LEARNING UDI COMMUNITY

AHRMM
Advancing Health Care through
Supply Chain Excellence

Unique Device Identifier (UDI) Impacts on Recall Management Work Group Report

AHRMM.ORG/LUC

VISION, MISSION AND CHARTER:

The UDI Impacts on Recall Management work group was established to evaluate the clinical, supply chain operational and patient safety impacts and benefits of using the UDI to enhance the recall process. To accomplish this Vision, the work group was guided by its Mission to 1) define the value to multiple stakeholders (suppliers, providers, patients, etc.) of incorporating and using the UDI in the recall process; 2) collect information on the current level of usage of the UDI in the recall management process, and 3) make recommendations to all stakeholder groups on increasing usage of UDIs to maximize the value as outlined in its Charter[1].

UDI Impacts on Recall Process Work Group and AHRMM CQO

AHRMM defined the Costs Quality and Outcomes (CQO) program to focus on integrated support for supply chain management activities to enhance health care. As such:

The CQO Movement looks at the intersection of, and the relationship between:

- Cost: all costs associated with caring for individuals and communities
- Quality: care aimed at achieving the best possible health
- Outcomes: financial results driven by exceptional patient outcomes

The efforts of this LUC Work Group impact all elements of the CQO.

CHALLENGE:

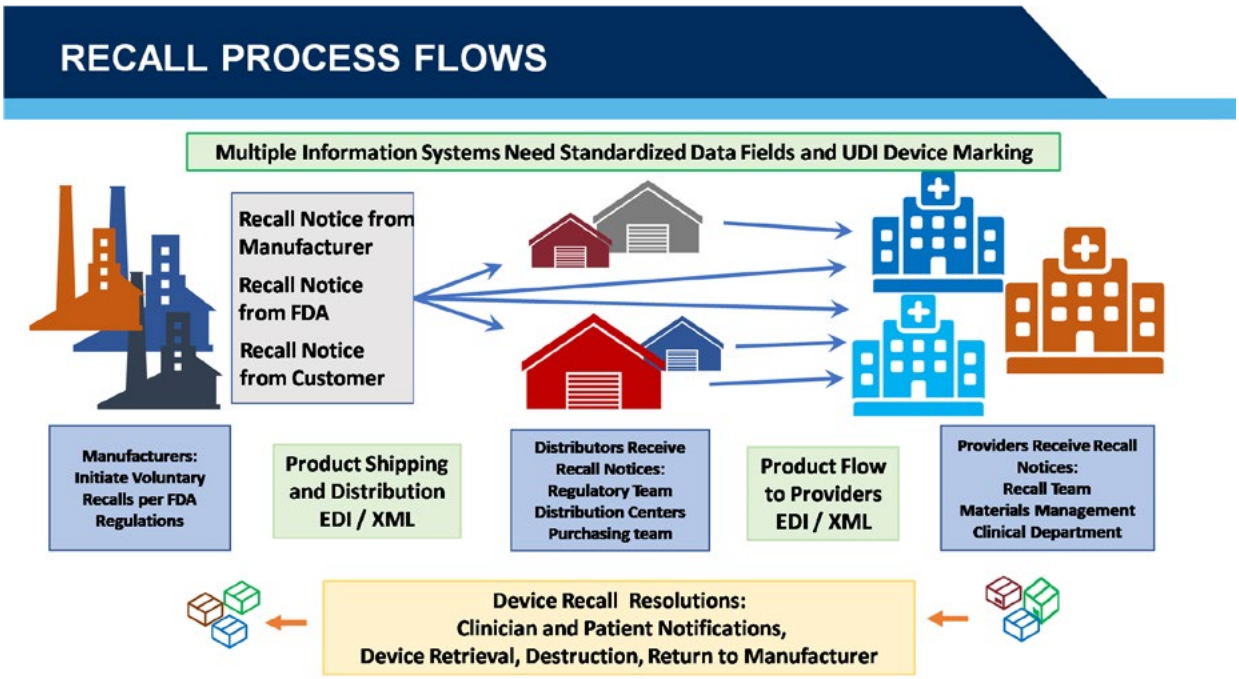

FIGURE: RECALL PROCESS FLOWS

[1] Appendix A - UDI Impacts on Recall Management Charter, UDI Impacts on Recall Management Supporting Information

Work group challenges included understanding the information flow for recalls across the supply chain from manufacturers to the FDA, distributors, health care providers and ultimately the patients. The following diagram provides a high-level overview of that flow. These segments provided the foundation for the establishment of task forces to evaluate UDI impacts on recall management processes. Note that product shipping and distribution is communicated via EDI/XML transaction sets, recall notice information is currently communicated manually and therefore provides significant opportunities for improvements.

PROCESS:

To ensure a comprehensive understanding of each stakeholder group's perspectives, a diverse work group was created. More than 70 members participated in this work group including representatives from: Distributors, FDA CDRH, GPOs, Health care providers, IT/Software Application providers, Manufacturers, Recall Services, Standards Agency and Trade Associations.

The work group's efforts were led by two co-leads and supported by an AHRMM project manager. It was determined the most efficient way to manage the project would be to establish five task forces (Distributors, IT/Technology, Manufacturers, Providers and Regulatory/Glossary) each of which would have its own set of co-leads.

The task forces sought to identify and evaluate different practices across the medical device supply chain, and to make recommendations to each health care stakeholder segment that would enhance recall practices and would contribute to improved patient safety and increased efficiencies through increased use of UDI in the recall process. Six specific recall examples were given to the task forces to use as references. The following provides highlights of each work group's scope of work and focus.

Manufacturer, Distributor and Health Care Provider Task Forces:

- Analyzed the current process for issuing recalls.
- Identified pain points, inefficiencies, and cost drivers. The distributor and health care provider task forces developed estimates of the time and costs associated with responding to recalls.
- Manufacturers partnered with AdvaMed, distributors with the Health Industry Distributors Association (HIDA) and health care providers with AHRMM and the Association of Healthcare Value Analysis Professionals (AHVAP) to develop and implement surveys to gain additional insight into the benefits and barriers of including the UDI throughout the recall process and transitioning the process from paper-based to electronic recall submissions.
- Analyzed the results of the surveys for insights on the best ways to expand utilization of the UDI throughout the recall process and better understand pain points related to the current process for reporting recalls to the FDA.

IT and Technology Task Force:

- Identified and compared the data elements contained in six manufacturers' recall letters and compared those data elements to those captured in the FDA's e-submitter portal.
- Worked with the provider and distributor task forces to determine the data elements each stakeholder group needed to effectively identify and remove recalled products.
- Reviewed the manufacturer survey results that identified pain points for manufacturers submitting recall information to the FDA.

Regulatory and Glossary Task Force:

- Created a comprehensive resource document that includes a summary emphasizing the various publicly available guidance documents with specific Code of Federal Regulations (CFR) references as well as a list of existing regulatory terms associated with recalls, both at the FDA organizational level as well as terms specifically used in the FDA Center for Devices and Radiological Health (FDA CDRH).

Additional details regarding the task forces' efforts, and detailed survey results are provided in the appendices in the UDI Impacts on Recall Management Supporting Information document.

FDA BACKGROUND

The work group quickly identified that to maximize the effectiveness of the individual task forces, it was imperative that the group develop a common understanding of the role of the FDA and its requirements related to the recall process. Additionally, it was important to understand FDA terminology, the volume and trends related to recalls and FDA data sources.

One of the first challenges was understanding the FDA classifications for recalls and how those related to its classification of medical devices. The scales are basically inverted so the most serious recall is a Class I recall while the most complex medical device is a Class III. In addition, the FDA also uses Arabic and Roman numerals for medical device classifications and device recalls. In this report we used Roman numerals. The following highlights key learnings.

- Class I Recall – A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- Class II Recall – A situation in which use of, or exposure to, a violative product may cause temporary or medically-reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III Recall – A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

The FDA categorizes medical devices based on their risks and regulatory controls necessary to provide a reasonable assurance of safety and effectiveness.

- Class I Medical Devices – Pose the lowest risk to the patient.
- Class II Medical Devices – Pose potential for non-life-threatening risks or injury.
- Class III Medical Devices – Pose the highest risk in use to patients and faulty device use may cause death.

RECALL VOLUME TRENDS

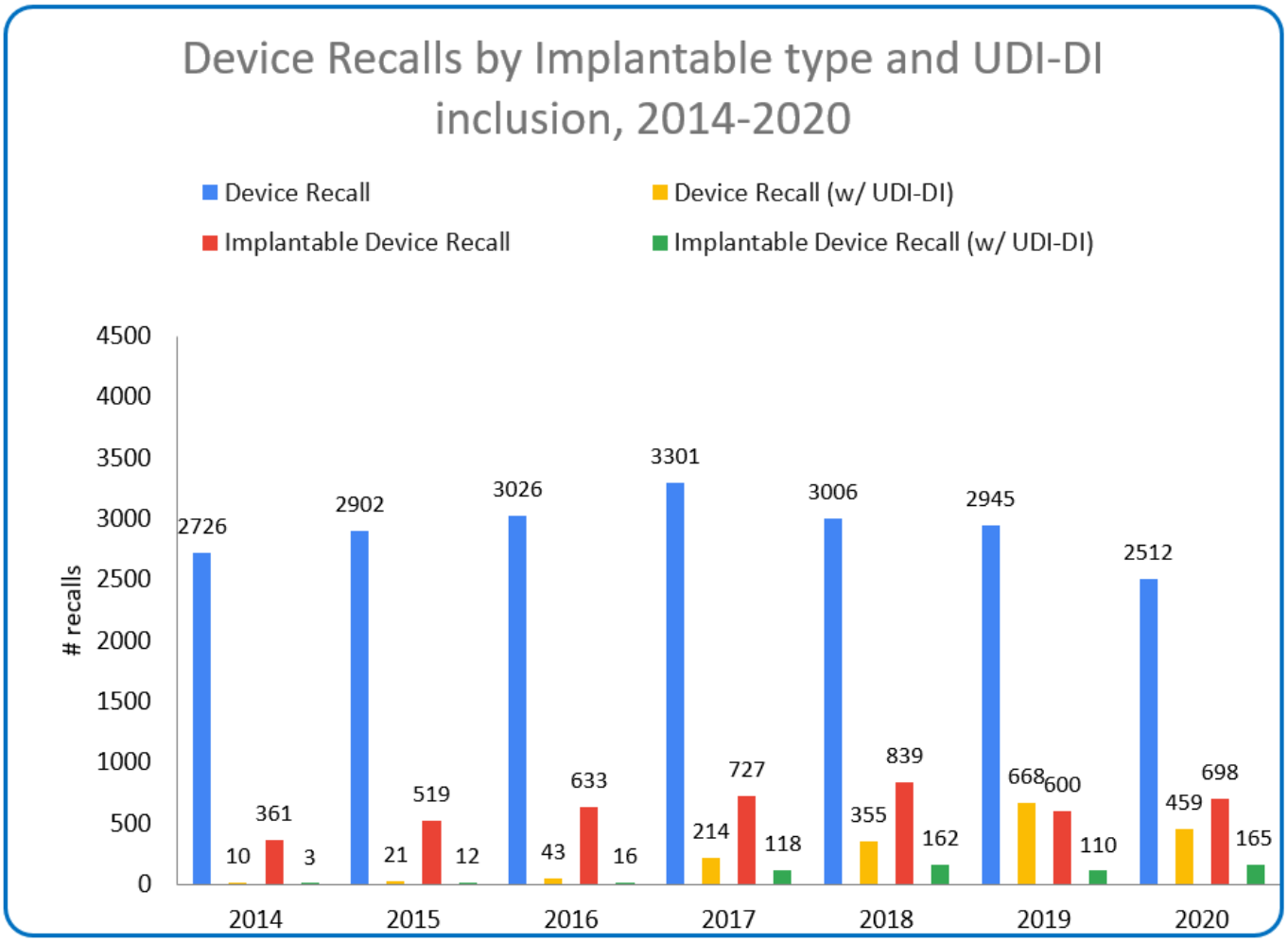

TABLE: RECALL VOLUME TRENDS (SOURCE: INFORMATION PROVIDED BY SYMMETRIC HEALTH SOLUTIONS. SEE FOOTNOTES[2, 3]

[2] Text from the Code-Info field was parsed to determine if UDI-DI existed in GUDID and the Implant Flag Status from the FDA Product Code assigned to the Recall in the FDA Classifications file.

[3] Data source: Open FDA Recalls and from the Recalls and Recall Enforcement Tables with table joined using the assigned Recall Number.

The analysis of this data indicates:

- The use of UDI-DI in recall notices continues to be low for Class III medical devices that pose the highest risk in use to patients and faulty device use may cause death.
- Total number of Device recalls did not significantly increase in 2020 compared to 2019.
- The percentage of recalls that contained UDI-DI went down from 2019 to 2020.
- The percentage of device recalls that contained the UDI in the FDA databases was consistent with the percentage identified through manual tracking of manufacturer recall notices by third party recall management organizations.

FDA DATA SOURCES

The following are all the different FDA data sources for recall and adverse event data. The same query posed to each source yields different results. Additionally, the process for accessing recall information is different for medical devices, biologicals and drugs.

Recall Data Sources (See Regulatory Resource Guide for URL links to these data sources and additional information):

- Medical Device Recall (Yearly Lists).
- Medical Device Recall (Database).
- OpenFDA.
- Compliance Dashboard.
- Enforcement Reports.
- Recalls, Market Withdrawals and Safety Alerts.
- Additional Information about Recalls.
- Archive for Recalls, Market Withdrawals & Safety Alerts.
- FDA.gov Archive.

Adverse Events Data Sources:

- MAUDE (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM)
- Medsun (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/searchreport.cfm)

MEDICAL DEVICE RECALL COSTS

The risk of patient harm or death is something that should motivate all parties to respond the recalls in an efficient and timely manner. The reality is that making changes to systems and processes has operating cost implications. Each stakeholder's costs vary based on the type and

scope of the recall and their internal processes. The following cost calculator was developed as an example of how stakeholders could go about analyzing the operational costs and benefits of including the UDI throughout the recall process. (Note: Additional templates are provided in Appendix L[4].)

Cost Calculator Sample Class II Recall - Implantable

Estimated Costs associated with Recalls			
Task Force Name: Providers			
Work done with assist of automated system: **Yes_x_No__**			Reccall Coordinator
Work done entirely with manual system: **Yes__No_x_**			SCM/End User
			Management to complete
	Current Process		**Future Process**
RECALL PRODUCT: >1 recall of same issue may have been reported	**Class 2 Rcall**		**Class 2 Recall**
Medical/Surgery Device: Implantable	***add hours below by action categories that are effected by the recall***		***add estimated hours below by action category that would be improved with use of UDI***
notification processing			
intake of notices, assuring you have notices	0.50		
moderate actions			
purchase history reports	3.00		
notification of internal stakeholders	2.00		
communication back to internal recall coordinator	2.50		
major actions			
Identify and gather affected products	15.00		
Destroying product:	2.00		
Returning product to manufacturer:			
Ordering replacement product			
Computer updating for inventory:	5.00		
Responding orgnization's policy on recall notice reporting:	0.50		
Working with Legal and the Practice to draft affected patient communication can take weeks and involves several FTE's	50.00		
Repeat notifications,	13.00		
expanded info	6.00		
Repeat notifications,			
no new info			
Inputs			
time spent by role (hrs)			
list role types			
- Recall Coordinator	21.00		
- SCM/End-User	78.50		
total time spent (hrs)	99.50		
avg hourly salary by role Range 25 - 50 per hour	$30.00		
total dollars spent	$2,985.00		
Determine extent of time and dollars: number of Class 2 recalls of same type of action process steps in a specified time e.g.calendar year			

FIGURE: SAMPLE COST CALCULATOR TABLE

DOWNLOAD COST CALCULATOR

[4] Appendix L – Medical Device Recall System Prototype, UDI Impacts on Recall Management Supporting Information

KEY FINDINGS

An analysis of each stakeholder's current situation, pain points 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 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 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 the 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-based, text format.

RECOMMENDATIONS

Work group members identified recommended practices for each stakeholder group that could improve the safety and efficacy of the recall process. Each task force's specific recommendations are included in the UDI Impacts on Recall Management Supporting Documents.

- Support the FDA's Technology Modernization Action Plan efforts[5] and encourage the use 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, electronic health records (EHR) and enterprise resource planning (ERP) systems software. This allows relevant stakeholders to quickly locate and remove recalled products as well as providing 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[6] 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.

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

[6] 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.

- 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.

APPENDIX A – WORK GROUP MEMBERS

The co-leads and facilitators for this work group were Barbara Strain MA, CVAHP, Principal, Barbara Strain Consulting LLC and former Director of Value Management, University of Virginia Health System, and Richard A. Perrin, CEO/Principal, Active Innovations.

The following provides a list of the members who contributed their time and efforts to this work group.

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Nancy	Anderson	SMI
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Carol	Baum	Medline
Tammy	Beasley	NDC
Dennis	Black	BD
Devin	Bobulski	EPIC
Jamie Lynne	Boutilier	VVH
Juan	Buitrago	Zimmer Biomet
Kraig	Butts	BJC HealthCare
Kevin	Capatch	Geisinger
Pete	Casady	InVita Healthcare Technologies
James	Casavant	TrackCore
Heather	Christensen	Medline
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Karen	Conway	GHX
Amy	Conway	Mayo Clinic
Jay	Crowley	USDM Life Sciences
Tomas	Dardet	Symmetric Health Solutions
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Josh	Diercks	Cardinal Health
Jeremy	Elias	TrackMy Solutions
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Jennifer	Kempf	BJC HealthCare
Todd	King	Cardinal Health
Dave	Kordik	Medline
Rich	Kucera	Symmetric Health Solutions
Danielle	Kulow	Kirby Health
Nancy	LeMaster	AHRMM
Kimberly	Lewis	Owens & Minor/Halyard Health
Keith	Lohkamp	Workday
Vicky	Lyle	Owens & Minor
Ryan	McManus	HIDA
Ken	MacDonald	Health Care Professional
Vijay	Madikonda	Johnson and Johnson
Bob	Matthews	Workday
Allison	Mehr	HIBBC
Joan	Melendez	Xcelerate UDI
Curt	Miller	Industry Supply Chain Organization
Behnaz	Minaei	FDA
TJ	Mitchell	Optivus Solutions Group
Karen	Morlan	Vanderbilt Medical Center
Susan	Morris	MedStar Mongomery Medical Center
Terri	Nelson	Mayo Clinic
Mike	Nolan	AIS
Lee-Ann	Norman	Johnson and Johnson
Dennis	Orthman	Access Strategy Partners
Brad	Pedrow	Veeva Systems
Dick	Perrin	Active Innovations
James	Phillips	FMOLHS
Trent	Pierce	Kermit PPI
Janet	Price	Cook Medical
Susan	Ramonat	Spiritus Partners
Yolanda	Redmond	Vanderbilt Medical Center
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Madris	Kinard	Device Events
Joyce	Trese	Roche Diabetes Care
Nam	Trinh	Securisyn Medical
John	VanGundy	Cerner
Wendy	Watson	University Health Network Canada
Beth	Wells	GS1