Medical Product Safety Network (MedSun) Final Survey Report
Topic: Hospitals' Adoption of Medical Device Unique Device Identification (UDI)
Year Conducted: 2015

Introduction

Over the last several years, Informatics specialists from FDA's Center for Devices and Radiological Health have been working with medical device manufacturers and other stakeholders on plans to have Unique Device Identification (UDI) available for medical devices in machine-readable form. They have also been developing the FDA's searchable Global Unique Device Identification Database (known as GUDID). When fully implemented, UDI will provide many benefits to industry, FDA, consumers, health care providers and health care systems by making it easier to identify and resolve medical device problems, among many other things.

As part of these efforts, FDA UDI specialists wanted to gauge the extent to which hospital staff responsible for operations related to medical device supply chain and materials management operations are aware of UDI implementation and/or published information about its benefits. They also wanted to know whether hospitals are actively planning to make use of UDI in their operations. To help learn more about these issues, the UDI team requested a survey of hospitals that participate in FDA's Medical Product Safety Network.

Methodology

A small sample of hospitals, most of which participate in FDA's Medical Product Safety Network (MedSun), was identified for the survey recruitment based on factors such as location, bedsize, and, in some cases, FDA staff's knowledge of their activities related to UDI (such as UDI-related conference participation during the previous year). After sites were recruited, FDA staff from the MedSun Survey team and FDA leaders in UDI activities had the opportunity to hear from staff from 6 healthcare organizations located in 6 areas of the continental US about their knowledge of and preparations for adopting UDI for ongoing use with various hospital activities.
The sites included two healthcare systems, one university-based hospital, two pediatric hospitals, and one not-for-profit hospital that was part of a large healthcare system. All of the hospitals had at least 200 beds, and most of them also had outpatient services such as clinics or outpatient diagnostic services associated with their organizations.

The respondents included biomedical or clinical engineers, applications/IT managers, directors of supply chain operations, procurement directors, and materials managers with lead roles in their hospitals' operations. Generally there were two primary respondents per site (e.g., the Director of Biomedical Engineering and either the Director of Supply Chain Operations or the Director of Materials Management).

Overview of Responses

The following sections describe the responses to this survey.

Knowledge About FDA's and Other Organizations' Implementation of UDI:

One hospital system's respondents were very well informed about the implementation of UDI, and they had been actively working on UDI adoption with their system's leadership and staff. They also were collaborating with others outside their organization, such as supply chain specialists in other healthcare systems known for their leadership in UDI adoption.

The respondents from the other sites expressed some knowledge of UDI gained from one or more sources, such as review of the FDA website, attendance at the Pew Charitable Trust conference held in December 2014, information they had received from an organization that has been certified by FDA to assign unique device identifiers, and/or review of information they received from the Association for Healthcare Resource and Materials Managers

(AHRMM). The pediatric hospitals mentioned the communications about UDI (specifically GTINs) from supply chain leaders in the Children's Hospital Association. Although all of these respondents had heard of UDI efforts related to medical devices, many indicated that they did not feel confident about their knowledge about all of the specific uses of UDI.

Knowledge About the Benefits of UDI for Hospitals:

One healthcare system's respondents were very knowledgeable about the documented advantages of UDI for hospitals. Two sites' respondents indicated that they were somewhat aware of the documented advantages; however they were not convinced at this time about the cost-savings or other benefits of UDI for supply chain operations.

Most of the hospital staff mentioned that they saw definite advantages of UDI adoption for recalls management purposes. Several respondents indicated that they thought that many of advantages of UDI for hospitals would take "many years" to be realized. Despite doubts two respondents expressed about some of the cost-saving advantages discussed in the advance materials provided before the interviews, all of the respondents indicated that they fully supported the development of UDI for medical devices and thought it would be important to their hospitals in future years.

Generally the respondents indicated that they thought that it would be helpful to hospitals' use of UDI for FDA staff (or others knowledgeable about UDI's advantages for hospitals) to encourage vendors of certain commonly used products to routinely include UDI fields for medical devices and related capabilities in their products. The types of products mentioned included:

- EHR (Electronic Healthcare Record) products (such as those offered by EPIC, Cerner and others),
- CMMS (Computerized Maintenance Management System) products, and
- ERP (Enterprise Resource Planning) products.

In this way, FDA and product vendors would be helping to lay the groundwork for hospitals to routinely include UDI when staff used these types of products. This would allow hospitals to be in a position to obtain the associated benefits without the expenses (in vendor charges and hospital staff time) of customizing these software products to accommodate UDI.

Hospitals Plans to Use UDI:

Currently most of the sites in the survey did not have feasibility studies or pilot programs in place concerning UDI adoption, often due to competing priorities for their time and attention as well as hospital resource constraints. However, one of the sites, a healthcare system, has been working very actively on plans to use UDI in their operations. This site, a healthcare system, has made great strides in this effort, and has developed several documents that they offered to share publicly for use by interested hospitals throughout the country. FDA UDI specialists plan to follow up on this offer in the coming weeks.

Another site, also a healthcare system, indicated that they had made progress in their use of GTIN identifiers, and that they insist that the manufacturers that provide them with products include the GTIN at the time of delivery or else the products are returned to the manufacturer. They have integration activities in place to link their ERP, Chargemaster, and Electronic Health Records systems.

A pediatric hospital indicated that they have had some success with the use of GTIN identifiers provided by their suppliers and that they will be involved in educating staff about the use of GTINs for a variety of processes in the coming months.

Current Use of Electronic Health Records and Methods to Record Medical Device Implant Information:

All of the hospitals in the survey had an Electronic Health Record. Generally the respondents indicated that a record was kept about patients' implanted medical devices, generally in a surgical record (which in some cases was

linked or otherwise transferred to the patient's electronic health record). Some hospitals kept medical device implant information in paper form for their records as well as in an electronic format. Specific identifiers such as Brand Name, Manufacturer, Catalog Number, were generally kept. Several respondents indicated that the information about patient implants was keyed into the surgical record, while others used a system for scanning the product information into the record.

Other Comments:

The respondents offered specific suggestions for organizations that FDA staff should contact to encourage their assistance with FDA's efforts to encourage UDI adoption. FDA staff will talk with representatives from several of these organizations in the coming weeks.

All of the respondents included in the survey indicated their willingness to be contacted again by FDA staff about their activities related to UDI adoption in the coming months as their plans become more definite; many of these sites may be candidates for partnering with FDA to track the benefits of UDI adoption.

There was some confusion expressed about which versions of certain software products include UDI. It may be useful, if possible, if FDA or relevant professional associations would routinely provide information for hospitals about the specific versions of the products that currently include UDI for their EHR, CMMS, ERP or other relevant software products.

Summary

All of the respondents that we spoke with indicated that they were supportive of UDI and thought that it will be very helpful to healthcare organizations like theirs in the future. They often mentioned the advantages for recalls management.

Some respondents indicated that they thought it would take several years before the benefits of UDI could be realized for their hospitals. Very few of the hospital representatives that we spoke with indicated that they were actively working on feasibility studies or other preparations to take full advantage of UDI. One hospital system's supply chain specialists indicated that they are dedicating substantial resources to adoption of UDI, and they provided a number of documents that have been developed for that purpose.

Most of the respondents indicated that they thought it would be very helpful if the various resources that they use (such as ERP systems, Electronic Health Records, CMMS systems) included UDI. They encouraged FDA to communicate with specific associations and relevant software vendors to encourage them to help move UDI adoption forward for use in the healthcare community.

The respondents to this survey provided very useful information for FDA's research into UDI adoption. The survey demonstrated the wide variations in knowledge about and planning for the UDI advances that are currently in process (e.g., the UDI requirements this year pertaining to implantable, life-supporting and life-sustaining devices and other requirements scheduled over the next few years).

The survey provides information that will lead to additional FDA communication about the advantages of UDI adoption with leaders from a variety of associations such as state biomedical engineering associations, supply chain-related associations and associations of particular types of hospitals, as well as with leaders from additional hospitals and healthcare systems.

Survey Limitations

Although the findings add to FDA's knowledge of hospitals' current and planned adoption of UDI, there are several limitations to the survey methodology. These include the small convenience sample of respondents. In view of these limitations, the respondents' perspectives may not represent the perspectives of all device users.

Therefore, these findings represent only one piece of information. No conclusions can be made based on this report alone. Instead, the report should be considered along with other information that may include adverse event reports, scientific publications, clinical trials, enforcement/compliance information, and other data sources that are part of FDA's monitoring of device performance.

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Surveying device users is one of many tools the FDA uses to evaluate the public health impact of potential problems associated with the use of medical devices. Typically, small sample surveys are used to collect qualitative information on post-market experiences of clinicians or facilities with medical device performance or use. The FDA selects survey respondents based on their experience with the topic or device, their availability, and their willingness to participate.

The FDA makes our scientific, medical, nursing, and engineering staff aware of the survey results as needed. If the FDA believes there is a significant risk of adverse events as noted from the survey, we will combine those results with data gained from other sources. The FDA will work with the manufacturers and health care provider organizations to make important information known to the clinical community. Additionally, the FDA continues to work with manufacturers to ensure the development, testing, and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, the FDA may convene a group of clinical, scientific, and regulatory experts to discuss any necessary action.