A fact sheet from THE PEW CHARITABLE TRUSTS | July 2014

Unique Device Identifiers

Improving Patient Outcomes and Care

Overview

Medical device failures can be debilitating and life-threatening for patients, especially when faulty technologies are not quickly identified and removed from the market. A new system developed by the Food and Drug Administration, or FDA, will help patients, clinicians, and hospitals spot problems more readily and make real-time assessments on the performance of devices used in patient care.

The unique device identifier

- The unique device identifier, or UDI, is a unique code consisting of two parts: one refers to the manufacturer and model of a device, and the other identifies additional information such as lot number and expiration date.[1]
- Devices classified by FDA at the highest risk level (Class III) will have UDIs by the end of 2014, and all devices will receive an identifier by 2018.
- Manufacturers will input the UDI and device information into FDA's publicly accessible catalogue of devices—the Global Unique Device Identifier Database, or GUDID—so patients and physicians can learn more about specific products.

Supply Chain Management

Hospitals, manufacturers, and distributors can achieve supply chain efficiencies by utilizing the UDI as a uniform, national identifier to track products in procurement and inventory management systems. The UDI will provide notifications of product expiration dates, limit excess product stock, and reduce the time providers need to manage inventory to increase their availability for patient care.[2]

Recalls

In more than half of the highest-risk recalls of devices, manufacturers were unable to locate all of the products in question and were therefore unable to correct or remove all problematic items.[3] Incorporating UDI into supply chain systems and electronic health records, or EHRs, will enable hospitals to track and find recalled devices in their inventory and to identify and notify affected patients.

Postmarket Surveillance

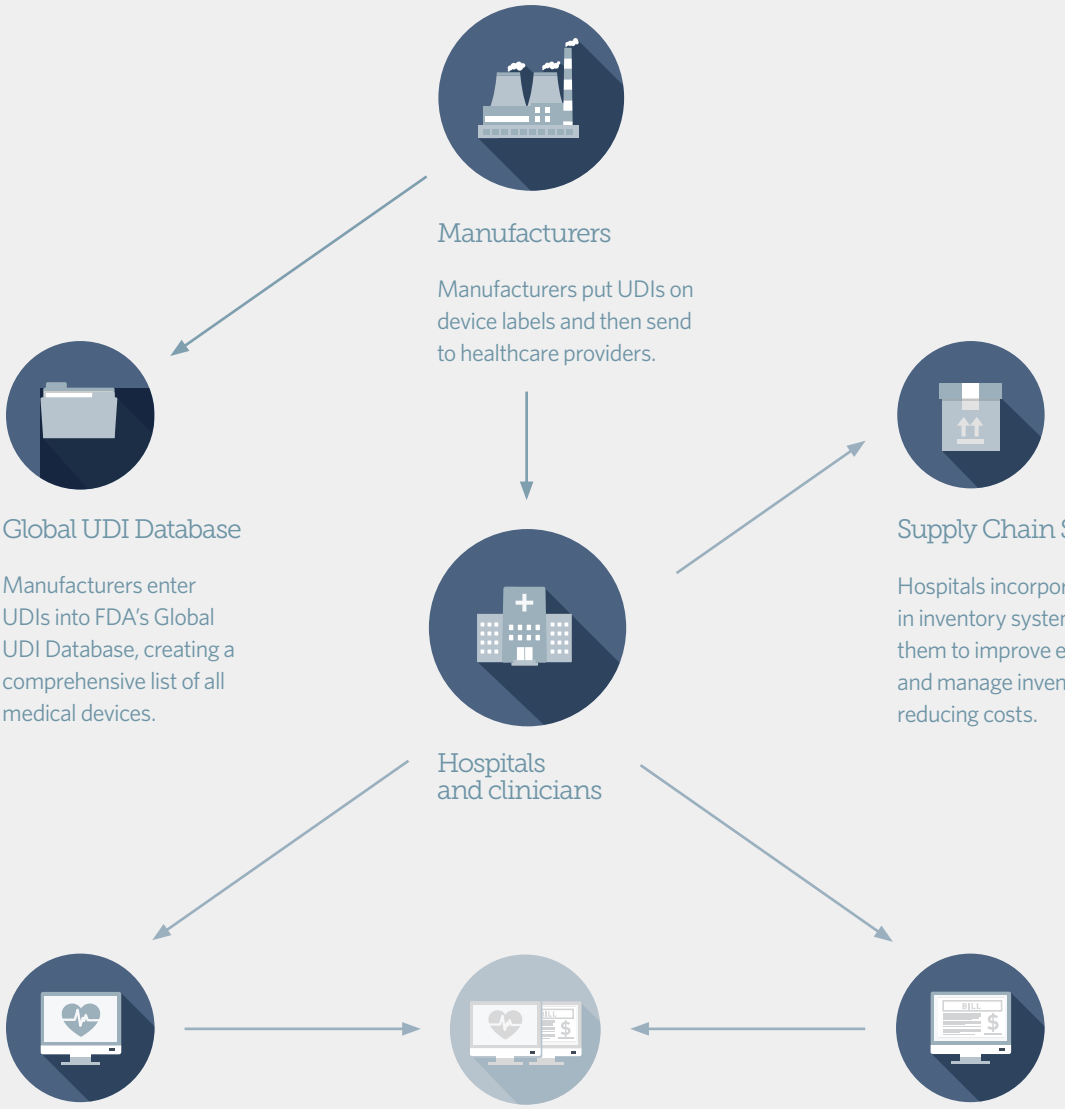
Patients, physicians, health plans, and FDA often lack information on long-term patient outcomes associated with approved medical devices. Integrating UDI into electronic health records, adverse event reports, registries, and insurance claims would allow health plans and FDA to understand how the device performs in large numbers of patients over long periods of time.[4]

Figure 1

A look at the unique device identifier

Figure 2

Integrating UDI into Patient Care



Manufacturers

Manufacturers put UDIs on device labels and then send to healthcare providers.

Global UDI Database

Manufacturers enter UDIs into FDA's Global UDI Database, creating a comprehensive list of all medical devices.

Supply Chain System

Hospitals incorporate UDIs in inventory systems, using them to improve efficiency and manage inventory, thus reducing costs.

Hospitals and clinicians

Providers record UDI in electronic health records

Patient engagement: Provides patients with accurate information on the devices they use.

Adverse event reports: Enables patients and providers to reference UDIs contained in health records when submitting adverse event reports, ensuring that FDA receives more accurate information on device failures and safety problems.

Benefits of UDI in both electronic health records and health insurance claims

Device performance: Assists health plans, hospitals, FDA, researchers, and registries—databases containing information on patient outcomes—with assessing the safety and effectiveness of specific medical devices. EHRs contain detailed information while claims provide large datasets to analyze device performance.

Recalls: Permits hospitals and health plans to identify and contact patients with a recalled device.

Providers submit UDI in health insurance claims

Payer assessment: Provides health insurers with data for robust analyses to ensure the quality and safety of devices used by their beneficiaries.

Sentinel: Allows FDA to use its Sentinel surveillance system to proactively identify devices safety problems.

Endnotes

1 U.S. Food and Drug Administration, "FDA Unique Device Identification," accessed Dec. 13, 2013, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/.

2 Natalia A. Wilson and Joseph Drozda Jr., "Value of Device Identification in the Digital Health Infrastructure," *Journal of the American Medical Association* 309 no. 20 (2013):2107-8.

3 U.S. Government Accountability Office, "Medical Devices: FDA should enhance its oversight of recalls," GAO-11-468 (2011), accessed Nov. 18, 2013 http://www.gao.gov/new.items/d11468.pdf.

4 Thomas P. Gross and Jay Crowley, "Unique Device Identification in the service of public health," *New England Journal of Medicine* 367 no. 17 (2012):1583-5.

For further information, please visit:

pewtrusts.org

Contact: Erin Weireter, senior associate, communications
Email: eweireter@pewtrusts.org
Project website: pewtrusts.org/UDI