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Re: Global Unique Device Identifier Database comments

Thank you for the opportunity to comment on the beta version of the Access Global Unique Device Identifier Database (AccessGUDID), which—with some enhancements—has the potential to give patients, doctors and researchers better information on medical devices to help inform clinical care, determine whether products are involved in a recall and enable more robust product performance evaluations. Starting tomorrow, the Food and Drug Administration (FDA) will require that manufacturers of all implantable, life sustaining and life supporting devices populate device information into AccessGUDID, thus providing an opportunity to ensure that these data are available to patients, clinicians and researchers. Additionally, this week FDA and the National Library of Medicine (NLM) announced the release of new features to provide developers of health information technology systems the ability to access data stored in AccessGUDID more easily.[1]

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

Pew has supported the development of the unique device identifier (UDI) system and encouraged its adoption by hospitals, health plans and registries, including through its addition to patients' health records and insurance claims. The ability to access information about particular devices through AccessGUDID will improve patient safety and allow hospitals and doctors to make better purchasing and clinical decisions.

AccessGUDID contains a list of all medical devices with UDIs and provides corresponding manufacturer, model, and other information, such as whether the product is sterile or prescription use only. The database does not contain any patient information or detailed data about specific lot numbers and expiration dates.

Changes needed to make AccessGUDID more effective

As a comprehensive database of marketed medical devices, AccessGUDID has the potential to give doctors, hospitals and patients more data on the devices they use. Specifically, the database could:

- Allow healthcare professionals to look up the device identifier of all products involved in a recall so they may contact their patients to schedule follow-up care;
- Enable hospitals to electronically link with AccessGUDID and extract information into their inventory and electronic health record (EHR) systems; and
- Facilitate patients' use of the database to look up recall information, learn about the indications for use of a device and obtain information on device performance.

However, for AccessGUDID to enable hospitals, clinicians and patients to realize these benefits, two changes are needed:

- AccessGUDID should be integrated with other various FDA databases to provide additional context for the devices listed; and
- Building on this week's release of the new download features, FDA should continue to ensure that health information technology systems can automatically extract all new updates from AccessGUDID, and the agency should widely publicize the new capabilities to developers to link device information to hospital information systems, such as electronic medical records and supply chain databases.

Linkage with other FDA databases

While AccessGUDID contains important information on medical devices, it is not linked to other existing FDA databases that already contain key data about products, such as whether they are recalled or the devices' approved labeling and indications. As a result, people seeking information about a device may have to go to many different databases that they may not even know about. Having AccessGUDID serve as a hub that connects with these databases can make it much easier for patients, clinicians and others to access information on products for clinical decisions and research on products.

To better provide this information and leverage existing FDA data, AccessGUDID should be linked to these databases:

- *Adverse event database*.[2] FDA, in its UDI regulations issued in 2013, required the inclusion of these identifiers in adverse event reports to improve the detection of problems associated with a particular device. Linking AccessGUDID to the adverse event database would allow patients and their physicians to know what adverse events have been reported for the devices they use or are considering utilizing.

- *Recall database*.[3] Linking AccessGUDID with the recall database would allow patients and physicians to know whether a device is recalled when looking up the product UDI. This information should be easily available to clinicians and patients when they are deciding what device to use and looking for whether an individual is implanted with a product that has been recalled.

- *510(k),[4] de novo,[5] and premarket approval (PMA)[6] databases.* As part of AccessGUDID submissions, manufacturers are already required to submit the premarket submission number (such as PMA or 510(k)) associated with their products, yet this information is not displayed in AccessGUDID.[7] Linking to these databases in AccessGUDID would help researchers, clinicians and hospitals obtain information on the data used to support the marketing of the product. For example, patients could view the side effects observed in a premarket trial, or a clinician could analyze the study protocols used to approve a product.

  In addition, researchers and hospitals could search AccessGUDID based on the premarket notification number to identify all UDIs associated with a particular 510(k) or PMA application. This capability can help researchers and providers when a device has different identifiers because it may have multiple components, come in varying sizes or be sold under several brand names. As a result, when recalls occur or as part of research on a particular device, all the relevant identifiers for a product would be available to the clinician, hospital or other stakeholder. Consider the following examples:
  - First, products can have multiple components, each with their own identifier, as part of a larger device. For example, Sedasys, a complex computerized sedation system, has a single approval application but multiple parts to the technology—including a drug delivery cassette, patient monitoring display and power unit. Linking AccessGUDID information to the same FDA approval or clearance number would make it clear to patients and clinicians that search the database based on the premarket notification number that each of these units is part of a single device.
  - Second, by searching AccessGUDID based on the premarket submission information, clinicians and researchers will have access to all the device identifiers for a single product that may come in different sizes. Given that each size of a device has its own AccessGUDID entry, locating all the relevant device identifiers of a single device model can help with research on a particular technology or in the event of a recall regardless of the product size.
  - Last, some manufacturers may have contracts to privately label their product for other companies. As a result, some products are on the market with the same premarket submission information but with different brand names and device identifiers. Linking products with their marketing authorization number in AccessGUDID will help patients and clinicians search AccessGUDID based on approval or clearance numbers to know all the associated products. FDA, at a minimum, should include this capability for all high-risk implantable devices listed in AccessGUDID given the increased safety concerns for patients.

- *Post-approval study[8] and 522 postmarket surveillance[9] databases.* Some devices are marketed with the condition that the manufacturer study the safety and performance of the device. FDA maintains databases that display the status of these post-approval and 522 studies—named after the relevant section of law—to list results and whether they are completed. These studies, which may provide more data on product safety and effectiveness than was known at the time of approval, give physicians and patients key information on the devices they use or when deciding on a new course of treatment.

Linking AccessGUDID to these databases would allow patients and physicians prompt access to the most up-to-date data available on the devices without requiring them to search on a separate database (and one that they may not know exists).

Automatic extraction of data from AccessGUDID

FDA announced this week the release of two new application program interfaces (APIs) that will provide information about specific devices from AccessGUDID. The first API will return all the fields from AccessGUDID associated with a particular device, and the second API will provide a list of all implanted devices. This release will allow more efficient integration of device data into patients' health records and other electronic databases.

This type of synchronization with AccessGUDID is especially important given a recent regulation from the Office of the National Coordinator for Health Information Technology (ONC) that requires certified EHR technologies to include a field for the UDIs of implanted devices and extract information from AccessGUDID directly into the patient's health record.[10] The newly released APIs were designed with the regulations in mind, and are needed for EHR developers to comply with the requirement.

While the new APIs will greatly enhance the functionality of AccessGUDID for compliance with the ONC regulations, FDA and NLM should monitor the use of these capabilities to ensure that various electronic databases other than EHRs—such as supply chain and claims processing systems—can also extract the information they need from the database.

In addition, these APIs could help other stakeholders—such as health plans—better determine whether a UDI they receive is valid. For example, there are existing efforts to include the UDI on claims sent from hospitals to health plans. Some health plans may need to validate that the UDI they received was not entered incorrectly—such as if there is no device associated with the UDI included on the claim. FDA should ensure that these APIs can help health plans automate this validation step by matching the device identifier to a record in AccessGUDID.

Given that the capability to push information from AccessGUDID into various health data systems is critical to its success in ensuring those sources contain accurate device data, FDA and NLM should widely publicize and educate software developers on the existence of the newly released APIs so that they can begin to integrate the functions of AccessGUDID into their products.

Conclusion

AccessGUDID has the potential to serve as an informative resource for researchers, physicians, patients, health information technology vendors and other healthcare stakeholders to obtain accurate information on the devices used in care. FDA and NLM should build upon the beta release of this database by both facilitating automated data extraction from AccessGUDID to other databases and linking the information with other agency databases to give patients and clinicians more robust information on products.

These changes can enhance AccessGUDID's ability to inform clinical decisions, educate patients on the products they use and facilitate comprehensive research on device quality. Should you have any questions or if we can be of assistance, please contact me at 202-540-6761 or jrising@pewtrusts.org.

Sincerely,

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

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[1] AccessGUDID, "New APIs and Download," Oct. 19, 2015, http://accessgudid.nlm.nih.gov/news-details?date=2015_10_19.
[2] Food and Drug Administration, MAUDE-Manufacturer and User Facility Device Experience Database, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM.
[3] Food and Drug Administration, Medical Device Recalls Database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm.
[4] Food and Drug Administration, 510(k) Premarket Notification Database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
[5] Food and Drug Administration, Device Classification under Section 513(a)(1)(de novo) Database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm.
[6] Food and Drug Administration, Premarket Approval (PMA) Database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.
[7] Food and Drug Administration, "GUDID Data Element Reference Table," May 1, 2015, http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/UCM396592.xls.
[8] Food and Drug Administration, Post-Approval Studies Database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.
[9] Food and Drug Administration, 522 Postmarket Surveillance Studies Database, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm.
[10] 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).