Unique Device Identifier (UDI) Impacts on Recall Management Executive Summary

EXECUTIVE SUMMARY:

The vision of having one consistent unique identifier assigned to a specific manufacturer and medical device model/version combination, allowing the device to be tracked from the point of creation through its journey across the supply chain and into a patient's health record, was what drove the creation of the Unique Device Identifier (UDI) regulation. The UDI was designed to have two components; the Device Identifier (UDI-DI) a mandatory, fixed portion of the UDI that identifies the labeler and the specific version or model of the device, and the Production Identifier (UDI-PI). The UDI-PI a conditional, variable portion of the UDI, identifies one or more of the following when included on the label of the device: lot or batch number, serial number, expiration date, manufactured date or distinct identification code as required for human cell, tissue, or cellular and tissue-based products.

The UDI was expected to improve patient and device safety by enhancing key patient safety systems like the product recall and adverse event reporting processes and improve device evaluation through research and real-world evidence to determine the clinical effectiveness of specific devices within defined patient populations. Additionally, the UDI would streamline and improve the efficiency of the health care supply chain by requiring manufacturers to submit the data associated with the UDI-DI to the Global UDI Data Base (GUDID) and make this information available to all stakeholders at no cost through AccessGUDID.

AHRMM's Learning UDI Community's (AHRMM LUC's) UDI Impacts on Recall Management work group was formed to support this vision by expanding and optimizing the use of the UDI throughout the recall process. Its mission included defining the benefits and barriers to health care stakeholders (manufacturers, distributors, providers, patients, etc.) of using the UDI throughout the recall process and developing recommended practices to increase its utilization.

Over 70 individuals representing Distributors, Food and Drug Administration Center for Devices and Radiological Health (FDA CDRH), Group Purchasing Organizations (GPOs), Health Care Consultants, Health Care Providers, Manufacturers, Recall Management Organizations, Software Application Providers, Standards Organizations and Trade Associations participated in various aspects of the work group's efforts. In addition to their own expertise and the experiences of the companies they represented, members conducted surveys and interviews to gain additional insights and develop recommended practices.

An analysis of each stakeholder's current situation and the benefits and barriers to including the UDI throughout the recall process resulted in the following key findings:

- The current recall process is manual, and paper/PDF-based. In some limited situations, manufacturers are submitting structured data via an FDA online tool called e-submitter but most submissions are done via email using PDF and Excel files. Recall notices sent from manufacturers to health care providers and distributors consist of paper documents sent via the mail or a delivery service (e.g., FedEx).

- Information requested by the FDA and provided to health care providers and distributors is variable. An analysis of six representative Class I recalls showed of the 17 data elements reported by manufacturers only eight were included in all six examples.

- FDA, health care providers, and distributors each manually transcribe the information into their internal systems or databases. Third party recall management organizations offer a range of services to health care providers to assist with this process. Some are provided at no charge, but most involve a fee.

- Stakeholders recommend that to effectively track a recalled implantable device to the affected patient, the UDI of the implanted device needs to be included in the recall notice and captured in both Electronic Health Record (EHR) and Enterprise Resource Planning (ERP) systems software.

- Health care providers estimated the labor for responding to recalls ranged from 16 to 104 hours per recall depending on the type and extent of the recall. One provider indicated they processed 42 Class I recalls during a 12-month period, estimated at a cost of $20,166. Manufacturers were unable to share their costs related to recalls but indicted the cost drivers included notification costs and provider response time.

- All stakeholders agreed that including the UDI throughout the recall process would improve patient safety and reduce the time required to respond to recalls.

- Manufacturers indicated the biggest barrier to including the UDI in recall information is the lack of an explicit requirement from the FDA and/or health care providers.

- Stakeholders also agreed the inclusion of the UDI in the recall process would yield minimal benefit if the data continued to be communicated in a paper/PDF based, text format.

Work group members identified recommended practices for each stakeholder group that could improve the safety and efficacy of the recall process. The most critical recommendations included:

- Support the FDA's Technology Modernization Action Plan efforts[1] and encourage the use of the UDI-DI as the "link" between all FDA databases. Leverage the information in GUDID to auto-populate fields used in manufacturer submissions and FDA postings of recall and adverse event information.

- Suggest the FDA consider using the IT structure and workflow developed by the UDI program for the GUDID and AccessGUDID as a model that could be replicated for the Recall process. The UDI System was set up with manufacturer submission of structured data stored in a publicly available database with multiple methods of access (downloads, APIs, etc.) by various stakeholders.

- In the case of recalls, a set of required and optional recall data elements should be identified for manufacturers to submit in a structured electronic format through a web interface portal.

- Like the GUDID, the manufacturer's recall information should be available to stakeholders in a timely manner and in a standardized digital electronic format so they can integrate it with internal procurement, inventory management, distribution,

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[1] https://www.fda.gov/news-events/fda-voices/fdas-technology-modernization-action-plan-accelerates-path-enhancing-and-promoting-people-first

electronic health record (EHR) and enterprise resource planning (ERP) systems software. This allows relevant stakeholders to quickly locate and remove recalled products as well as to provide notification and instructions to clinicians and patients depending on the circumstances.

- To support the GUDID's role as the "link" between all FDA CDRH databases[2] and the source to auto populate manufacturer's submissions, robust feedback-based enhancements to GUDID should be part of digital transformation and data modernization efforts to ensure the timely updating and synchronization of all CDRH databases.

- Encourage manufactures and all FDA communications to immediately begin including the UDI-DI and UDI-PI in all recall related communications.

- Health care providers should continue to educate manufacturers that in addition to improving patient safety and quality of care, the inclusion of the UDI can enhance providers' ability to respond quickly and accurately to a recall, thereby reducing manufacturer's costs.

- Health care providers should ensure they have formal policies and procedures for managing the recall process and consider identifying a recall coordinator or point person to coordinate the process. Additionally, they should consider incorporating the requirement for manufacturers to include the UDI-DI and UDI-PI in recall information into their contracting process.

- Form an advocacy coalition of key stakeholder organizations to elicit support from Congress and the FDA for creating and maintaining a structured electronic recall process. This will increase patient safety and reduce operating expenses by providing better access to standardized recall data and a searchable database available to manufacturers, distributors, health care providers and other stakeholders.

The full report can be found here. The work group created a comprehensive Regulatory Resource Guide which can be found here. Additionally, all the detailed reports, surveys and summary presentations created by work group members can be found in the Supporting Information document which can be found here.

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[2] Each system in CDRH is "owned" by a separate business group within FDA. See Regulatory Resource Guide for information on Code of Federal Regulations and various databases, e.g., UDI, Access GUDID, eMDR,/MAUDE, Registration and Listing, Recalls, eSubmitter, that are relevant to success.