



System Safety in Healthcare

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Unique Device Identification (UDI): A New Government Initiative to Improve Patient Safety

Unique Device Identification (UDI) is a recent development to protect patients from hazards in medical devices. The UDI relates to adverse event reporting, identifying and analyzing devices in use. Currently, hospitals are unable to report many adverse events because the device identification has to be manually located — and often, they are not easily readable, or the person reporting makes an error in reading or documenting the identification information. If a cardiac monitor malfunctions, it's critical for the information in the adverse event report to match the manufacturer's product identification system; otherwise, the adverse event may go unreported to U.S. Food and Drug Administration (FDA), and the device may not be recalled as soon as it should. The same urgency holds for a product recall sent from a manufacturer to the doctor, hospital or patient. An inability to identify the device affected by the recall could have potentially disastrous results for patients. In addition, if the device is for personal use, the user may not have access to information about the hazards other users of the device have experienced. With this new system, a user can easily search for hazards.

Urgent Need of UDI

In a five-year period, the FDA received about a half million adverse event reports involving medical devices. More than 280,000 of these reports noted injury to the patient. In about 18,000 reports, the patient outcome was death [Ref. 1].

The FDA: Spearheading the Process

The FDA has recently established a UDI system to adequately identify medical devices through their distribution and use. The goal of the UDI system is to enhance patient safety by requiring manufacturers to make device labels machine readable, as well as readable by humans. When fully implemented, the label of most devices will include a device identifier, a production data identifier, a serial number, a lot number,

a batch number and an expiration date. All this information goes on the machine-readable bar code.

The key players are FDA, which accredits the issuing agencies that assign UDIs, and the labelers who ensure the uniqueness of the code. The labeler can be the manufacturer or an outsourced party. The labeler will also submit certain information about each device to FDA's Global Unique Device Identification Database (GUDID). Consumers who go to this database can access this information, which will help everyone manage device recalls and also support the global distribution change. This system will modernize device post-market surveillance and facilitate communication among stakeholders. It will also require the issuing of new labels every time there is a version change or a major engineering change.

The same responsibility applies to changes in the software. Regardless of whether software is distributed in packaged form, or as stand-alone software regulated as a medical device, it must provide its UDI through either or both of the following:

- An easily readable plain-text statement displayed whenever the software is started
- An easily readable plain-text statement displayed through a menu command

Challenges

UDI implementation is particularly challenging because it involves the “convergence of a very diverse set of data attributes,” said Siobhan O’Bara, senior vice president of industry engagement, GS1 US, a standards organization and an FDA-accredited agency for issuing UDI. “Most companies have a variety of systems that are not interoperable, and they manage their master data with a blend of paper and electronic systems, so they need to focus on the quality of that data” [Ref. 2]. Right now, all Class 3 devices, which contain high-severity hazards, are required to have a UDI. All life-supporting devices, life-sustaining devices and implantable devices are required to have a

UDI by September 2016. All other devices must have a UDI by September 2018. Many countries and governments — including Australia, the European Union, Brazil and Japan — are planning to introduce their own systems. It is unknown at this time as to how difficult integration of various systems will be.

Implementation Process

There are three distinct steps to the UDI development process and adoption [Ref. 3]. First, we must develop a standardized system to create unique device identifiers. Here, the key player is the FDA, which accredits the issuing agencies. When the agencies have met the requirements set forth in the regulations, the agencies that issue UDIs according to the International Standard ISO15459 must ensure uniqueness of the code. The labeler is the party that applies the label to the device, or replaces or modifies the label with the intent to commercially distribute the device without any subsequent replacement or modification of the label. In most cases, the labeler will be the device manufacturer. However, a labeler is not a distributor. A distributor merely adds its name and contact information as the distributor of the device.

The second step is to place the UDI in two formats: *human readable*, plain text as is stated in the regulation, and *machine readable*, using the automated identification and data capture (AIDC) system on the label and packaging. There are some exceptions: Class I devices (very low severity) do not require UDI labeling until September 2018. One-time use devices do not require UDI on the device itself; a carton containing several devices, however, does require a UDI label. Products solely designed for export do not currently require a UDI.

The last step in establishing the UDI System is creating, maintaining and using the global UDI database, the GUDID. Here, key players are the FDA, which creates

and maintains the GUDID, the labelers who enter data into the GUDID and the public, including hospitals and other clinical users who access and use the data in the GUDID.

The GUDID is a secure Web interface. Access is by account, so submission of device information is done via data entry, one record at a time, by labelers. Accounts are established, along with log-ins. Users then log in and submit the information in a secure fashion. There is also a search and retrieval of device information function for public users. For search and retrieval, there is no need to have an account. Anybody can pull these records from the system.

There is also another data submission option: the HL7 SPL option. HL7, which stands for “Health

Level Seven,” is a standards organization that works on messaging standards in health care. The idea is to enable standard formats to send and receive health care information. “SPL” stands for “structured product labeling,” and is a standard way to receive labeling information.

More information about UDI and its uses is available from the following sources:

- FDA UDI Help Desk (Web portal for questions): www.fda.gov/udi
- FDA Webinar: GUDID HP7 SPL Submission Option Overview: <http://www.fda.gov/downloads/Training/CDRHLearn/UCM430216.pdf>
- FDA Helpline: (888) 463 6322
- UDI Issuing Agencies: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/default.htm>
- Enhancements and Fixes to GUDID: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDI-DatabaseGUDID/ucm393134.htm> ●

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References

1. PTC, Inc. “UDI: Complexities of Compliance,” http://www.ptc.com/File%20Library/Topics/Unique%20Device%20Identification/The_Regulatory_Reality_PTC_UDI_ebook.pdf, accessed September 6, 2015.
2. Allen, Daphne. “UDI Implementation Challenges Often Pertain to Data,” *Pharmaceutical and Medical Packaging News*, <http://www.pmpnews.com/news/udi-implementation-challenges-often-pertain-data-says-gs1-us-150416>, published April 16, 2015.
3. Howell, Heather (moderator). “Intro to UDI and GUDID Overview – Transcript,” U.S. Food and Drug Administration presentation. <http://www.fda.gov/training/cdrhlearn/ucm379674.htm>, December 18, 2013.