

Implementing the Unique Device Identifier

Device makers are currently phasing in a new unique device identifier (UDI) for all of their medical devices.

The UDI holds promise to improve medical device safety and create supply chain efficiencies. The transition to the UDI will require significant changes to hospital operations and information systems. Technology vendors and hospitals will need time to learn how best to incorporate the UDI into complex supply chain and clinical information systems. The priority must be to implement the UDI in clinical care to benefit patients. However, the AHA also is working with other stakeholders to determine the most efficient way to add the UDI on claims submitted to payers.

BACKGROUND

The Food and Drug Administration (FDA) is rolling out rules for medical devices to be accompanied by a UDI that can be used to improve patient safety, facilitate recalls of devices that malfunction and improve supply chain efficiency. The packaging of the device must be accompanied by automatic identification and data capture technology, such as a barcode or a radio-frequency identifier (RFID), so that hospitals and other organizations that use medical devices in clinical care can use scan technology to automate their systems.

The transition to the UDI will take until 2020. The scope of medical devices that will have the UDI is vast, and includes everything from bandages to implantable cardiac devices. The actual identifier on a medical device can be as long as 75 characters. The identifier contains both a device identifier (DI) and a production identifier (PI). The DI contains information to capture the brand and model of the device. The PI includes details such as the lot, serial number and expiration date (see Figure 1).

To obtain a UDI, the device manufacturer must go to one of three issuing agencies chosen by the FDA. Each agency has its own format for the UDI, so it is not a single standard, but multiple standards.

IMPLEMENTATION CHALLENGES

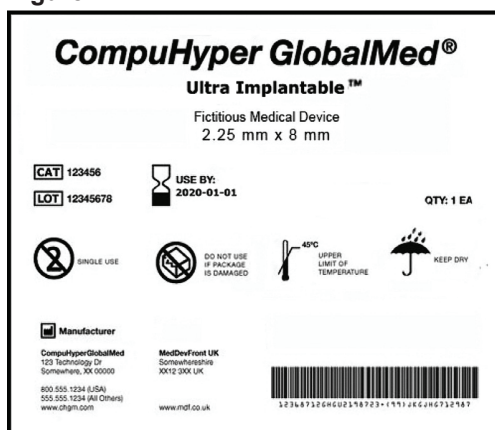
Hospitals are making changes to their materials management systems to recognize the UDI. This process is proving to be challenging and costly, given the complexities of the UDI itself and the many hospital information systems that need to be updated to handle all of the components that are part of the UDI. The UDI will flow through hospital information systems following the path taken by the device itself – procurement, inventory management, then use in clinical care and possibly billing. Figure 2 illustrates the complex systems involved. Connecting and maintaining these systems will be a significant challenge.

Using the UDI in Clinical Systems

The most important benefits of the UDI for patients will come from including the UDI in existing clinical information systems that support hospital care. This will make it possible for patients and providers to have a clear record of the artificial hips, pacemakers or other devices used. The UDI will serve as a link between the patient and the device, and it will facilitate recalls and allow patients to be more informed about their care. The central clinical system is the electronic health record (EHR), but there also are other systems that will be involved, such as systems unique to the operating room or cardiac catheterization lab. These clinical systems also include relevant clinical data needed to understand whether medical devices are working properly or creating unintended problems.

Hospitals rely on their IT vendors to design systems that support clinical work. However, the EHRs certified to meet federal requirements do not yet support the capture and use of the UDI, although the next certified EHR version, expected to be in use in 2018, will include a field for the UDI. Hospitals also will need to upgrade equipment and train staff on how to implement the UDI and use it for clinical care and inventory management.

Figure 1



Source: FDA

Continued on reverse

Improving Patient Safety

FDA rules also include new requirements for hospitals and other end-users when they submit adverse event reports to the agency. The new requirements mandate including the UDI when a medical device has a problem. Thus, FDA can begin to conduct post-market surveillance using the UDI in the near term. Hospitals are willing to work with FDA to improve those existing processes to fully benefit from the UDI. Leading hospitals and health systems already have participated in a successful pilot to automate adverse reports for devices (ASTER-D). Understanding of medical devices also can be improved by including the UDI in the clinical information used in registries or other research endeavors such as sentinel reporting.

Using the UDI in Supply Chain Systems

Hospitals could use the UDI to better manage their medical inventories and reduce costs. To realize supply chain efficiencies from the UDI, however, hospitals will need to upgrade and integrate a number of different data sources. For example, hospitals use ordering systems to procure devices from the manufacturers. They also use materials management information systems to control their inventories. IT vendors will need to revise these systems, and hospitals will need to learn how best to implement them. Many outstanding implementation issues exist, such as how to connect supply chain

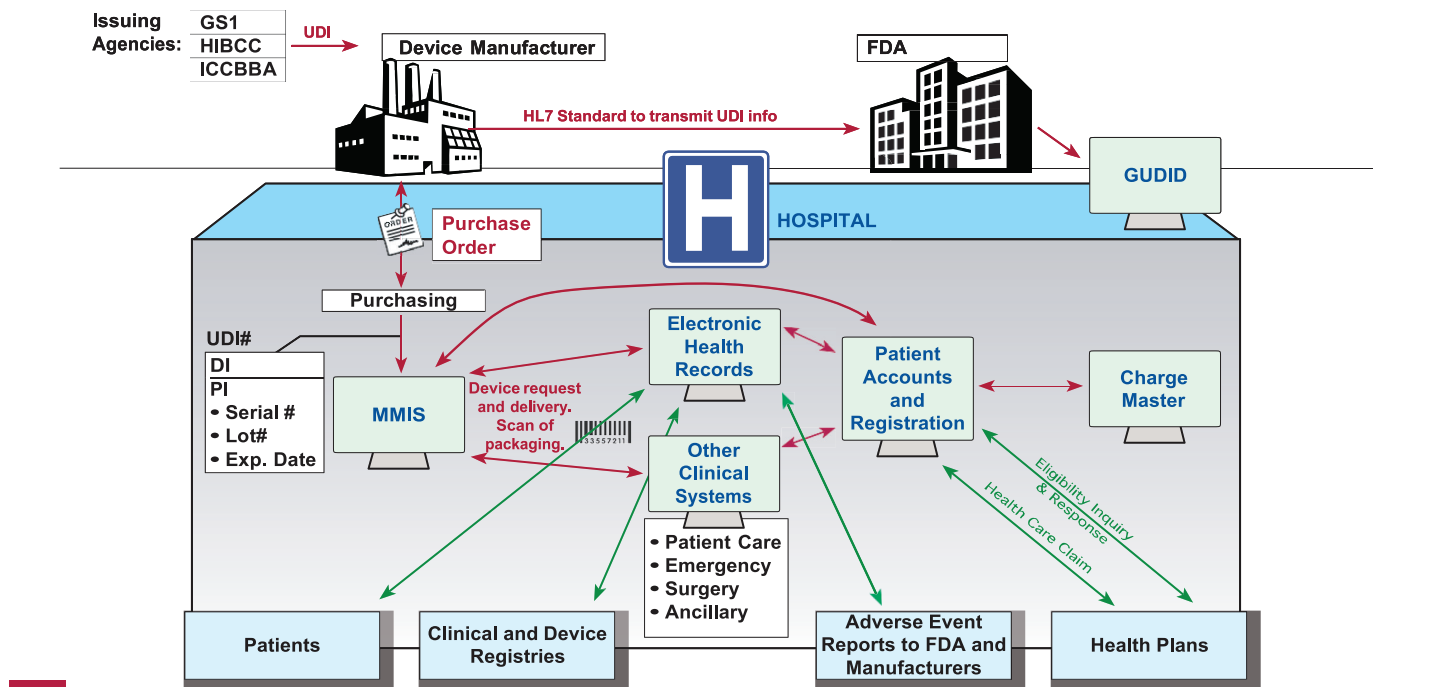
systems with clinical systems, so that as devices are used they can be tracked back to inventory.

Using the UDI on Claims

Some have suggested establishing an early warning process monitoring the safety of high-risk implantable devices by using claims data to evaluate devices after they are in use. Given that clinical systems are most important for patient safety benefits, the AHA believes that we must prioritize using the UDI in clinical systems. However, the AHA also is working with other stakeholders to determine the best approach to placing the UDI on claims that maintain efficiency in claims processing. The health care system saves \$2.3 billion per year by fully automating the claims process. The AHA believes a successful approach will require:

- Adding only the DI portion of the UDI, as opposed to the full UDI;
- Reporting the UDI at a place on the claim that minimizes required changes to billing systems (the claim level, not the line item level);
- Having a refined list from the FDA of the specific high-risk UDIs it wants to track; and
- Having a list from the FDA of the payers that have volunteered to provide the agency claims data for use in post-market surveillance.

Figure 2: Schematic Flow of UDI Through Hospital Information Systems



KEY

FDA – Food and Drug Administration
GUDID – FDA’s Global Unique Device Identification Database (GUDID), listing each manufacturer’s device.
GS1 – Global Standards 1, standards body named by FDA to issue identifiers.

HIBCC – Health Industry Business Communication Council, standards body named by FDA to issue identifiers.
ICCBBA – International Council for Commonality in Blood Banking Automation, standards body named by FDA to issue identifiers
MMIS – Materials Management Information Systems

UDI/DI/PI – Unique Device Identifier. A 75 character number that includes two main components – the DI (which is the manufacturer and model number of the device and the portion of the UDI that is communicated to the FDA), and the PI (which includes numbers for lot, serial number, and expiration date).