White Paper

The value of unique device identification across healthcare

By Natalia Wilson, MD, MPH

Executive summary

The Unique Device Identification (UDI) System Proposed Rule was published by the U.S. Food and Drug Administration (FDA) on July 10, 2012. The UDI rule sets the foundation for use of UDI across healthcare and establishes a common language for medical devices. The potential benefits of UDI are many, including greater accuracy and efficiency in the procurement process, improved charge capture, a standard for device documentation in clinical care and post-market surveillance, enhancement of post-market surveillance activities, greater efficiency and comprehensiveness in recalls, and the ability to track a device across its lifecycle. Achieving the full value of UDI across healthcare will require implementation and adoption of UDI in multiple areas, including supply chain, clinical care, and post-market surveillance, as well as integration between these areas. Research, key constituent involvement, and education efforts are ongoing to address implementation and adoption of UDI across the healthcare industry.

Table of Contents

Historical and regulatory background

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of drugs, biological products, medical devices, food, cosmetics, and radioactive products.[1] In 1999, the landmark Institute of Medicine (IOM) report To Err is Human: Building A Safer Health System stated that between 44,000 and 98,000 patients die in US hospitals each year due to preventable medical errors.[2]

In 2004, the FDA released the Pharmaceutical Barcode Rule, addressing medication error, one type of preventable medical error. The Pharmaceutical Barcode Rule requires drug and biological products to have linear bar codes on their labels containing the drug's National Drug Code (NDC). The rule was intended to encourage adoption and use of information systems to support the reduction of medication error in patient care settings.[3] At the time, the FDA entertained the thought of a similar rule for medical devices, but the lack of a unique identifier for devices precluded further action.

Fast forward to the FDA Amendments Act of 2007, which directed the FDA to create a unique device identification system for medical devices.

1 U.S. Food and Drug Administration. About FDA. http://www.fda.gov/aboutfda/whatwedo/
2 IOM (Institute of Medicine). 2000. To Err is Human: Building a Safer Health System. Washington, DC: National Academy Press.
3 Bar Code Label Requirements for Human Drug Products and Biological Products; Final Rule. Federal Register;69(38):9120-71.

"Secretary shall promulgate regulations establishing a unique device identification system for medical devices requiring the label of devices to bear a unique identifier, unless the Secretary requires an alternative placement or provides an exception for a particular device or type of device. The unique identifier shall adequately identify the device through distribution and use, and may include information on the lot or serial number."[4]

The UDI Proposed Rule underwent a period of public comment until November 7, 2012. The FDA Safety and Innovation Act, signed into law by President Obama on July 9, 2012, included language focused on UDI. This language specified release of the proposed UDI rule no later than December 31, 2012 and finalization of the rule no later than six months after the close of the comment period. It also stated that manufacturers of implantable devices would be required to implement the rule no later than two years after the final rule was released.[5]

On November 19, 2012, the FDA released an amendment to the UDI proposed rule in response to provisions within the FDA Safety and Innovation Act. Specifically addressed is the timeline for implementation of UDI for implantable devices.[6]

The UDI proposed rule

As stated in the proposed rule, UDI is required on the packaging and labels of medical devices. For Class II and III devices, UDI must include a device identifier: manufacturer and model, and a production identifier: lot number, serial number, expiration date and/or date of manufacturer. The production identifier is exempt for Class I devices. UDI is required in plain text form and through Automatic ID and Capture Technology (AIDC). Additionally, submission of data elements to the FDA's Global Unique Device Identification Database (GUDID) is required at the same time as the UDI labeling requirement.

Per the proposed rule, UDI must be issued by an FDA-accredited issuing agency. Direct part marking will be required on implantable devices, devices intended for greater than one use with sterilization in-between, and standalone software. There are a number of exceptions to the rule that include over-the-counter devices, single-use Class I devices distributed in a package, devices intended for export, and production identifiers on Class I devices.

The timeline for proposed UDI implementation follows a phased in approach. For Class III devices, UDI will be required one year after the final rule is released; for Class II, three years after the final rule is released; and for Class I, five years after the final rule is released. Per the FDA Safety and Innovation Act, all implantable devices must have UDI two years after release of the final rule. For those devices requiring direct part marking, this will be required two years after the proposed UDI rule labeling timeline. The final rule is expected in May 2013.

4 U.S. Food and Drug Administration, regulatory information, http://www.fda.gov/regulatoryinformation/legislation/federalfood-drugandcosmeticactfdcact/significantamendmentstothefdcact/foodanddrugadministrationamendmentsactof2007/.
5 U.S. Food and Drug Administration, medical devices, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ucm310927.htm.
6. Federal Register. Unique Device Identification System Proposed Rule. https://www.federalregister.gov/articles/2012/11/19/2012-28015/unique-device-identification-system

The proposed UDI rule contains much additional detail including required data elements for submission to the GUDID, other exceptions to the rule, detail on combination products and convenience kits, and economic data including costs and benefits. This is best ascertained by reviewing the proposed rule in the Federal Register.[7] The final UDI rule will reflect the FDA response to comments received during the public comment period, as well as changes based on the FDA Safety and Innovation Act, per above.

UDI across healthcare

UDI has potential value in multiple areas, including supply chain management, clinical care, and post-market surveillance. The value is not only specific to these individual areas, but also gained through integration between these areas.

Characteristic of most hospital supply chains is a level of inefficiency and error in the procurement process and recall management. Additionally, there generally exists a lack of optimal integration between the internal and external supply chain and between supply chain and clinical care in hospital systems. UDI supported by information technology (IT) has great potential to increase accuracy in procurement, enhance transparency, lead to cleaner data, reduce inefficiency and rework, and lead to cost savings in supply chain management. Ongoing work has started to outline more detailed outcomes from the use of UDI in hospital supply chains. These include reduction in days payable outstanding, reduction in discrepancies, fewer calls to customer services, and better charge compliance.[8]

In addition to these discussed benefits, developing the needed processes within a supply chain for use of UDI is supportive of use of UDI across a hospital system. In order for a device to be scanned at the point of care, an accurate database and IT integration must exist. The supply chain item master is an ideal database. Integration between supply chain and clinical IT systems using UDI provides the ability to capture enhanced real-time data on utilization, clinical outcomes, and cost.

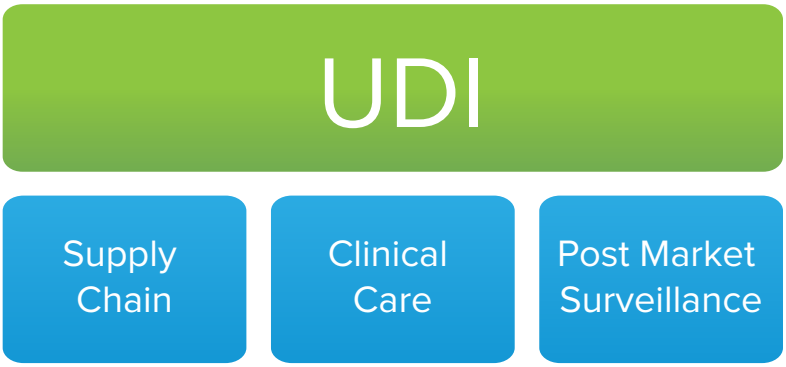
UDI in clinical care has importance for facilitation of device use at the point of care, providing a standard for documentation of devices used in a patient and a standard to facilitate recalls for devices used in a patient. Similar to use of electronic medication administration record (e-MAR), scanning a device UDI prior to use and a patient's wristband barcode could provide important information on a patient allergy, a recalled device, or other incompatibility prior to use of the device in a patient. Scanning a device UDI at the point of care after the device has been used in a patient and flow of this information to the electronic health record (EHR) would provide a standard for documentation. Maintaining device information in the EHR clearly links the device and patient. In the case of a recall, the EHR system could be queried using the UDI, producing a list of affected patients.

7 regulations.gov. Unique Device Identification System. http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0090-0001
8 PR Newswire. Mercy/ROi and BD Collaborate to Improve Quality of Care and Reduce Costs. http://www.prnewswire.com/news-releases/mercyroi-and-bd-collaborate-to-improve-quality-of-care-and-reduce-costs-137718398.html

Post-market surveillance includes important activities to monitor devices once in the market and used on many patients. This includes adverse event reporting, clinical registries, post-market studies, comparative effectiveness research, etc. Currently there are limitations in device post-market surveillance that could be much improved with the use of UDI. UDI as the standard in adverse event reports would improve clarity and completeness of needed information. UDI as the standard in clinical registries and research data sets could facilitate the creation of larger data sets for analysis and research. UDI in EHR would allow for more robust use of device data for post-market surveillance activities. UDI as standard practice would also facilitate the linking of device databases at the FDA.

Ongoing work funded by the FDA's Medical Device Epidemiology Network (MDEpiNet) includes a Brookings Institution workgroup addressing UDI use cases, challenges to implementation, and education on UDI via expert workshops and webinars.[9] Research is also ongoing utilizing UDI for cardiac stents in the cardiac catheterization laboratory and developing an extended dataset of device attributes for orthopedic surgery.[10, 11] Additional research is assessing current processes for device documentation and identification and surgeon perception of the best method to clearly identify implants in orthopedic surgery.[12]

The implementation and adoption of UDI in the supply chain, clinical care, and post-market surveillance brings specific benefit to these areas and also enhanced value through integration. The supply chain supports clinical use; clinical use provides data for post-market surveillance; post-market surveillance provides information to inform clinical care and the supply chain.



9 Brookings Institution UDI Implementation Work Group http://www.brookings.edu/research/topics/health-it
10 FDA, medical devices, MD Epidemiology Network Initiative (MDEpiNet), http://www.fda.gov/MedicalDevices/ScienceandResearch/EpidemiologyMedicalDevices/MedicalDeviceEpidemiologyNetworkMDEpiNet/default.htm.
11 Brookings Institution, Developing the Capabilities for Device Surveillance through the Medical Device Epidemiology Network, http://www.brookings.edu/events/2012/04/09-device-surveillance-mdepinet.
12 AAHKS 22nd Annual Meeting. Poster Presentations, www.aahks.org/meetings/Posterlist.pdf.

Moving forward with UDI

- Gain and share knowledge about UDI and its value.
- Think through the clinical and business use cases for UDI.
- Communicate internally and externally to your organization.
- Talk to your software vendors.
- Create a process to maintain a comprehensive and accurate Item Master.
- Collect data on areas of inefficiency and rework.
- Evaluate barcode scanning technology to be able to scan UDI.
- Evaluate IT system capability to store UDI.
- Develop the vision for needed IT connectivity.
- Present to the leadership within your organization.
- Move forward.

Author bio

Natalia Wilson, MD, MPH is co-director of the Health Sector Supply Chain Research Consortium (HSRC-ASU) in the WP Carey School of Business at Arizona State University. She is a physician researcher with clinical experience as a partner in a community-based private internal medicine practice where she focused on preventive medicine and women's health. Focuses of her current work and research include unique device identification, physician engagement in the supply chain, collaborative relationships in healthcare, and healthcare reform. To learn more about HSRC-ASU, visit: http://wpcarey.asu.edu/hsrc-asu/

641 Avenue of the Americas
New York, NY 10011
800-260-2640
infor.com

HEALTH SECTOR SUPPLY CHAIN RESEARCH CONSORTIUM

ASU W. P. CAREY SCHOOL of BUSINESS
ARIZONA STATE UNIVERSITY

About Infor

Infor is the world's third-largest supplier of enterprise applications and services, helping more than 70,000 large and mid-size companies improve operations and drive growth across numerous industry sectors. To learn more about Infor, please visit www.infor.com.

Disclaimer

This document reflects the direction Infor may take with regard to the specific product(s) described in this document, all of which is subject to change by Infor in its sole discretion, with or without notice to you. This document is not a commitment to you in any way and you should not rely on this document or any of its content in making any decision. Infor is not committing to develop or deliver any specified enhancement, upgrade, product or functionality, even if such is described in this document.

INFDTP1293110-EN-US-1212-1