistance, please contact Josh Rising, director of healthcare programs at The Pew Charitable Trusts, at 202-540-6761 or jrising@pewtrusts.org.

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