U.S. FDA to establish unique identification system for medical devices

ABSTRACT

On September 27, 2007, the president signed into law the Food and Drug Administration (FDA) Amendments Act of 2007. This act includes language related to the establishment of a Unique Device Identification (UDI) System (section 226). This new system when implemented will require:

- The label of a device to bear a unique identifier, unless an alternative location is specified by FDA or unless an exception is made for a particular device or group of devices.
- The unique identifier to be able to identify the device through distribution and use.
- The unique identifier to include the lot or serial number if specified by FDA.

If used by all healthcare stakeholders, UDI can improve visibility of device movement, recalls, post-market surveillance, adverse-event reporting, and anti-counterfeiting, among other benefits. A properly implemented UDI will also facilitate the integration of medical device data across disparate IT systems, including those that support the supply chain, clinical and reimbursement functions.

By **Jay Crowley**

Introduction

Over the last few years, the U.S. healthcare industry has rallied around establishing a unique device identification (UDI) system that will provide a platform for communicating accurate, reliable information about medical devices to stakeholders who need information about the device. A UDI system will enable many benefits, including faster and easier recalls, improved traceability, more effective counterfeit detection and abatement, increased accuracy in electronic transactions and information sharing, reduced costs and, most importantly in the healthcare industry, improved patient safety. For patient safety reasons, the U.S. Food and Drug Administration (FDA) is not only interested in developing a UDI system in the U.S., but would like to see the adoption of such a system globally for the healthcare industry.

Challenges in medical device identification

The U.S. medical device industry is diverse, and devices vary dramatically in size, complexity, packaging and use. Medical devices cover a wide range of products – everything from complex imaging systems, implants, hospital equipment and supplies, clinical lab products, dental care, home care and over the counter devices. Some items are packaged individually, others in boxes, and some are not "packaged" at all. They may be implanted in patients, used once and thrown away, used and reprocessed, or used for many years until next generation models are launched.

Sharing information about a device is inherently complex. From the time a device is manufactured to the time it is used in patient care, information about the device is passed up and down the healthcare supply chain many times with all of the distributors, group purchasing organizations, hospitals and users in between. The lack of data standardization adds further complexities to these interactions, as the information shared is oftentimes inaccurate, duplicative, out of date or confusing.

Today, hospitals and their suppliers use thousands of different numbers to electronically track devices. The U.S. Healthcare information systems are filled with inaccurate and manually created item and company names, and self-created numbering systems that differ from user-to-user and vendor-to-vendor, creating an environment for data exchange that is fraught with errors and inconsistencies which creates both inefficiencies throughout the supply chain and potential impact on patient safety.

Lack of consistent device identifiers in healthcare has been a long-standing problem, yet is one that can be solved with the industry-wide adoption of consistent global identification standards across the industry and the implementation of systems to provide accurate data throughout the healthcare system. After many years of research and industry input, hospitals, distributors, manufacturers and other key stakeholders are now coming together to collaborate on the use of data standards to improve patient safety.

The solution: Critical visibility through UDI

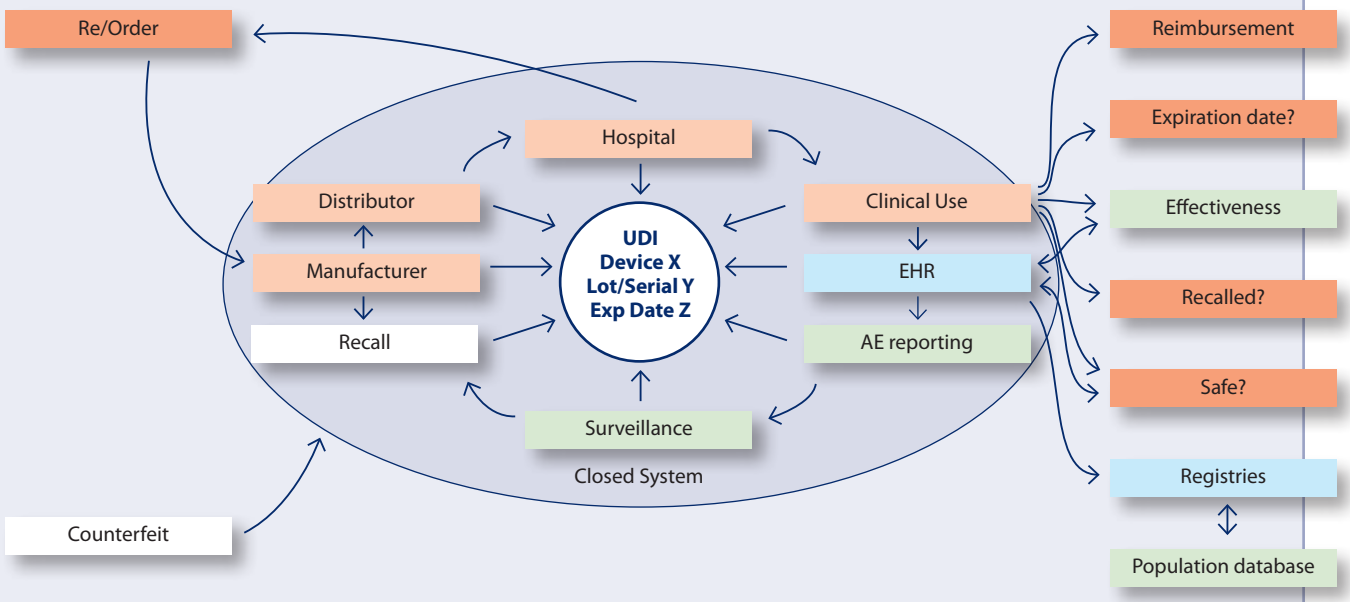
The FDA's Sentinel Initiative is intended to strengthen FDA's ability to query data systems for relevant device information after a device is on the market. In today's environment, with no UDI system in place, there are many challenges in doing so. UDI will vastly improve our understanding of medical device use, post-market surveillance, and adverse event reporting. UDI will facilitate the ability to identify and locate medical devices, whether physically in route to a hospital or recorded in a patient's EHR, or in hospital information systems.

Inaccurate and inconsistent data about medical devices plague the healthcare system today, with potential serious consequences. For example, in 2007, the FDA received more than 100,000 reports of adverse events associated with medical/surgical devices: 15% of the reports lacked model or catalog numbers, 50% of the reports lacked lot numbers or other production identifiers, and more than 10% lacked needed information in both categories. Because there is no consistent, systematic way to gather information about these devices, the FDA receives information that varies widely from one reporter to the next. With a UDI system in place, the reporting of adverse events would be more seamless, with more complete information, so that the FDA can strengthen its ability to monitor the safety and effectiveness of device use and adverse events and take action when needed.

Also in 2007, manufacturers issued more than 1,000 recalls. A single recall can represent thousands to hundreds-of-thousands of individual items, ranging from disposable devices to testing strips to implantable devices. In a recall situation, limited information causes delays in identifying and removing recalled items from the shelf. The problem is further compounded if the device is an implantable, as tracing it to the patient can be extremely difficult and time-consuming. As shown in Figure 1 *Future Information Cycle* with UDI in place, the use of UDI will allow improvements in the ability to identify medical devices.

Once a device is on the market, the FDA uses post-market surveillance tools to monitor patient safety and quality related to the use of the medical device. The UDI will also help improve the ability to find medical devices, wherever that item may be – an important ability when considering recalls, for example. Consistent, accurate information about medical devices communicated in a language all players can understand has an important role in improving patient safety. In addition, it is important that the implemented UDI system will address needs beyond the U.S., serving as a basis for accurate and sharable information globally.

Figure1: **Future Information Lifecycle**



Advantages of UDI

UDI Can Improve... Visibility

- Medical device recalls
- Adverse event reporting and postmarket surveillance
- Tracking and tracing, supply chain security; and anticounterfeiting/diversion
- Comparative effectiveness (e.g. registries)
- Disaster/terror preparation and shortages/substitutions
- Reduce medical errors
- Documenting medical device use in patient's EHR/PHR, hospital information systems, claims data
- Sentinel Initiative – strengthening FDA's ability to query data systems for relevant device information

The long road to UDI

In 1999, the Institute of Medicine published a study that revealed as many as 98,000 people die each year as a result of medical errors1. Automation of many of the key processes involved in patient care delivery could help prevent many of the mistakes that happen in the hospital setting. As such, the FDA issued its Pharmaceutical Bar Code Rule in 2004, which applies to certain human drugs and biological products and requires that a linear bar code containing the National Drug Code (NDC) number be placed on these product labels. The Bar Code Rule helps facilitate systems to ensure the "five rights " of medication delivery by enabling healthcare professionals to check whether they are giving the right drug via the right dose and right route of administration to the right patient at the right time.

Realizing that the same potential for error exists when using medical devices, in 2005 the FDA began to look at the possibilities for bar code standards for medical devices. The FDA issued calls for comments, held workshops and public meetings. The FDA Amendments Act of 2007 includes language requiring the FDA to establish a UDI system (section 226). This new system requires:

- The label of a device to bear a unique identifier, unless an alternative location is specified by FDA or unless an exception is made for a particular device or group of devices.
- The unique identifier to be able to identify the device through distribution and use.
- The unique identifier to include the lot or serial number if specified by FDA.

The FDA is interested in adopting global standards in an unambiguous way, with an understanding that the promised benefits of UDI can only be realized if used by all stakeholders.

1 To Err Is Human: Building a Safer Health System. Institute of Medicine (1999). The National Academies Press.

In 2008, the Global Harmonization Task Force (GHTF), an international partnership between regulatory authorities and industry, established an ad-hoc unique device identification working group to facilitate a global approach to UDI.

Creating an "implementable" UDI system

Only a few people will actually physically touch a medical device, but many more constituents will need to know information about that item, including patients, clinicians and researchers.

The FDA would like to create a UDI system that is:

- Consistent
- Unambiguous (differentiates among all dimensions)
- Standardized
- Unique at all levels of packaging
- Harmonized internationally

The FDA sees the establishment of a UDI system taking place in four distinct steps:

- Create a standardized UDI, it must use globally accepted standards for device identification.
- Require the UDI to be placed in human readable and/or AutoID format, directly on the device, its label, or both. It is important to remain technology neutral in this area and will not establish a rule defining which data carrier (i.e. linear bar code, 2D data matrix bar code) to use.
- Create and maintain a UDI Database that facilitates the storage, exchange, and integration of data and systems.
- Drive adoption and implementation. The entire industry must work together to make UDI work.

The UDI System: Making useful information available

Establishing a UDI System

Combination of 4 distinct steps:

1 Develop a standardized system to develop the unique identifiers (UDI)
2 Place the UDI in human redable and/or Auto ID on a device, its label, or both
3 Create and maintain the UDI Database
4 Adoption and Implementation

In order to implement a UDI system, we need to be able to make information about medical devices available to people who need it. The UDI code will include product "static" information (device identifier) and may also include "dynamic" information (production identifiers). The static part of the UDI code identifies the specific device. A significant change to any of the device characteristics would require that a new UDI code be allocated to the device. The dynamic part of the UDI code identifies production information about a particular device (i.e. the lot number, serial number or expiration date).

The UDI code is developed and maintained by the manufacturer. It should be both human readable and encoded in a form of automatic identification technology (such as a bar code). Some devices may have direct part marking (DPM), such as implants and those that require reprocessing, cleaning, or sterilization between patients' use.

A UDI Database (UDID) will contain certain identifying attributes for each device. It will not include dynamic information, pricing or other manufacturer-proprietary information. Recently, the GHTF released a call for comments for guidelines for the development of a global UDI system including attributes that might be included in a global UDI database[2] (See Figure 2).

2 GHTF Discussion Paper (in view of preparation of a draft guidance on) UDI for Medical Devices: Unique Device Identification (UDI) System, GHTF, 2009

Figure 2: **GHTF's recommendations for "core identification attributes" are[3]:**

- Unique Device Identification Code
  – This is the static part (device identifier) of UDI code.
- Manufacturer Name
- Manufacturer Contact Information
  – Address, including Country Name and Contact Point information.
- Nomenclature
  – Global Nomenclature code (e.g. GMDN).
- Device Name (generic name)
- Trade Name (brand name)
- Device model number (or reference number)
- Controlled by serial and/or lot/batch number and/or manufacturing and/or expiration date - check box [ ]
- Quantity and Packaging level
  – E.g. Box of ten items, kit of 100 tests
- Size including units of measures (volume / …)
  – Device size when it is needed clinically, (e.g. 8F catheter).
- Storage conditions (as labeled on the product and/or the IFU) (e.g. needs to be refrigerated)
- Labeled as single use – check box [ ]
- Sterility
  – Package Sterile – Yes/No
  – If Yes: Sustainability of the sterile package ()
- Need to be sterilized before use – Yes/No
- Restricted number of use (number)
  – Only if the device's label indicates a limited number of use.
- Labeled and /or IFU (Instructions for Use) as containing allergens/materials of concern – Yes/No
  – If YES
  – Indicate the name of the allergens/materials of concern (e.g. Latex) (limited list to be defined and managed by the GHTF)
- Regional authorised representatives as labelled (list of countries)
  – Information about the regional representatives information such as the address or telephone number, when applicable.
- URL for additional information – Web address
- Special Instruction for use – If it is necessary to inform to the user about special indication for the device, such as: "Contraindications", "Intended Use or Part of Use," etc.

3 Draft attributes as of March 31, 2010.

The FDA recently completed a pilot test of a prototype UDID. The goal of the pilot was to assess the feasibility of collecting, storing and retrieving UDI data from device creation (manufacturer) to point of use (hospital). Hospitals viewed the concepts for the UDID favorably, as the UDID prototype provided the data hospitals regularly need. Some manufacturers experienced difficulties during the pilot and are currently working through challenges they experienced in the pilot with data definitions, the ability to obtain data from various sources and working with the data formats for the UDI upload.

Looking to the future: The time is right – now!

Looking down the road, a fully actualized UDI system will provide the foundation for improved patient safety, as it will enable more efficient and effective device recalls, improved post-market surveillance, better adverse event reporting, and better device identification in registries. UDI will give us the ability to document specific device use in patients and to track devices in patient's electronic health records. The FDA will be able to conduct better population-based results from device usage. The safety benefits of a UDI system however can only be realized if the UDI is captured, stored, integrated and exchanged by ALL stakeholders.

In addition, UDI will facilitate better information sharing, as data will be integrated across disparate systems. With this integration comes insight and visibility to assess the effectiveness of devices in certain patient populations or in particular environments. This is especially important when investigating ways to reduce medical errors.

Exposure to the allergen latex is a significant concern in the healthcare setting. The UDI database will help to identify which devices contain latex and, as such, will help prevent exposure to latex in the future. UDI will help the healthcare community understand and determine the role medical devices play in medical errors across patient populations.

After many years of industry mobilization around establishing a UDI in the U.S., the time is right for a UDI system. An increased focus on the benefits of information technology in healthcare (the U.S. government's investing more than $19 billion to improve IT infrastructure in the U.S. healthcare system) and greater attention to reducing medical errors are adding to the urgency. The FDA's vision is a UDI system that is integrated and harmonized with global efforts to ensure patient safety benefits are realized worldwide.

The Global Harmonization Task Force (GHTF)

The Global Harmonization Task Force was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems. This is being done with two aims in mind: enhancing patient safety and increasing access to safe, effective and clinically beneficial medical technologies around the world.

A partnership between regulatory authorities and regulated industry, the GHTF is comprised of five Founding Members: European Union, United States, Canada, Australia and Japan. The chairmanship is rotated among the Founding Members and presently resides with Canada. For more information, go to www.ghtf.org

ABOUT THE AUTHOR

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Jay Crowley is Senior Advisor for Patient Safety in FDA's Center for Devices and Radiological Health. Jay is interested in developing new methods and techniques to identify, analyze, and understand problems occurring from medical device use within the healthcare environment. He has been working at FDA for nearly 20 years in a variety of positions. Jay holds degrees in Risk Analysis and Engineering.