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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
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Rockville, MD 20852

Submitted electronically via regulations.gov

Re: Docket ID: FDA-2015-N-2048-0001: Medical Device Epidemiology Network Registry Task Force Report; Availability, Web Site Location and Request for Comments

Thank you for the opportunity to comment on the report, "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge Clinical Care and Research," from the Medical Device Registry Task Force. We agree with the task force's recommendations to improve the data available on devices throughout the produce lifecycle through ubiquitous inclusion of the unique device identifiers (UDIs) in health information data sources, enhancements to registries and better coordination of research activities.

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.

Data on patient outcomes are currently collected in a variety of sources—including clinical studies, electronic health records (EHRs), claims and registries. Each of these data sources have their strengths and weakness, with different databases shoring up the weaknesses of the others. Linking these data sources as part of a coordinated network can provide researchers, manufacturers, health plans and the Food and Drug Administration (FDA) with robust, detailed information on patients to both facilitate innovation and enhance postmarket surveillance.

This type of coordinated registry network, as the task force envisions, has already shown some promise. For example, researchers in Europe recently conducted a registry-based clinical trial at a fraction of the cost of traditional randomized controlled studies using information from electronic health records.[1] Similarly, FDA approved indication expansion for a heart valve from Edwards Lifesciences using registry data instead of requiring the establishment of a new clinical study.[2] Finally, manufacturers use registries to meet both FDA's and health plans' postmarket data collection requirements.

Fully realizing the coordinated registry network envisioned by the task force requires several enhancements to existing policies and the infrastructure utilized to collect data.

- First, UDIs, which are codes corresponding to product brands and models, must be incorporated throughout the healthcare system, including EHRs, claims and registries.

- Second, electronic information sources must utilize common data standards and enhanced patient matching methods to improve the flow of data between linked data sources—including EHRs and registries.
- Third, the development of a coordinating entity can help develop policies for the use of multiple data sources and prevent duplication of efforts.

UDI adoption in health data is essential

As emphasized by the task force, UDI incorporation in health data sources will enable researchers to know which products are associated with safety problems or other patient outcomes. FDA established the UDI system to provide a national method of identifying the devices used in these data sources, which, until now could not include product information in a standard manner. To achieve the task force's vision for UDI adoption "into the health information systems of healthcare enterprises, from point of entry in the supply chain through billing," this data must be included in EHRs, registries and health insurance claims.

Progress made to include UDI in EHRs

EHRs are already utilized by some health systems and as part of large data networks to conduct detailed analyses of patient outcomes. The incorporation of UDI in EHRs can help ensure that there is sufficient information in these systems about the specific devices used in care. Until now, there was no standard field in the EHR to record what specific brand and model of device is implanted in patients.

However, the Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid Services (CMS) recently finalized regulations that will require that EHRs contain a field for the UDIs of implanted devices and are able to exchange this information as part of summary of care documents.[3]

When the regulations take effect, hospitals and researchers will be able to use device-specific data from EHRs as part of the coordinated registry network envisioned by the task force.

UDI in registries

Independent registries are increasingly used to track outcomes associated with specific medical devices. While registries contain detailed data on patient care and outcomes, they typically only collect data for a set period of time—such as until patient discharge or a several months after a procedure. To obtain long-term outcomes, registries often link to other information sources—such as claims.

UDI incorporation into registries can help ensure that the registry has specific data on the product used. Additionally, UDI data can help registries better link with other data sources by using the specific product identifier to match patients.

The task force should clarify that registries collecting information on procedures involving implants should begin integrating fields for the UDIs of products used and evaluate outcomes based on the device used.

UDI in claims

Finally, as the task force emphasizes, claims data as part of the envisioned registry network are extremely useful for obtaining outcomes information across providers and payers. Because claims are standardized, they are easily aggregated and provide longitudinal data on patients years after treatment. As stated by the task force, individual registries lack the totality of information needed to assess products and thus requires "linkages to other registries, EHRs, or claims data, especially to accomplish long-term tracking."

However, claims currently only list procedures—such as a knee replacement—and lack information on the specific device used. Incorporating a field for UDI in claims can help ensure that this data source contains device-specific information so that researchers and FDA can evaluate product performance. For example, adding a field for UDI would allow FDA to expand the Sentinel Initiative—a claims based surveillance system that has been used to study safety of drugs—to medical devices as was required by Congress in 2012.

Additionally, UDI incorporation in claims will help link the data with other information sources to provide longitudinal data. As mentioned, registries could use the UDIs of devices to help match patients between their own data systems and claims databases to obtain patient outcomes years after data collection concludes.

Claims transactions are only updated periodically, with the next version expected in approximately 2020. Missing this window to incorporate a field for UDI would delay the inclusion of this information until the late 2020s—if not later.

Given that the envisioned coordinated registry network relies on claims data—and UDI incorporation into it—the task force should more forcefully express the importance of creating a field in claims for this information.

Enhancements to registry policies

Data located in individually operating registries, EHRs, claims and other information sources are often difficult to aggregate for research because they a) lack standard data models and b) have difficulty linking information on the same patient across the different data sources.

Common data model

Registries and other data sources must use a common data model to ensure that information can be seamlessly transmitted within the envisioned registry network. Since such a model is not in place, registries and other information sources often develop proprietary data elements and record information differently, making it difficult to aggregate the information and conduct analyses using multiple databases.

To compound the problem, EHRs also use different definitions and data elements, so it is difficult to get information from patient records to the numerous registries in which a hospital participates. As a result, hospitals often must manually enter data into registries or build custom interfaces to their EHR system. This is not only inefficient, but also increases costs for hospital participation in registries.

As a result, the registry task force recommends the use of standardized clinical vocabularies, common data elements and outcome definitions. This recommendation reflects findings in two reports on clinical registries—one from Pew, the MDEpiNet Science and Infrastructure Center and Blue Cross Blue Shield Association, and another prepared by Avalere Health for Pew. [4,5]

Use of common data models would greatly improve data quality, reduce costs and make data more useful for comparison. To help resolve this problem, the Registry Task Force, FDA, ONC, and other stakeholders should continue to develop and implement a common data model that can be adopted by all registries and EHRs.

Patient matching

The concept of a coordinated registry network relies on the ability to obtain information on a patient from multiple data sources. However, it is often difficult to identify the same patient in those sources because individuals often have identical names, birth dates or other demographic information. As mentioned regarding the utility of claims information, adding UDI to the various data sources would help with patient matching, but better algorithms and patient identification methods would also alleviate the problem.

In order to ensure that patient records are providing correct conclusions to researchers, it is crucial for ONC, hospitals and EHR vendors to develop better matching algorithms or find other ways to match patients across data systems.

Development of a coordinating center

In addition to UDI, common data standards and better patient matching, the infrastructure needed to support a coordinated registry network requires better organization of this multi-stakeholder device evaluation system. The envisioned structure of a series of linked networks comprised of individually operating groups will need an overarching organization to ensure that the proper connections are in place, methodologies are developed and that data is being used appropriately and securely. The report references the creation of a coordinating entity that would perform this function, which the National Medical Device Postmarket Surveillance Planning Board describes as central to improve the evaluation of products after approval. The coordinating center can also facilitate expansion of the activities of the device evaluation system to other health products as well, including drugs, biologics and others.

As the task force and planning board continue their efforts to improve device evaluation, they should work with FDA, ONC, CMS, private health plans, hospitals, manufacturers and others to ensure that this coordinating entity is created, has a sustainable funding model and a business

plan that identifies specific uses cases, and can serve as a dissemination source for various models that have shown value for stakeholders.

Conclusion

The task force articulates a vision for more efficient device evaluation throughout the product lifecycle based on accessing data from multiple independent sources. To realize this vision, however, these data sources must contain device-specific information, utilize common data standards, better match patients and coordinate efforts to more efficiently and effectively evaluate the safety, performance and quality of medical devices. The task force, through its role as a multi-stakeholder group of experts, can help make progress on each of these efforts to improve care for patients that rely on life-saving and life-changing medical devices.

Should you have any questions or if we can be of assistance, please contact me at jrising@pewtrusts.org or 202-540-6761.

Sincerely,

Josh Rising, MD
Director, Healthcare Programs
The Pew Charitable Trusts

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[1] Ole Fröbert, et al., "Thrombus Aspiration during ST-Segment Elevated Myocardial Infarction," *New England Journal of Medicine* 369 (2013): 1587-1597, doi: 10.1056/NEJMoa1308789.
[2] Larry Husten, "Using Registry Data, FDA Expands Indication For Edwards' Sapien Transcatheter Heart Valves," *Forbes*, Sept. 23, 2013.
[3] 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications, 80 Fed. Reg. 62601 (Oct. 16, 2015), and Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017, 80 Fed. Reg. 62761 (Oct. 16, 2015).
[4] The Pew Charitable Trusts, Blue Cross Blue Shield Association, Medical Device Epidemiology Network, "Medical Device Registries: Recommendations for Advancing Safety and Public Health," Sept. 2014, http://www.pewtrusts.org/en/research-and-analysis/reports/2014/09/medical-device-registries.
[5] Avalere Health, "Innovative Approaches to Accessing, Extracting, and Aggregating Electronic Health Data: Experience from Five U.S. Medical Device Registries," July 2015, http://avalere.com/expertise/providers/insights/innovative-approaches-to-accessing-extracting-and-aggregating-electronic-he.