LEARNING UDI COMMUNITY

AHRMM
Advancing Health Care through
Supply Chain Excellence

# Unique Device Identifier (UDI) Impacts on Recall Management Supporting Information

AHRMM.ORG/LUC

# UDI IMPACTS ON RECALL MANAGEMENT SUPPORTING INFORMATION

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## APPENDIX A - UDI IMPACTS ON RECALL MANAGEMENT CHARTER

This appendix provides the work group charter to provide guidance on the activities and efforts of this AHRMM LUC Work group.

### Work Group Focus

UDI Impacts on Recall Management – Evaluating clinical and supply chain operational, and patient safety impacts and benefits of using the UDI to enhance the recall process. The work group is expected to build upon prior work by the AHRMM LUC Benefits of UDI Work Group and Strategic Marketplace Initiative (SMI).

### Work Group Executive Charter

The mission of the UDI Impacts on Recall Process Management work group is to: 1) define the value to multiple stakeholders (suppliers, providers, patients, etc.) re: the use of UDIs in the recall process; 2) collect information on current level of usage of UDIs in the recall management process, and 3) make recommendations to increase usage of UDIs to maximize value.

### Work Group Leaders

Barbara A. Strain, MA, CVAHP, Managing Principal, Barbara Strain Consulting, LLC, Charlottesville, VA 22903 email: Barbara@BStrainConsulting.com, Work 434-459-1642.

Richard A. Perrin, CEO/Principal, Active Innovations, LLC, Riva, MD 21140, RAPerrin@ActiveInnovations.org, Work 410-507-5482.

### Affected Stakeholders

Note – A list of participating work group members is provided in Appendix M of this document.

The work group will be diligent in gathering validated perspectives from different stakeholders involved in the product recall processes for their organizations. As such, the work group will seek input and participation from across the health care supply chain including:

- Manufacturers
- Distributors
- Hospitals and other health care settings
- Clinicians
- Patients
- Technology vendors (see note immediately below)
- FDA
- Associations, e.g., SMI, AdvaMed

Note – Technology vendors will include recall and inventory management systems vendors as well as others that may provide important perspectives, e.g., AIDC systems, ERP/MMIS systems, content management systems, eProcurement systems.

## Background

Research has shown an increasing number of medical device recalls. The number of recalls issued in 2018 was the highest in five years, while the average number of Class I units recalled per quarter increased more than 64 percent from 2016 to 2017. According to a 2017 McKinsey report, a major recall can have a negative impact on perceived manufacturer shareholder value, not to mention the significant risk to patient safety if the devices in question are not removed from the market and patients treated with those devices, especially implantables, cannot be identified.

The ability to better manage medical device recalls was one of the primary drivers behind the UDI regulation. Still, the use of UDIs in recall notices by manufacturers remains limited.

This work group will seek to identify and evaluate different practices across the medical device supply chain and make recommendations to improve patient safety and increase efficiencies through increased use of UDI in the recall process.

Key elements to be considered by this work group include:

- Data and process for submitting recalls to the FDA (including UDI-DI [Device Identifier(s)] and UDI-PI [Production Identifier(s)]),
- Processes and systems used to manage recalls (by suppliers, health care system supply chain and clinical teams, FDA, and technology systems),
- Data required to effectively manage recalls by various stakeholders,
- Information and workflow related to the recall management process, and
- Current processes, reasons, and levels for generating medical device recalls.

One anticipated recommendation is to increase the number of recalls that include UDI-DI and UDI-PI and to clarify the structure and format of recall data that would best meet the needs of those managing recalls – for both manufacturers and health care systems.

## Process & Deliverables

A three-pronged approach is planned for this work group's efforts:

1) Place a call for formal case studies from organizations highlighting their operational and patient safety benefits from incorporating the UDI into their recall process,
2) Develop and distribute survey(s) to gather data on current practices, capabilities and use of UDI in recalls, and
3) Develop recommended practices showing the value for use of UDIs in recalls management.

## Communication Plan

The following approaches are projected to be used in communicating results of this work group:

- Review, validation, and dissemination of relevant information gathered from surveys, interviews, business communications, etc.
- Submission of recommendations to AHRMM Learning UDI Community and FDA including posting(s) to AHRMM LUC webpage.
- Preparation of White Paper regarding UDI Impacts on Medical Device Recalls.
- Distribution to AHRMM LUC, AHA, HFMA, ARHMM, HIDA, HIMSS, HDMA, HSCA, IAHSCM, SMI, HPN, HHN, Beckers, etc.

## APPENDIX B – WORK GROUP STRUCTURE AND TASK FORCES

### Task Force Structure

The efforts of the Work group were organized around task forces comprised of representatives of different health care supply chain segments.

- Document current state workflows/swim lanes,
- Identify triggers for actions, e.g., sources of recall notices received, formats (e.g., electronic, PDF's, etc.), and post-recall wrap-up,
- Document Use Cases for Recall Processes for validation, distribution, disposition,
- Identify / document available information on costs and/or resource requirements,
- Recommendations for future enhancements, and
- Each Task Force was provided a road map of specific objectives to guide their work.

### Standardized Use Cases Recall Items Reviewed by Task Forces

The following items were suggested for each of the task forces to facilitate synergistic outputs for recommendations and reports. The approach was to use six (6) Class III representative recalls from 2019 – 3 for medical equipment, and 3 for medical devices. The following are the items reviewed by each of the task forces to develop initial observations and swim lanes.

Source: https://www.fda.gov/medical-devices/medical-device-recalls/2019-medical-device-recalls

- Consumables:
- Ethicon Recalls ECHELON FLEX™ ENDOPATH® Staplers for Failure to Completely Form Staples 10/30/19 https://www.fda.gov/medical-devices/medical-device-recalls/ethicon-recalls-echelon-flextm-endopathr-staplers-failure-completely-form-staples
- Allergan Recalls Natrelle Biocell Textured Breast Implants Due to Risk of BIA-ALCL Cancer 09/12/19 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=175500
- Edwards Lifesciences Recalls Swan-Ganz Thermodilution Catheter Due to Incorrect Assembly Causing Reversal of Lumens 02/15/19 https://www.fda.gov/medical-devices/medical-device-recalls/edwards-lifesciences-recalls-swan-ganz-thermodilution-catheter-due-incorrect-assembly-causing
- Equipment:
- Becton Dickinson (BD) (CareFusion 303, Inc.) Recalls Alaris Pump Module Model 8100 Bezel Assembly Which Could Result in Free Flow, Over-Infusion, Under-Infusion, or Interruption of Infusion 07/18/19 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=172627
- GE Healthcare, LLC Recalls Giraffe Infant Warmers and Panda i-Res Infant Warmers Due to Bedside Panels and Latch Areas Cracking or Breaking 07/12/19 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=171685
- Physio-Control Recalls LIFEPAK15 Monitor/Defibrillator Due to Risk of Device "Lockup" (Freezing) 02/27/19 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=170355

## Data Sources for the Six Representative Recalls

The following chart highlights the essential elements for processing recalls and shows the various FDA databases to be accessed for different recall information[1].

| Data fields in current recalls forms | Products | | | | | |
|---|---|---|---|---|---|---|
| **Field names** | **Ethicon Flex Endopath** | **Allergan implants** | **Edwards Catheter** | **BD Pump** | **GE Warmer** | **Physio Lifepak** |
| **Recall Class** | x | x | x | x | x | x |
| **Company name** | x | x | x | x | x | x |
| **Recalled Product Names** | x | x | x | x | x | x |
| **Recalled Product Codes** | x | x | x | x | x | x |
| **manufacturing dates** | x | | x | | | |
| **Distribution Dates** | x | | x | | | |
| **Quantity of Devices recalled** | x | x | x | x | x | x |
| **Date recall was initiated by company** | x | x | x | | x | x |
| **Description of device use** | x | x | x | x | x | x |
| **Description of Reason for recall** | x | x | x | x | x | x |
| **Description of Who may be affected** | x | | x | | | |
| **Description of what to do** | x | x | x | x | x | x |
| **Description of Contact information** | x | x | x | x | x | |
| **Recall Status** | | x | | x | x | x |
| **Recall Number** | | x | | x | x | x |
| **Recall event ID** | | x | | x | x | x |
| **PMA number** | | x | | | | |
| **Product classifications** | | x | | x | x | x |
| **Create date** | | x | | | x | |
| **510(K) number** | | | | x | x | x |
| **date posted** | | | | x | | x |
| **Lot Numbers** | x | x | x | x | | |
| **serial numbers** | | | | | x | x |
| **number of fields found on recall form** | 14 | 17 | 14 | 16 | 17 | 16 |
| | Ethicon Flex Endopath | Allergan implants | Edwards Catheter | BD Pump | GE Warmer | Physio Lifepak |
| **Web service data source** | FDA.gov | accessdata.fda.gov | FDA.gov | accessdata.fda.gov | accessdata.fda.gov | accessdata.fda.gov |
| **Does the mfg use UDI?** | **yes** | **yes** | **no** | **yes** | **yes** | **unknown** |
| Note: Data fields differ depending on source used | | | | | | |

TABLE: DATA SOURCES FOR SIX REPRESENTATIVE RECALLS (SEE FOOTNOTES)

## Characteristics of the Six Representative Recalls

Data presented in the following chart is representative of information that was available at the time of review in 2020. The citations and references are from the enforcement report available from the FDA. The data in the chart were extracted from the data sources listed in the preceding table (Data Sources for the Six Representative Data Recalls). As shown previously, there were 17 different fields used by the six recalls and eight of those were used by all six recalls.

The LUC Recalls IT work group was assigned the task of identifying the data fields associated with initializing the recall of a medical device, a seemingly complex process. At the beginning of the analysis there were well over 100 data fields that seemed to be built into the existing recall system used by the FDA. There were suggestions to look at additional potential data sources from standards organizations to ensure all data sources were identified and there were no redundancies. A brief look into these revealed that there was a potential for several hundred data fields, many of which were redundant and many others of little value.

To find out which of these data fields were important, a second separate approach was made to look at the actual data fields reported to the FDA in six recent major recalls. After building a

[1] Use the following URL for access to FDA information shown in the chart: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm

table of the fields found in the actual recalls, it was determined that there were only 17 fields that were used to announce the recalls.

During the investigation discussions included review of instances where data field entries were incorrect. In pursuing this, it was determined that of the 17 fields being used, 9 could be found in the GUDID database. By referencing the UDI DI in the GUDID over half of the fields needed to initialize a recall can be perfectly entered without error or ambiguity.

To show the community how the recall initialization process could be made easier, more accurate, more immediate, and transparent a simple electronic model was created with the required remaining data fields and the automatically entered fields from the GUDID. This model form is intended to link to both the GUDID and Recalls databases. See 'Appendix N – Medical Device Systems Prototype' that provides an easy-to-understand simulation of how the current processes can be simplified and improved.

The following table 'Summary Information on 6 Recent Recalls' illustrates the information extracted from various FDA databases to summarize details on each of the six recent major recalls used for review by each of the task forces.

| Announced by/via | Recall Class | Number of Products | Number of Lots | Total Quantity of Items | Date Initiated | Instructions with Announcement | Used UDI To Identify Product | Who Is Responsible for Returns | Return By _Date_ For Replacement | Controlled Announcement | Controlled Returns $$ |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Ethicon via Letter to Customers | 1 | 4 | 27 | 5,733 | 3-Oct-19 | Yes – Quarantine and Return | No | Provider – Use BRF Shipping and Use Prepaid Shipping | 31-Dec-19 Stericycle | No | Partly – No Replacements After 3 Months |
| FDA Contacted Allergan About Too Many Problems and Allergan Reacted | 1 | 30-40 | 50-60 | 4,026,287 | Press Release 7/24/19 - Customer Letter /9 | Yes – Quarantine and Return | Yes - Many | Customer | Yes (Inmar) | No | No – But Provider Only Had 5 days to Return Inventory Form Showing What They Have in Stock |
| Edwards Lifesciences | 1 | 5 | 11 | 1,426 | 12/21/2018 | Yes – Quarantine and Return | No | Customer | Return Direct to Edwards | No | No – Open Ended |
| BD – May Have Been Prompted by FDA | 1 | 27 | 300 or 17,000 | 183,572,651 | 5/6/2019 and Posted July 11, 2019 | Destroy | Yes | Customer | Destroy | No – Letter From BD First Then FDA | No – Open Ended |
| GE Giraffe Warmer | 1 | | Thousands | 9,094 | 15-Mar-19 and Posted July 2019 | Customer Inspects and GE Fixes Bad Ones | Yes | Yes | Yes for Fix | No | No – Open Ended |
| Stryker Lifepack | 1 | 1 | 13,005 Serial Numbers | 13,005 | 1-Feb-19 and Posted 29-Feb-19 | Customer Inspects and Stryker Fixes | Unknown - FDA Does Not State | Customer | Stryker Fixes at Provider Location | ? | Maybe Controlled Using Responses And Stryker Records |

TABLE: SUMMARY INFORMATION ON 6 RECENT RECALLS

## APPENDIX C – MANUFACTURERS TASK FORCE SUMMARY REPORT

The Manufacturers Task Force Lead was Shana Harton, Senior Analyst, Johnson & Johnson.

### Background

The manufacturer task force was comprised of representatives from manufacturers, distributors and software application providers. The task force members examined their own company's recall process and identified pain points and areas of opportunity. They also partnered with AdvaMed to distribute a survey to other manufacturers to gain additional insights and recommendations.

### Current Situation

The vast majority of medical device recalls are initiated by the manufacturer in consultation with the FDA. Manufacturers consult the regulations included in 21 CFR Part 806: Medical Devices; Corrections and Removals for guidance on the specific data elements to provide to the FDA and include in the recall notice. There is, however, significant variability in the data elements contained in recall notices. A review of six representative Class I recalls for equipment and devices identified 17 different data elements were reported and only eight data elements appeared in all six recall notices. In addition, manufacturers indicated the data requested by the FDA varies based on which district is involved.

Survey results from 20 manufacturers indicted 60% submit their recall information to the FDA via email to its portal or ORA mailbox. Eighty-five percent (85%) use PDF documents or a combination of PDF and Excel spreadsheets to submit data. Since the data is not structured or standardized, the FDA then manually keys the information into its database. Seventy-five percent (75%) of manufacturers surveyed indicated they included the UDI in the information provided to the FDA. However, a recall alert management company that tracks the percent of recalls that included UDIs found on average only 20% of recall notices included the UDI. See Appendix D for detailed survey results.

### Key Findings of Manufacturers Task Force

Manufacturers identified key pain points as:

- Slow FDA response time - delays in recall classification designation and close out process.
- Confirming customer receipt of notification and customer response.

Feedback from health care providers indicated that the lack of standardized data that included the UDI and was unavailable in an electronic format negatively impacted their ability to quickly respond to recall notices.

The primary cost drivers for the manufacturers are the customer notification and follow up process, the product reconciliation process and the FDA submission and communication

process. Internal restrictions prohibited manufacturers from sharing specific cost data or cost ranges. Manufactures did agree that if the inclusion of the UDI and a standardized, electronic submission process coupled with a publicly accessible databases (like the UDI system) improved health care provider responsiveness and improved the efficiency, that it would potentially reduce their operating costs.

Key findings and implications of an electronic recall process on manufacturers' current processes identified by the Manufacturers task force included the following:

- Lack of UDIs in notification process.
- An electronic process would eliminate data entry errors between what is submitted by the manufacturer and what the FDA publishes. Would have to have a backup process if the systems were down – that could cause additional work.
- If GUDID was used to auto-populate any of the data, quality control would need to be incorporated to make sure the process functioned correctly and accurately. Then users could upload Excel spreadsheets that included the PI information. In large companies, different individuals are populating the GUDID from those that manage recalls and there needs to be collaboration between these individuals/groups.
- Manufacturers would prefer an all-electronic system. Previously, the FDA was concerned that some companies do not have electronic systems and could not comply. Thus, there is a need to follow up with FDA and determine who are the "owners" for the recall data submission process.
- Standardized documents from FDA (806 Report - primary document) that tells manufacturers what data elements to include when submitting a recall. FDA needs to make the reporting of the UDI mandatory when the product has a UDI on its label. The FDA procedure manual chapter 7 gives broader guidance regarding the recall process.
- Important to be able to get information electronically so providers can compare the recalled product to their inventory by scanning the barcode.

### Recommended Practices

- Manufacturers should always include the UDI-DI and UDI-PI in all recall notices both to the FDA, distributors and to health care providers. They should follow the FDA's "red letter guidance" when formatting their recall notices.
- The FDA should consider using the IT structure and workflow developed by the UDI program 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, manufacturers need to submit standardized recall information in a structured, electronic format based upon the specification of required and optional data elements. Like the GUDID, the manufacturer's recall information

should immediately be available to stakeholders in a standardized digital electronic format so they can integrate it with and Enterprise Resource Planning (ERP) systems software supporting internal procurement, inventory management, distribution, and electronic health record (EHR) systems. 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.

- Government agencies should update regulations and require inclusion of the UDI. Specifically, the UDI final rule makes changes to certain parts of 21 CFR governing FDA's existing regulatory systems and processes to integrate UDIs and device identifiers. These changes, known as the conforming amendments, affect part 803 (Medical Device Reporting), part 806 (Medical Devices; Reports of Corrections and Removals), part 814 (Premarket Approval of Medical Devices), part 820 (Quality System Regulation), part 821 (Medical Device Tracking Requirements), and part 822 (Postmarket Surveillance). The FDA should require the inclusion of the UDI-DI and UDI-PI consistently in all the FDA medical device databases specified in the UDI conforming amendments.

- Encourage the FDA to study other agencies, such as those responsible for food and drug recalls, to identify best practices to improve the timeliness of recall classifications and terminations.

## Costs Benefits Analysis

The following table is provided as a template for use by manufacturers in completing an internal costs and benefits analysis for their company and operating divisions. This presents fields for representative estimates of costs and benefits from use of UDIs for enhanced medical device recall activities.

| **AHRMM LUC UDI Impact on Recalls Workgroup** | | | | | | |
|---|---|---|---|---|---|---|
| **Estimated Costs associated with Recalls that require a return of product by enduser** | | | | | | |
| **Task Force Name: Manufacturers** | | | | | | |
| | **Current Process by Recall Class** | | | **If UDI Utilized adjust inputs by Recall Class** | | |
| | **Class 1** | **Class 2** | **Class 3** | **Class 1** | **Class 2** | **Class 3** |
| *example of categories below included in cost calculation* | | | | | | |
| letters notification process | | | | | | |
| interacting with FDA, others | | | | | | |
| moderate actions e.g. relabeling | | | | | | |
| major actions e.g. product return | | | | | | |
| patient notifications | | | | | | |
| | | | | | | |
| **Inputs** | | | | | | |
| *add rows as you need like role titles, etc.* | | | | | | |
| time spent by role (hrs) | | | | | | |
| | | | | | | |
| avg hourly salary by role | | | | | | |
| | | | | | | |
| total time spent (hrs) | | | | | | |
| | | | | | | |
| total dollars spent | | | | | | |
| | | | | | | |
| system changes to implement | | | | | | |
| | | | | | | |
| number of recalls in a specified time e.g.calendar year | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

**TABLE: SAMPLE COSTS BENEFITS ANALYSIS**

## APPENDIX D – MANUFACTURERS TASK FORCE SURVEY RESULTS

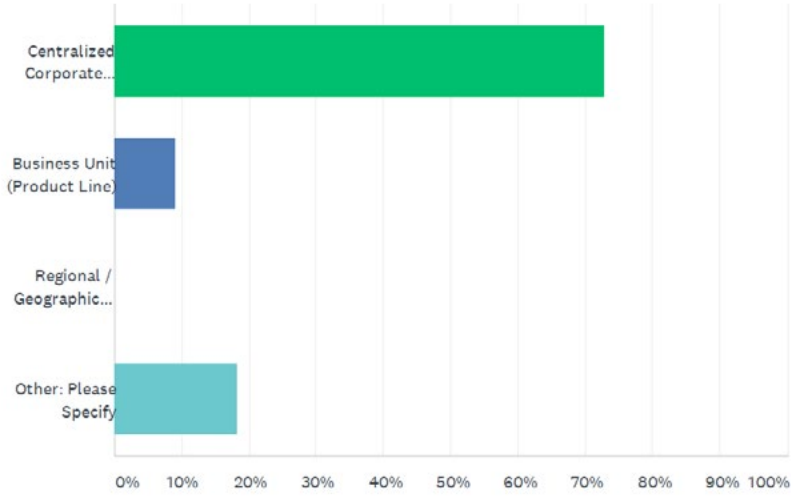
This Appendix presents the results collected from the survey tool on UDI Impacts developed and distributed by the Manufacturers Task Force. Q1 was a request for responder's email address and is not included here.

**Note:** The survey was completed in the 3rd and 4th quarter of 2020.

### Manufacturers Task Force Survey Results

Q2 Within your organization who is responsible for issuing and tracking recalls and field correction notices?

Answered: 11 Skipped: 12

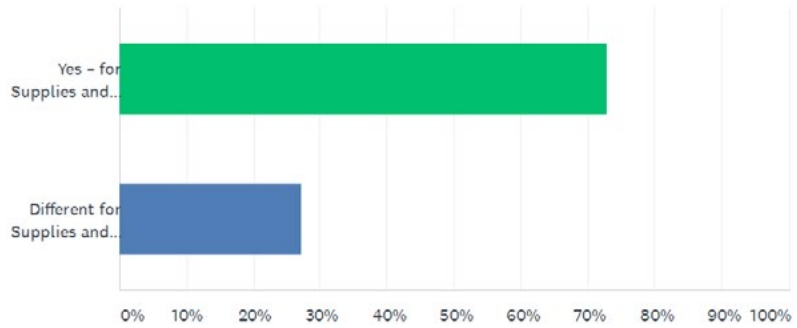



| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Centralized Corporate Department | 72.73% | 8 |
| Business Unit (Product Line) | 9.09% | 1 |
| Regional / Geographic Offices | 0.00% | 0 |
| Other: Please Specify | 18.18% | 2 |
| TOTAL | | 11 |

## Manufacturers Task Force Survey Results

Q3 Does your organization use the same process for issuing and tracking recalls for supplies as you do for equipment? If not, what are the differences?

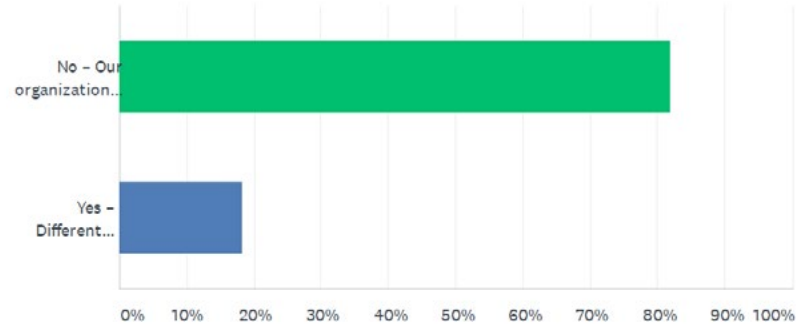
Answered: 11 Skipped: 12




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes – for Supplies and Equipment | 72.73% | 8 |
| Different for Supplies and Equipment: Please describe | 27.27% | 3 |
| TOTAL | | 11 |

Q4 Does your organization have separate processes for recalls of software for medical devices?

Answered: 11 Skipped: 12

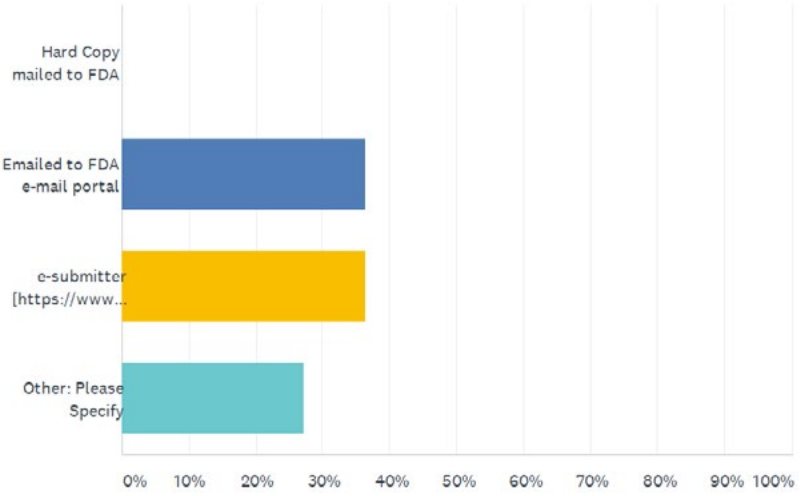



| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| No – Our organization uses the same process | 81.82% | 9 |
| Yes – Different process is used for software: Please describe | 18.18% | 2 |
| TOTAL | | 11 |

## Manufacturers Task Force Survey Results

Q5 How does your organization submit information to the FDA ?

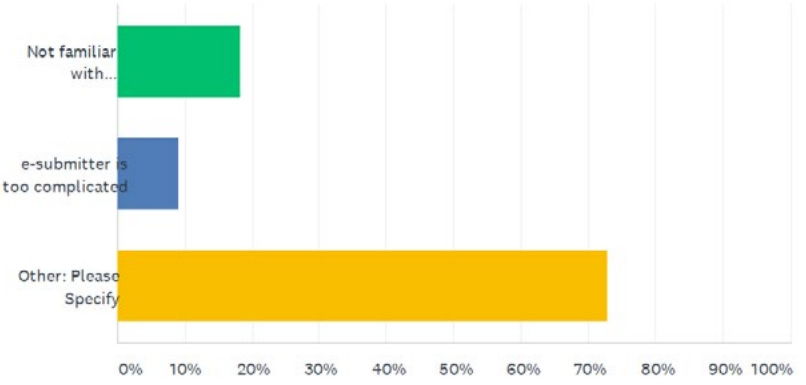
Answered: 11 Skipped: 12




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Hard Copy mailed to FDA | 0.00% | 0 |
| Emailed to FDA e-mail portal | 36.36% | 4 |
| e-submitter [https://www.fda.gov/industry/electronic-submissions-gateway] | 36.36% | 4 |
| Other: Please Specify | 27.27% | 3 |
| TOTAL | | 11 |

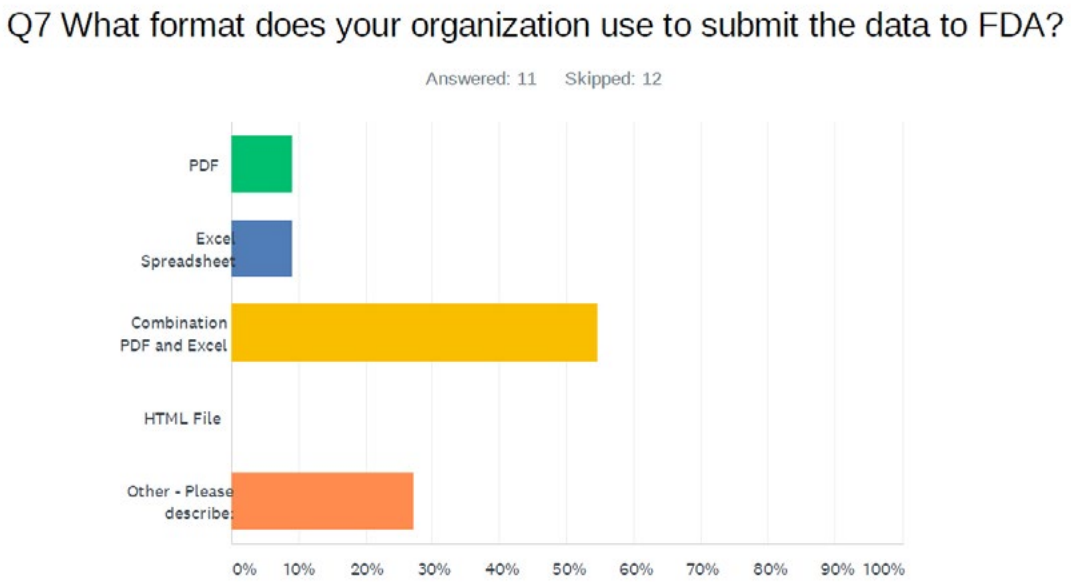
Q6 If your organization does not use the FDA's e-submitter website to submit data, why?

Answered: 11 Skipped: 12




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Not familiar with e-submitter | 18.18% | 2 |
| e-submitter is too complicated | 9.09% | 1 |
| Other: Please Specify | 72.73% | 8 |
| TOTAL | | 11 |

## Manufacturers Task Force Survey Results

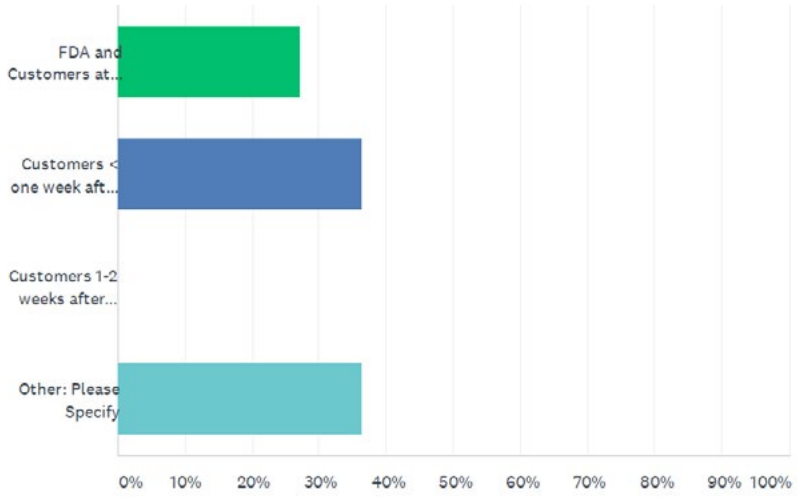



| ANSWER CHOICES | RESPONSES |
|---|---|
| PDF | 9.09% |
| Excel Spreadsheet | 9.09% |
| Combination PDF and Excel | 54.55% |
| HTML File | 0.00% |
| Other - Please describe: | 27.27% |
| TOTAL | 1 |

## Manufacturers Task Force Survey Results

Q8 Once your organization has determined a recall is necessary, what is the timeline for notifying the FDA and customers?

Answered: 11 Skipped: 12

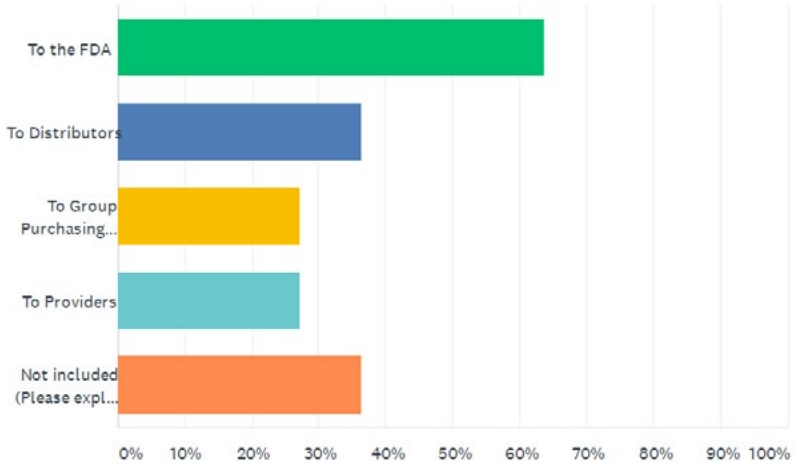



| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| FDA and Customers at the same time | 27.27% | 3 |
| Customers < one week after notifying FDA | 36.36% | 4 |
| Customers 1-2 weeks after notifying FDA | 0.00% | 0 |
| Other: Please Specify | 36.36% | 4 |
| TOTAL | | 11 |

## Manufacturers Task Force Survey Results

Q9 Does your organization include the UDI in your recall notices? (Check all that apply)

Answered: 11 Skipped: 12




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| To the FDA | 63.64% | 7 |
| To Distributors | 36.36% | 4 |
| To Group Purchasing Organizations | 27.27% | 3 |
| To Providers | 27.27% | 3 |
| Not included (Please explain why) | 36.36% | 4 |
| Total Respondents: 11 | | |

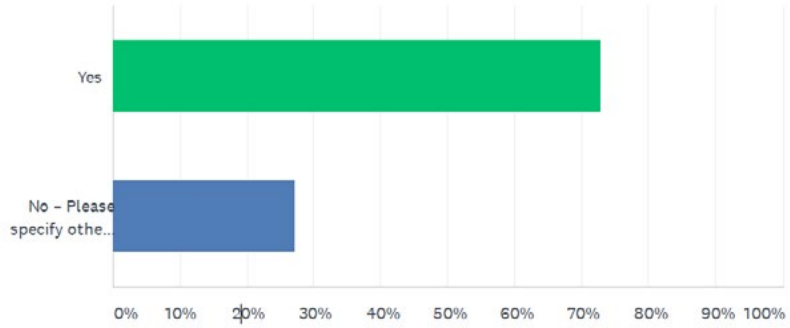
## Manufacturers Task Force Survey Results

Q10 If your organization does not include UDI in recall notices, what would increase your likelihood of including the UDI going forward?

Answered: 6 Skipped: 17

Q11 Do you use the FDA March 2020 Procedure Manual[2] to determine what recall information is submitted?

Answered: 11 Skipped: 12

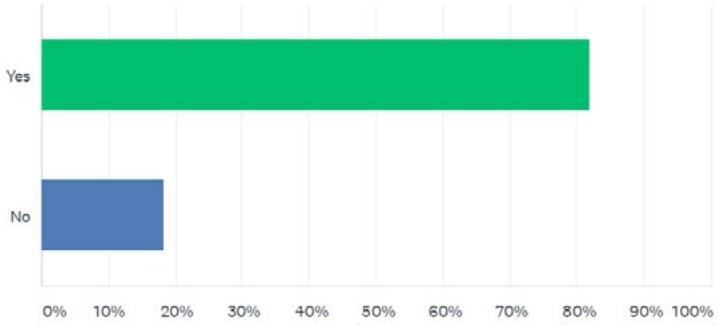



| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes | 72.73% | 8 |
| No – Please specify other guidance source: | 27.27% | 3 |
| TOTAL | | 11 |

## Manufacturers Task Force Survey Results

Q12 Do you have assigned contacts at FDA that you interact with on a regular basis, e.g., FDA Division Recall Coordinator (DRC) for assigned state of region?

Answered: 11 Skipped: 12




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes | 81.82% | 9 |
| No | 18.18% | 2 |
| TOTAL | | 11 |

## Manufacturers Task Force Survey Results

Q13 What does your organization consider to be the biggest pain point in the recall process?

Answered: 11 Skipped: 12

Q14 Please share any additional information that would provide insight into the recall process from the manufacturer's perspective.

Answered: 2 Skipped: 21

## APPENDIX E – DISTRIBUTORS TASK FORCE SUMMARY REPORT

The Distributors Task Force Lead was Vicky Lyle, VP Industry Associations Owens & Minor.

### Background

The distributors task force was comprised of representatives from four distribution companies: two large, one midsize, and one representing multiple small distributors. The task force members examined their own company's recall processes, identified pain points and areas of opportunity, reviewed current workflows, functional areas involved in the recall process, and recommendations for improved processes. Distributors participated in a survey to identify cost and potential savings of using the UDI as part of the recall process. Survey responses can be found in Appendix F.

### Mission and Challenges

The mission of the Distributors Task Force included:

- Document high level current state workflows/swim lanes,
- Identify triggers for actions by distributors, e.g., sources of recall notices received, formats (e.g., electronic, PDF's, etc.), and post-recall wrap-up,
- Processes for validation and distribution of information (use cases),
- Identify and document any available information on costs or resource requirements, and
- Recommendations for future enhancements.

The Task Force brainstormed top challenges for Distributors. Those included:

- Determining the first ship date of the recalled product,
- Trying to get a complete list of effected lot numbers – combined list the incorporates all warehouse shipments,
- Getting list into a format that can be used – not a PDF. Need an electronic format.
- Lack of consistency in how manufacturers communicate recalls,
- Returns process varies on a case-by-case basis – distributor may be bypassed, and end user send product directly back to manufacturer,
- Timeliness of communications and the response of the hospital providers, and
- Process variation between large acute, non-acute and small independent distributor responses.

### Current Situation

The current recall process creates confusion in the market and is time consuming. Manufacturers send the recall notices in various formats including e-mail with PDF, e-mail with Excel, and mailed hard copy. Distributors receive the notices from the manufacturer, FDA, or from the customer. Although distributors may have a central regulatory department for recalls, recall notices are often sent to the facility that shipped the product. Distributors are required to notify all customers that received the product of the recall and depending on the manufacturer

instructions may or may not be required to manage the recall return from the provider. See high level distributors' recall process below.

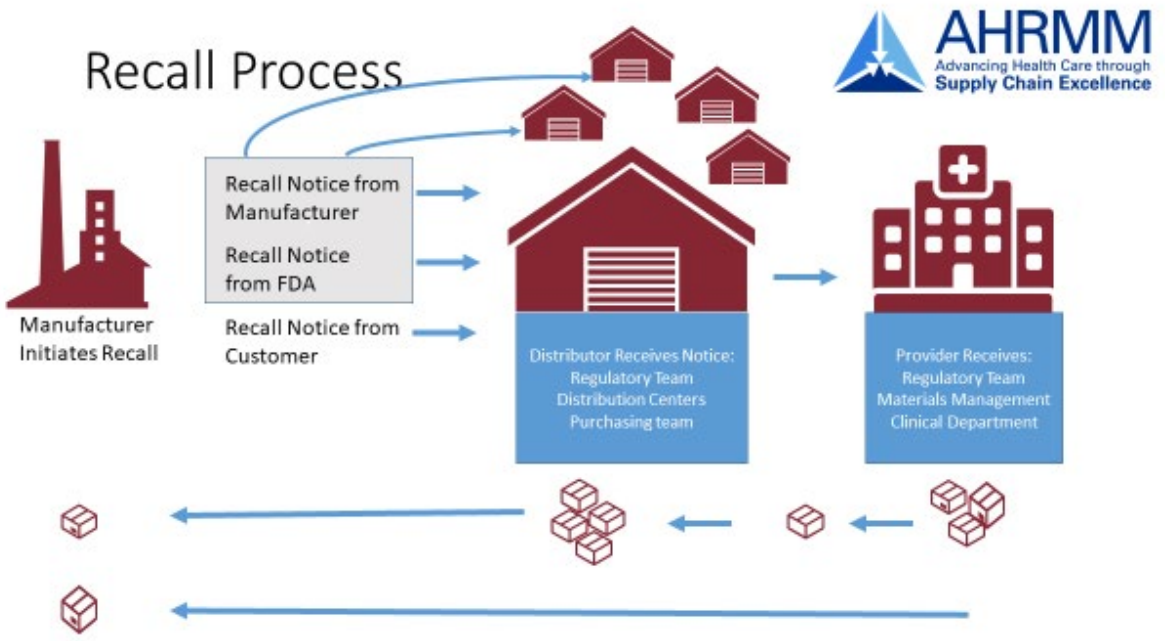



Figure: Overview of Distributors' Recall Process

While distributors carry the UDI in their product master files for order transactions and reporting, they do not carry the UDI for Class I non-implantable devices in their warehouse management systems. The reason is that it is too expensive to capture for large volume of products with very fast turnover. For this reason, the distributor utilizes the first ship date and the last ship date to identify the transactions that may have had been impacted by the recall and whether there is potential to have shipped the product to a customer.

## Projects Completed

The Distributors Task Force completed the following projects to fully evaluate UDI use and potential impacts on medical device recalls:

- Developed Distributors Survey to illicit feedback to inform process steps and cost estimate of current time/function vs. if UDI adopted.
- Summary of survey key results:
    - No respondents were capturing UDIs in their warehouse management systems but were capturing the UDIs in their ERP systems as an attribute, and
    - Average days to process a recall was 43 days (varies based on type of recall) versus estimated days if UDI was available 25 days.

- If UDI was available, the recall would:
  - Be initiated quicker,
  - Reduce the risk of placing affected items into the network,
  - Improve ability to contact customers who had been shipped affected product, and
  - Reduce number of facilities impacted by recall activities.
  - Improve systematic approach to isolate recalled products across a distributors network.
  - Created action categories to capture hours spent on recall processing by role.

### Current Process Pain Points

The following process pain points were identified by the Distributors Task Force:

- Determining the first ship date of the recalled product. This is required to identify the customers that could have potentially received the product.
- Trying to get a complete list of effected lot numbers. A combined list that incorporates all warehouse shipments is needed.
- Getting the list into a format that can be used – not a PDF. Need an electronic format that can be imported into distributor's information systems.
- Lack of consistency in how manufacturers communicate recalls.
- Returns process varies on a case-by-case basis – distributor may be bypassed, and end user required to send product directly back to manufacturer.
- Timeliness of communications from the manufacturer.
- Slow response time from hospital providers.
- Process variation between large acute, non-acute and small independent distributor responses

### Recommended Practices

After analyzing current processes and considering ways to improve the recall process, the distributor task force provided the following recommendations:

- Recall notices should be electronic and in a consistent format that can be imported into a distribution system.
- Recalls should have the UDI, First Ship Date and Last Ship Date.
- Recalls should be housed in a central repository that can be accessed by both the distributor and provider with consistent information sharing.
- Recall return processes need to be clear and consistent so distributors can provide accurate communication to its customers.

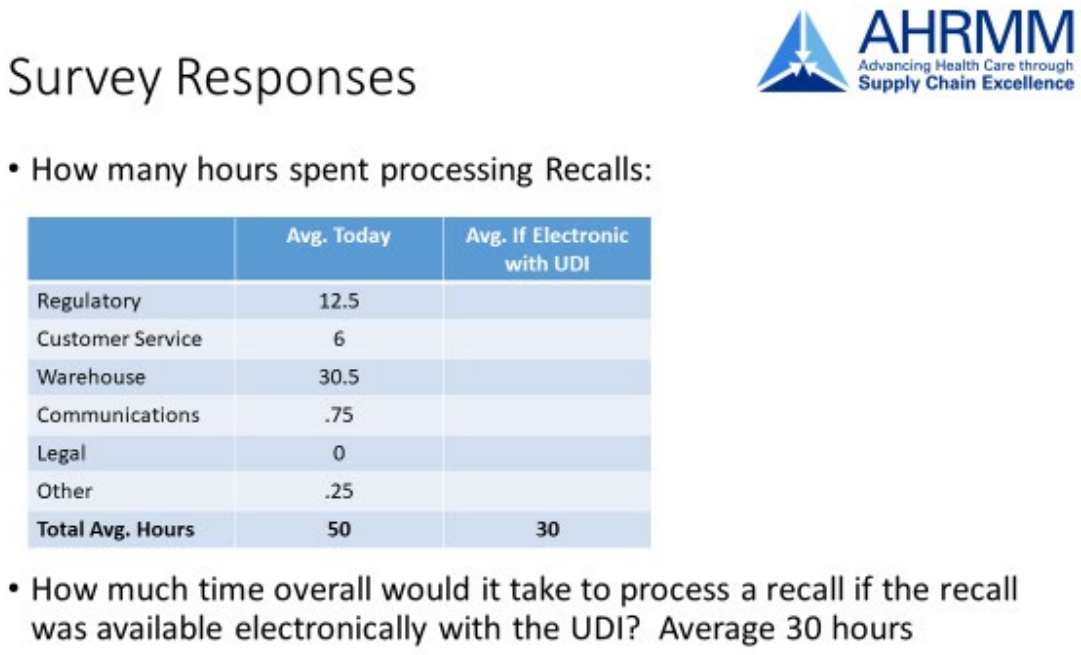
Distributors understand there will be cost involved in adding the UDI to its process, but also understands it would help to capture the recalled products more accurately and more quickly remove the recalled product from the shelf. The task force attempted to identify the costs and benefits of incorporating the UDI into the recall process and moving to an electronic process.

## Costs Benefits Analysis

The table provided at the end of this section is intended to serve as a template for use by distributors in completing an internal costs and benefits analysis for their company and operating divisions. This table presents fields for representative estimates of costs and benefits from use of UDIs for enhanced medical device recall activities.

Distribution survey respondents reported that currently on average they spend 50 hours managing a recall to closure. They estimate that if UDIs were used throughout the recall process they would spend an average of 30 hours which is a 40% reduction in time which would assist in accomplishing the recommended practices.

Estimates for time impacts were derived from the survey results. See Appendix F – Distributor Task Force Survey Results – Questions 6 and 7 for the source of the following information that was extracted to provide the estimated time impacts for the cost benefit analysis that follows.




| | Avg. Today | Avg. If Electronic with UDI |
|---|---|---|
| Regulatory | 12.5 | |
| Customer Service | 6 | |
| Warehouse | 30.5 | |
| Communications | .75 | |
| Legal | 0 | |
| Other | .25 | |
| **Total Avg. Hours** | **50** | **30** |

Figure: Summary of Distributor Survey Responses Questions 6 and 7

Costs of modification for software were also estimated from survey data. See Appendix F – Distributor Task Force Survey Results – Questions 10 for the source of the following information extracted to provide the estimated costs for modification to distributor computer systems for the cost benefit analysis that follows.

## Survey Responses

- Systems Impacted:
  - Warehouse Management
  - Master Data Management
  - Other
- Cost to change systems: $100K - >$500K
- Other Cost: Employee training in all distribution centers throughout the world.

FIGURE: SUMMARY OF DISTRIBUTOR SURVEY RESPONSES QUESTION 10

**AHRMM LUC UDI Impact on Recalls Workgroup**

**Estimated Costs associated with Recalls**

**Task Force Name: Distributor**

| | Current Process by Recall Class | | | If UDI Utilized adjust inputs by Recall Class | | |
|---|---|---|---|---|---|---|
| | Class 1 | Class 2 | Class 3 | Class 1 | Class 2 | Class 3 |
| **Add hours spent by action categories by class of recall** | | | | | | |
| Regulatory compliance with recall instructions | | | | | | |
| General Customer Service | | | | | | |
| Warehouse- checking/removing affected products | | | | | | |
| Warehouse-processing product returns | | | | | | |
| Communication with Manufacturer | | | | | | |
| Communication with affected Customers | | | | | | |
| Legal review | | | | | | |
| | | | | | | |
| | | | | | | |
| **Inputs** | | | | | | |
| time spent by role (hrs) | | | | | | |
| add role titles performing the above actions | | | | | | |
| | | | | | | |
| total time spent (hrs) | | | | | | |
| total dollars spent | | | | | | |
| | | | | | | |
| number in recalls in a specified time e.g.calendar year | | | | | | |

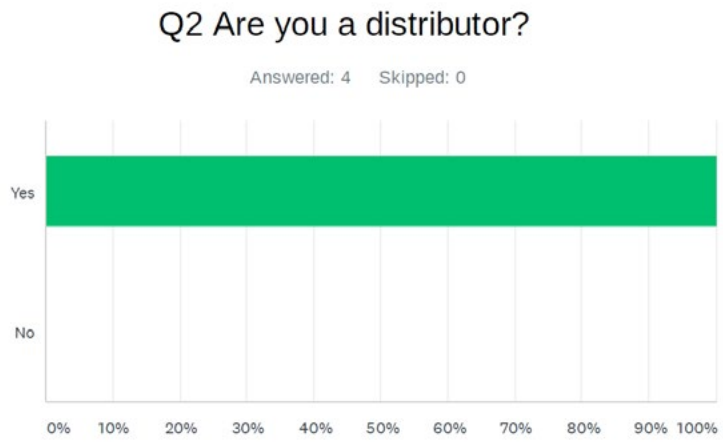
TABLE: SAMPLE COSTS BENEFTS ANALYSIS

## APPENDIX F – DISTRIBUTORS TASK FORCE SURVEY RESULTS

This Appendix presents the results collected from the survey tool on UDI Impacts developed and distributed by the Distributors Task Force. Q1 was a request for responder's email address and is not included here.

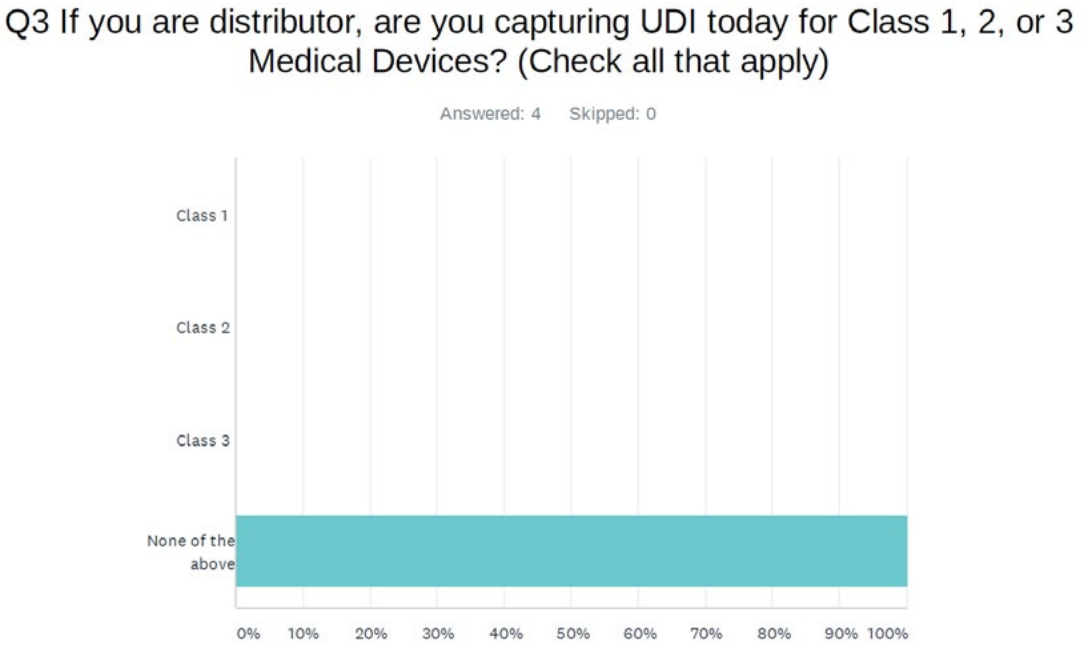
Note: The survey was completed in the 3rd and 4th quarter of 2020.

### Distributors Task Force Survey Results




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes | 100.00% | 4 |
| No | 0.00% | 0 |
| TOTAL | | 4 |

## Distributors Task Force Survey Results

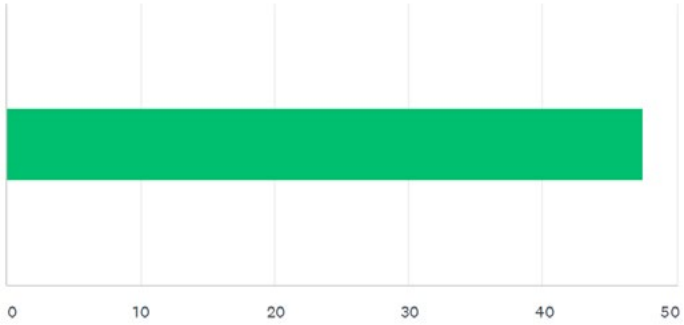



| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Class 1 | 0.00% | 0 |
| Class 2 | 0.00% | 0 |
| Class 3 | 0.00% | 0 |
| None of the above | 100.00% | 4 |
| Total Respondents: 4 | | |

## Distributors Task Force Survey Results

Q4 On average how many days are spent processing a recall - from the time of notification to the time of closure?

Answered: 4 Skipped: 0




| ANSWER CHOICES | AVERAGE NUMBER | TOTAL NUMBER | RESPONSES |
|---|---|---|---|
| | 48 | 190 | 4 |
| Total Respondents: 4 | | | |

| # | | DATE |
|---|---|---|
| 1 | 14 | 12/16/2020 9:54 PM |
| 2 | 21 | 12/16/2020 9:47 PM |
| 3 | 95 | 12/16/2020 9:39 PM |
| 4 | 60 | 11/25/2020 1:20 PM |

## Distributors Task Force Survey Results

### Q5 What job functions are involved in your recall process and on average how many hours total are spent processing a recall?

Answered: 4 Skipped: 0

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Regulatory | 100.00% | 4 |
| Customer Service | 100.00% | 4 |
| Warehouse | 100.00% | 4 |
| Communications | 100.00% | 4 |
| Legal | 75.00% | 3 |
| Other | 50.00% | 2 |

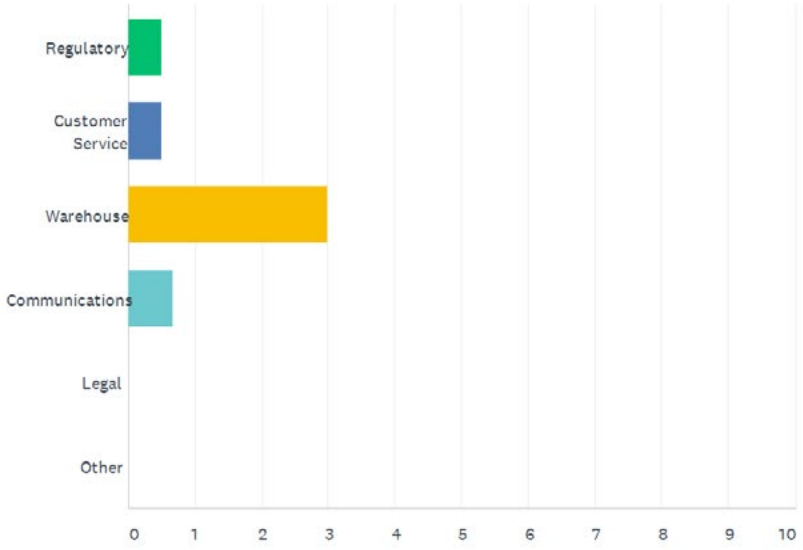
| # | REGULATORY | DATE |
|---|---|---|
| 1 | 20 | 12/16/2020 9:54 PM |
| 2 | 2-80 depending on the recall | 12/16/2020 9:47 PM |
| 3 | 2 FTE's; Approx 4 hours to process a single recall | 12/16/2020 9:39 PM |
| 4 | 2 | 11/25/2020 1:20 PM |
| # | CUSTOMER SERVICE | DATE |
| 1 | 20 | 12/16/2020 9:54 PM |
| 2 | 0 | 12/16/2020 9:47 PM |
| 3 | 4 hours on a single recall to contact and log responses for record-keeping | 12/16/2020 9:39 PM |
| 4 | 0 | 11/25/2020 1:20 PM |
| # | WAREHOUSE | DATE |
| 1 | 20 | 12/16/2020 9:54 PM |
| 2 | 2-20 depending on recall | 12/16/2020 9:47 PM |
| 3 | 2 FTE per site x 40 facilities; 2 hours per recall | 12/16/2020 9:39 PM |
| 4 | 2 | 11/25/2020 1:20 PM |
| # | COMMUNICATIONS | DATE |
| 1 | 0 | 12/16/2020 9:54 PM |
| 2 | n/a | 12/16/2020 9:47 PM |
| 3 | This is part of the customer service response | 12/16/2020 9:39 PM |
| 4 | 3 | 11/25/2020 1:20 PM |
| # | LEGAL | DATE |
| 1 | 0 | 12/16/2020 9:54 PM |
| 2 | n/a | 12/16/2020 9:47 PM |
| 3 | N/A | 12/16/2020 9:39 PM |

| # | OTHER | DATE |
|---|---|---|
| 1 | 0 | 12/16/2020 9:54 PM |
| 2 | AP Service fee - 1 hour per recall | 12/16/2020 9:39 PM |

## Distributors Task Force Survey Results

Q6 If the recall information was available electronically with the UDI information, allowing you to scan the barcode on the product, how many hours would this save?

Answered: 4 Skipped: 0




| ANSWER CHOICES | AVERAGE NUMBER | TOTAL NUMBER | RESPONSES |
|---|---|---|---|
| Regulatory | 1 | 2 | 4 |
| Customer Service | 1 | 2 | 4 |
| Warehouse | 3 | 12 | 4 |
| Communications | 1 | 2 | 3 |
| Legal | 0 | 0 | 2 |
| Other | 0 | 0 | 2 |
| Total Respondents: 4 | | | |

| # | REGULATORY | DATE |
|---|---|---|
| 1 | 0 | 12/16/2020 9:54 PM |
| 2 | 0 | 12/16/2020 9:47 PM |
| 3 | 1 | 12/16/2020 9:39 PM |
| 4 | 1 | 11/25/2020 1:20 PM |

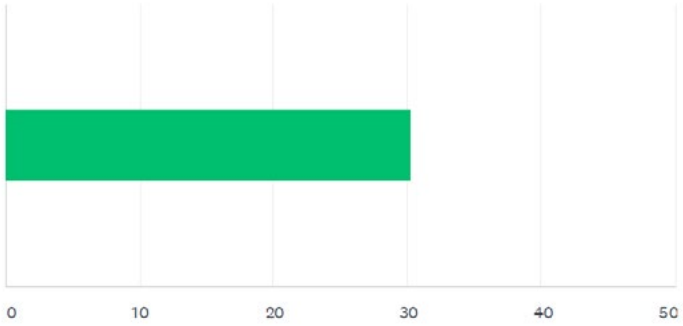
## Distributors Task Force Survey Results

| # | CUSTOMER SERVICE | DATE |
|---|---|---|
| 1 | 0 | 12/16/2020 9:54 PM |
| 2 | 0 | 12/16/2020 9:47 PM |
| 3 | 2 | 12/16/2020 9:39 PM |
| 4 | 0 | 11/25/2020 1:20 PM |
| # | WAREHOUSE | DATE |
| 1 | 10 | 12/16/2020 9:54 PM |
| 2 | 0 | 12/16/2020 9:47 PM |
| 3 | 1 | 12/16/2020 9:39 PM |
| 4 | 1 | 11/25/2020 1:20 PM |
| # | COMMUNICATIONS | DATE |
| 1 | 0 | 12/16/2020 9:54 PM |
| 2 | 0 | 12/16/2020 9:47 PM |
| 3 | 2 | 11/25/2020 1:20 PM |
| # | LEGAL | DATE |
| 1 | 0 | 12/16/2020 9:54 PM |
| 2 | 0 | 12/16/2020 9:47 PM |
| # | OTHER | DATE |
| 1 | 0 | 12/16/2020 9:54 PM |
| 2 | 0 | 12/16/2020 9:47 PM |

## Distributors Task Force Survey Results

### Q7 If the recall information was available electronically with the UDI information, how much time overall would it take to process a recall?

Answered: 4 Skipped: 0




| ANSWER CHOICES | AVERAGE NUMBER | TOTAL NUMBER | RESPONSES |
|---|---|---|---|
| | 30 | 121 | 4 |
| Total Respondents: 4 | | | |

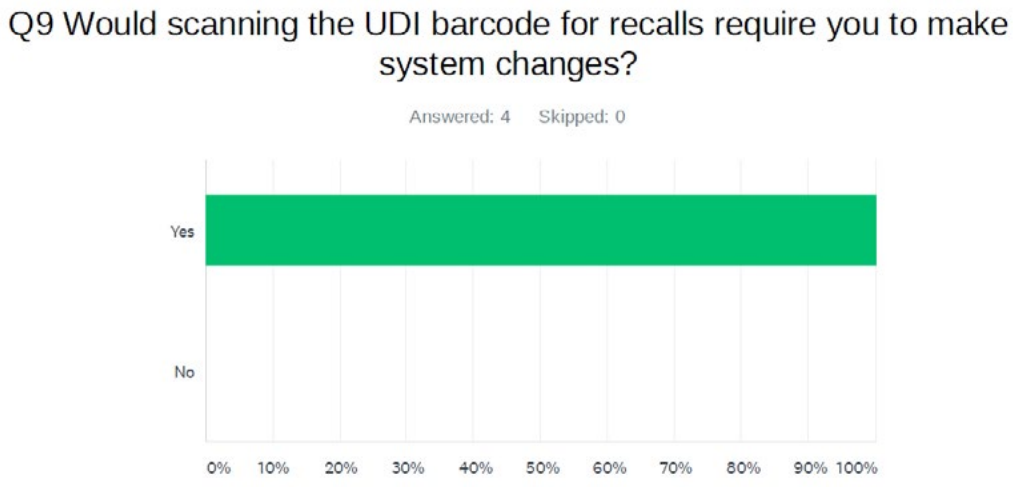
| # | | DATE |
|---|---|---|
| 1 | 13 | 12/16/2020 9:54 PM |
| 2 | 26 | 12/16/2020 9:47 PM |
| 3 | 37 | 12/16/2020 9:39 PM |
| 4 | 45 | 11/25/2020 1:20 PM |

### Q8 Beside time savings, are there other benefits (quantitative & qualitative) to creating an electronic recall process?

Answered: 4 Skipped: 0

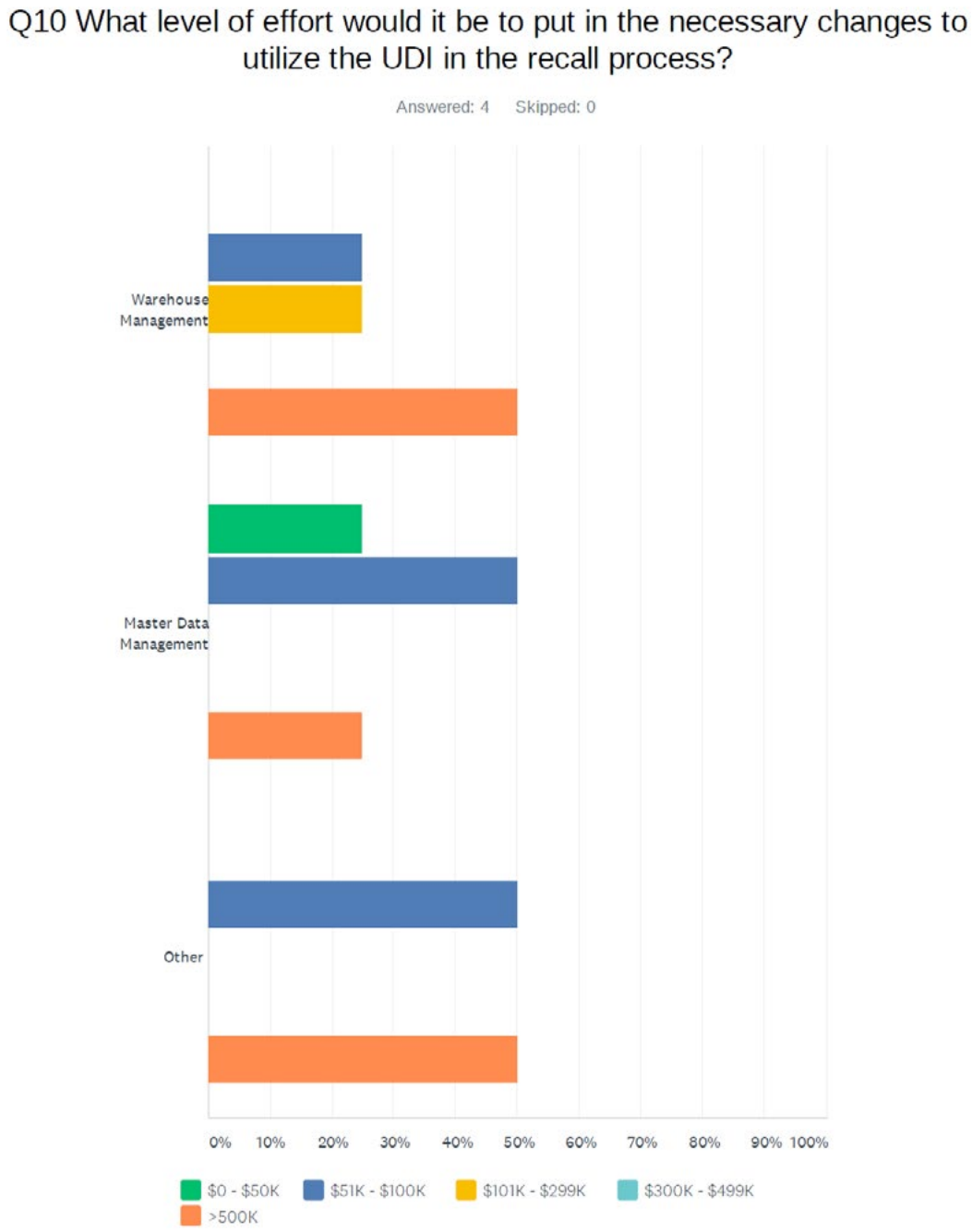
| # | RESPONSES | DATE |
|---|---|---|
| 1 | Quicker to initiate, more accurate information. | 12/16/2020 9:54 PM |
| 2 | none | 12/16/2020 9:47 PM |
| 3 | Reduction in the risk of placing affected items in the network; Improved ability to contact customers with affected product; Reduction in the number of facilities impacted by recall activities; Improved systematic approach to isolate recalled items across our network. | 12/16/2020 9:39 PM |
| 4 | accuracy and quality along with time savings | 11/25/2020 1:20 PM |

## Distributors Task Force Survey Results




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes | 100.00% | 4 |
| No | 0.00% | 0 |
| TOTAL | | 4 |

## Distributors Task Force Survey Results



## Distributors Task Force Survey Results

| | $0 - $50K | $51K - $100K | $101K - $299K | $300K - $499K | >500K | TOTAL |
|---|---|---|---|---|---|---|
| Warehouse Management | 0.00%<br>0 | 25.00%<br>1 | 25.00%<br>1 | 0.00%<br>0 | 50.00%<br>2 | 4 |
| Master Data Management | 25.00%<br>1 | 50.00%<br>2 | 0.00%<br>0 | 0.00%<br>0 | 25.00%<br>1 | 4 |
| Other | 0.00%<br>0 | 50.00%<br>1 | 0.00%<br>0 | 0.00%<br>0 | 50.00%<br>1 | 2 |

### Q11 Besides system cost, are there other costs that would be added by creating an electronic recall process?

Answered: 4 Skipped: 0

| # | RESPONSES | DATE |
|---|---|---|
| 1 | Employee training in over 100 distribution centers throughout the world. | 12/16/2020 9:54 PM |
| 2 | none | 12/16/2020 9:47 PM |
| 3 | Yes, training, other IT interfaces could be impacted, increased warehouse space to store one lot number per location for all SKU's. | 12/16/2020 9:39 PM |
| 4 | training | 11/25/2020 1:20 PM |

## APPENDIX G – IT TECHNOLOGY AND DATA TASK FORCE SUMMARY REPORT

The IT Technology and Data Task Force Co-Leads were Mike Nolan, President AIS, and Vicky Lyle, VP Industry Associations, Owens & Minor.

### Background and Analysis

The IT task force was comprised of representatives from software application and service providers. The task force was assigned the task of identifying the data fields associated with initializing the recall of a medical device as well as identifying opportunities to improve downstream systems' ability to capture the recall in a timely and consistent manner to remove the product from the supply chain as quickly as possible.

- Review of past documents (gain insights from previous work groups):
  - LUC, SMI,
  - Swim lanes to determine who is involved, processes, etc., and
  - Recall details.
- Collect relevant materials (black box theory – inputs & outputs of process):
  - What regulations are in play other than UDI?
  - What documents are now used to initiate a recall – what data (fields) are required?
  - What documents are now used to manage a recall? At provider, at distributor, at manufacturers, and the FDA?

### Current Situation

The task force determined there were multiple ways of submitting a recall to the FDA, including FDA's e-Submitter, Email, and Mail (and infrequently by call-ins or faxes). The data in all three primary methods were inconsistent.

| Type | Description | Findings |
|---|---|---|
| E-Submitter | FDA's electronic recall process | Complex with more than 100 fields and is not specific to the health care field. |
| Email | Email to the FDA with PDF and Excel documents. | Multiple formats and inconsistent data elements. |
| Mail | Sent through postal service | Not timely enough and prone to data errors with manual entry of the recall. |

TABLE: METHODS FOR SUBMITTING RECALL DATA TO FDA

- At the beginning of analysis, it was determined there are well over 100 data fields built into the existing FDA recall systems.
- The task force briefly reviewed additional potential data sources from standards organizations to ensure all options were identified with no redundancies.
- A brief review into alternative data sources from the standards organizations revealed there was a potential for several hundred data fields, many that were redundant and/or many others that provided little value.
- To find out which of these data fields were significant, the task force reviewed the actual data fields reported to the FDA in the 6 representative recalls used by all task forces.

For additional information see: Appendix B – Work Group Structure and Task Forces, and sub sections 'Data Sources for the Six Representative Recalls' and 'Characteristics of the Six Representative Recalls.'

- Appendix B provides a table built of the fields found in the recalls reviewed and disclosed that there were only eight common fields used by all six standard recalls.
- During task force review, it was determined that of the 17 fields used, nine could be found in the GUDID database.
- By referencing the UDI DI in the GUDID over half of the fields needed to initialize a recall can be accessed without error or ambiguity.

Using a standard identifier across the health care segments is critical and UDI (DI and PI) would be the best approach. The data needed in the initial notification must be actionable, at least partially pending the addition of more information, i.e., lot numbers, serial numbers, etc. While not all products require a UDI today, it is significant future direction for health care.

### Recommended Simplification

A simple electronic Medical Device Recall System Prototype application was created to show health care stakeholders in the AHRMM LUC community how the recall initialization process could be made easier, more accurate, more immediate, and transparent. In the prototype, when a UDI is entered, the form would pre-populate required data from the GUDID automatically and the remaining required fields could be populated either through an upload process or manually.

If the model prototype is adopted, it could be used by the FDA to update the recall database automatically with a pending FDA review status to allow downstream systems to access this critical information on a timely basis to alert health care stakeholders in the supply chain.

Additionally, the FDA could leverage the IT structure and workflow developed by the UDI program for the GUDID and AccessGUDID as a model 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.

Using the UDI as a linking key and populating the electronic recall prototype with data from the GUDID would improve accuracy and reduce the burden on manufacturers. It would also enhance health care providers ability to respond quickly and accurately to a recall thereby improving patient safety.

The following graphic provides a high-level overview of the simplified process envisioned in the Medical Device Recall System Prototype. Appendix L provides a more detailed perspective on the Recall Model envisioned as a data modernization initiative to be considered.

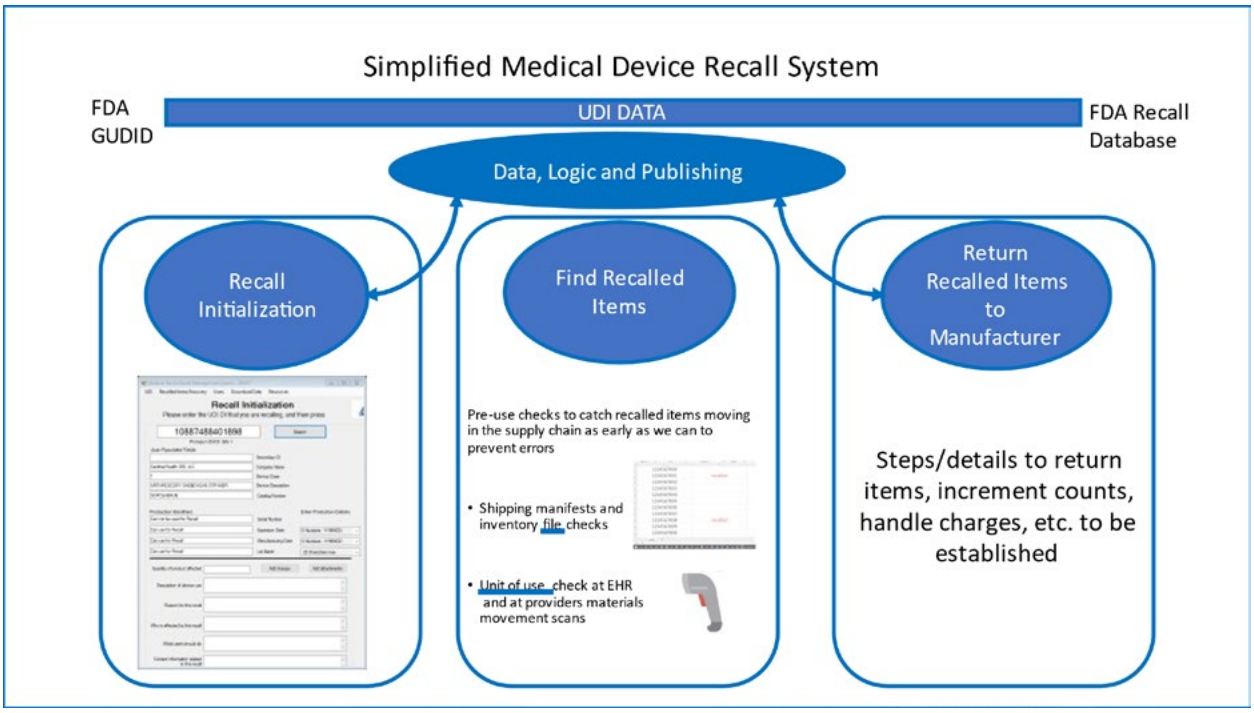



FIGURE: OVERVIEW OF SIMPLIFIED MEDICAL DEVICE RECALL SYSTEM

This system is envisioned to be cloud based. Entries will be made using an electronic interface to guide the user, check field entries for length and data type, check for entry in mandatory fields, check for authorized user ID of the person creating the recall. Entries will be shared as they are completed.

To overcome the delay in announcing a (pending) recall, the recall would be announced in stages with the initial notification containing enough information to be actionable based on initial reviews. The FDA official acceptance for a recall would signal a new release with the FDA entered fields, and additional announcements would be provided on as additional information became available to update the community until completion and a recall is no longer 'active.'

A full history of announcements regarding a specific recall will be maintained and available for viewing by all.

## APPENDIX H – PROVIDERS TASK FORCE SUMMARY REPORT

The Providers Task Force Co-Leads were Terri Nelson, Director Supply Chain Operations, CQVA Mayo Clinic, Amy Conway, Value Analyst Recall Coordinator, Mayo Clinic, and Joan Melendez, President, XcelrateUDI.

### Background and Analysis

The AHRMM LUC UDI Impacts on Recalls Work Group Providers Task Force was comprised of individuals who manage recall notifications which includes representatives from health care provider and recall management service organizations. The goal of this task force was to identify how recall notifications are managed and how current Recall Management practices incorporated the UDI into the process.

The Task Force first met in March 2020 and identified the following objectives that would be used to drive the activities of the group. These were to:

1. Review previous relevant studies (e.g., AHRMM LUC reports, SMI, other) for providers,
2. Document UDI use in recall notes for providers including GPO roles and current representative workflows/swim lanes, and gap analysis, post-recall wrap-up and metrics/reports,
3. Identify and document any available information on costs or resource requirements,
4. Identify representative use cases and best practices for improvements in UDI use for recalls,
5. Summarize recommendations for enhancements and educational needs/methods to share best practices and enhance recall processes.

### Current Situation

The task force reviewed previous completed UDI work which helped to outline recall management processes by providers, identify recall management "pain points", develop a recall cost calculator and review best-in- practice principles. As part of this process a survey was created to obtain more in-depth input from health care Providers regarding their current processes for managing recall notifications, as well as input on the implications of digitizing that process and expanding the use of the UDI.

The provider members of taskforce developed a Recall Cost Calculator Tool. This incorporated reviews and processes modeled by provider members – none of which were using UDIs at the time of the study. The costs were determined using the time in hours spent administering the steps of the recall process, by role of the individual or department of the provider organization, and by class of recall by device type. The average cost/hour of the staff performing the recall actions was agreed upon by all participants at rates as projected and presented in the following example tables.

## Cost Calculator Modeling Highlights

| Recall Class | Type of Device | Average Hours/Recall | Primary Role | Cost/Recall |
|---|---|---|---|---|
| Class I | Medical Surgical | 16 | Recall Coordinator | $ 480 |
| Class II | Medical Surgical | 29.25 | Recall Coordinator | $ 528 |
| Class II | Med Surg Par Inventory | 104 | Supply Chain | $3120 |
| Class II | Implantable | 99.5 | Department | $2985 |
| Class II | Laboratory/Pathology | 17 | Recall Coordinator | $ 510 |
| Class II | IV Pump | 27.5 | Bio Med Engineering | $ 825 |

TABLE: COST CALCULATOR MODELING HIGHLIGHTS

One provider calculated that it processed 42 Class I Medical Surgical recalls in a 12-month period at an estimated cost of $20,160.

## Case Studies Reviews

The following information presents the summary findings from the results of individual case studies completed by the Providers Task Force.

**Product Recall: Case Study #1**

Date of Notification: 12/17/20
Recalled Item Category: Clinical Lab/Pathology
Reason for recall: Yielding incorrect values.

**Timeline**:
12/30/20

- Recall was received from Manufacturer via FedEx.
- A search of purchase history determined potentially affected product being purchased.
- The items were used in the Clinical Lab/Pathology departments.
- The notice was entered into the recall database and an email communication was sent to all Clinical Lab/Path distribution lists with a requested due date of 1/4/21.

1/5/21

- All responses were received from affected areas.
- No affected product was found at any sites.
- The recall was closed in the system.
- An acknowledgment was sent to Manufacturer indicating that the notice was received and distributed to all affected or potentially affected sites.

**Product Recall: Case Study #2**

Date of Notification: 1/13/2021
Recalled Item Category: Med/Surg
Reason for recall: Open seals found in sterile packaging.

**Timeline**
1/13/21

- Recall notification was received from Distributer, with the original Manufacturer notice attached.
- The recall consisted of (1) item number and (1) affected lot.
    - Purchase was found onsite.
    - Notice and purchase history report was added to the recall system.
    - Purchase was shown to be in the department of Surgery.
- It was communicated to all Surgical departments.
- Recall was also sent to each individual that ordered the product within the last 2 years.

1/15/21

- Notice was communicated with a requested due date for response by 1/20/21.
- Responses were received but not from affected sites.

1/21/21

- Second notice was issued on to non-responding departments with a requested return date of 1/23/21.
- Recall is still not completed in the system.

**Product Recall: Case Study #3**

Date of Notification: 1/7/21
Recalled Item Category: BioMed
Reason for recall: Variability in tubing performance may lead to alarm situations.

**Timeline:**
1/19/21

- Recall was received from an internal source; it was not sent to the recall inbox.
- It was determined the item was tracked and maintained by Healthcare Technology Management (HTM) (the Mayo Clinic Division of Healthcare Technology Management, formerly known as Biomedical Equipment Services).
- A request was sent to HTM for a list of assets and their locations.
- The affected asset was found to be at one site.
- The recall was issued to HTM contacts with a requested response date of 1/22/21.

1/20/21

- HTM completed the recall, responding on behalf of all locations.

- The recall was closed in the system.
- An acknowledgment was sent to the Manufacturer indicating that the notice was received and distributed to all affected or potentially affected sites.

**Product Recall: Case Study #4**

Date of Notification: 1/7/21
Recalled Item: Med/Surg/Commodity
Reason for recall: Recalled item contained in kit.

**Timeline:**
1/11/21

- Recall notification was received from Manufacturer via email.
- A purchase history search indicated kits were purchased at all locations.

1/12/21

- Recall was entered into database as "Informational" – which indicates to end-users that there is no response required, that this for their information only.
- The recall was issued to all affected sites and departments:
    - Pharmacy
    - Ophthalmology
    - Radiology
    - Surgery
    - Emergency Department
    - Clinical Lab/Path
    - Nursing
    - Oncology
    - Respiratory
    - Dermatology
- Since no response was required, the recall was closed in the system on the same day it was sent.

1/13/21

- An acknowledgment was sent to the Manufacturer indicating that the notice was received and distributed to all affected or potentially affected sites.

## Costs Benefits Analysis Calculator Samples

This section provides a collection of templates for use by provider organizations in completing an internal costs and benefits analysis for their organization. Four different templates are provided including: Cost Calculator Sample Class I Recall Med/Surg, Cost Calculator Sample Class II Recall Par Stock, Cost Calculator Sample Class II Recall Implantable, and Cost Calculator Sample Class II Recall BioMed.

### Cost Calculator Sample Class I Recall Med/Surg

| | | | |
|---|---|---|---|
| **AHRMM LUC UDI Impact on Recalls Workgroup** | | | |
| **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 Example** | | **Future Process** |
| RECALL PRODUCT: ≥1 recall of same issue may have been reported | **Class 1 Recall** | | **Class 1 Recall** |
| **Medical/Surgery Device** | ***add hours below by action category 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/compare to recall notice product information | **3.00** | | |
| notification of internal stakeholders | **2.00** | | |
| communication back to internal recall coordinator | **2.50** | | |
| major actions | | | |
| destroying product | **1.00** | | |
| gathering affected products for return | **1.00** | | |
| logistics of product returns | **1.00** | | |
| patient notification | | | |
| recall closure and documentation | **1.00** | | |
| Repeat notifications, | | | |
| expanded info | **3.00** | | |
| Repeat notifications, | | | |
| no new info | **1.00** | | |
| **Inputs** | | | |
| time spent by role (hrs) | | | |
| - Recall Coordinator | **13.00** | | |
| - SCM/End-User | **3.00** | | |
| total time spent (hrs) | **16.00** | | |
| | | | |
| avg hourly salary by role Range 25 - 50 per hour | **$30.00** | | |
| | | | |
| total dollars spent | | | |
| | **$480.00** | | |
| Determine extent of time and dollars:<br>number of Class 1 recalls of same type of action process steps in a specified time e.g.calendar year | | | |

TABLE: SAMPLE COST CALCULATION FOR CLASS I RECALLS

## Cost Calculator Sample Class II Recall Par Stock

| | | | |
|---|---|---|---|
| **AHRMM LUC UDI Impact on Recalls Workgroup** | | | |
| **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 Recall** | | **Class 2 Recall** |
| **Medical/Surgery Device** | ***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 | **37.50** | | |
| Destroying product: | **0.50** | | |
| Returning product to manufacturer: | **0.50** | | |
| Ordering replacement product/replenish | **37.50** | | |
| Computer updating for inventory: | **0.25** | | |
| Responding orgnization's policy on recall notice reporting: | **0.75** | | |
| use # of par unit areas, # of items effected in each area, hours to do work | | | |
| Repeat notifications, | | | |
| expanded info | **13.00** | | |
| Repeat notifications, | **6.00** | | |
| no new info | | | |
| **Inputs** | | | |
| time spent by role (hrs) | | | |
| - Recall Coordinator | **21.00** | | |
| - SCM/End-User | **83.00** | | |
| total time spent (hrs) | **104.00** | | |
| | | | |
| avg hourly salary by role Range 25 - 50 per hour | **$30.00** | | |
| | | | |
| total dollars spent | **$3,120.00** | | |
| | | | |
| 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 | | | |

TABLE: SAMPLE COST CALCULATOR SAMPLE FOR CLASS II RECALL PAR STOCK

## 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:<br>number of Class 2 recalls of same type of action process steps in a specified time e.g.calendar year | | | |

TABLE: SAMPLE COST CALCULATOR SAMPLE FOR CLASS II CLASS II RECALL IMPLANTABLE

## Cost Calculator Sample Class II Recall BioMed

| | | | |
|---|---|---|---|
| **AHRMM LUC UDI Impact on Recalls Workgroup** | | | |
| **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** | | **Class 2** |
| **BioMed - Heathcare Technology Maintenance (HTM)** | ***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 | **1.00** | | |
| notification of internal stakeholders | **2.00** | | |
| communication back to internal recall coordinator | **1.00** | | |
| major actions | | | |
| Identify and gather affected products | **0.50** | | |
| Destroying product: | **0.00** | | |
| Returning product to manufacturer: | **1.50** | | |
| Ordering replacement product | **1.00** | | |
| Computer updating for inventory: | **0.50** | | |
| Responding orgnization's policy on recall notice reporting: | **0.25** | | |
| Other recall-related tasks: Setting up Work Orders for each asset | **2.00** | | |
| **Inputs** | | | |
| time spent by role (hrs) | | | |
| - Recall Coordinator | **4.50** | | |
| - SCM/End-User | **21.00** | | |
| total time spent (hrs) | **25.50** | | |
| | | | |
| avg hourly salary by role Range 25 - 50 per hour | **$30.00** | | |
| total dollars spent | **$765.00** | | |
| | | | |
| 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 | | | |

TABLE: SAMPLE COST CALCULATOR SAMPLE FOR CLASS II CLASS II RECALL BIOMED

## Current Recall Process Flow

A Current Recall Process Flow helped to visualize the number of steps by the areas directly involved in the recall chain. Where applicable the information gathered from the results of the providers survey were used to inform where gaps exist and where adoption of the UDI would improve the overall recall process.

(Note: Please see 'Recall Management Process Workflow' for the graphic representation developed by the Provider Task Force.)

## Provider Survey Results Summary Perspectives

The results of the Provider survey were reviewed by the task force to assess the potential gaps in the use of the UDI and to inform additional deliverables. The 14-question survey was distributed with 23 individual respondents completing the survey. Results of three key areas specifically related to UDI adoption and use are highlighted below. (For complete results refer to Appendix I: Provider Survey Results.)

| **If the UDI DI (device identifier(s)) and/or the UDI PI (production identier(s)) were included in the recall notice would your organization use it? (% allocation of 'Yes' responses listed below)** | **% Yes** |
|---|---|
| Yes, if it were in the form of a scannable bar code | 50% |
| Yes, if it were in a format that could be downloaded | 20% |
| Yes, only if it had a barcode with human-readable identifiers | 15% |

| **Does your organization currently use the UDI when provided in the recall notice?** | **80% = No** |
|---|---|
| **Responders were asked: If they replied "NO" to select why from a list of reasons. The top reasons are listed below:** | |
| Our Supply Chain Technology/ERP does not have the functionality to capture UDI | |
| Our Electronic Health Record/Ancillary Clinical Systems have not been enabled or use the functionality to capture UDI | |
| Cost prohibitive | |
| Not familiar with the FDA, ONC or CMS UDI regulations and guidelines | |

| **From your perspective what do you consider to be the primary pain point in the recall process? (responders could check 'all that apply' from a list of 10). Reasons having a total of 10% or greater responses are listed below.** | |
|---|---|
| There is no consistent manner describing the product, e.g., catalog number, product number, item numbers, order number, UDI | 30% |
| Recall notices are not in a standard format | 15% |
| Too many notifications of the same recall are received by my organization | 10% |
| No recall notices received; If a recall notice has not been received it takes too much time for the manufacturer to respond | 10% |

## Proposed Practices to Key Recall Process Stakeholders

### Providers

- Key findings of the survey identified the need for education of the role of the UDI within recall notifications and associated processes.
- The task force identified leading practices which would include creating an organizational policy and procedure to formalize the recall process.
- Refer to Recall Procedure Template attachment.
- Health care providers should consider assigning a recall coordinator or a point person responsible for overall coordination of the process.
- Refer to Recall Coordinator Key job responsibilities.

### Manufacturers

- The taskforce proposes that manufacturers use a standard recall notification template formatted to easily retrieve product identifiers, including manufacturer number, catalog numbers, lot number, serial number, production, and expiration date, etc. in a format that easily readable/scannable such as the UDI-DI and UDI-PI.
- The template should use the same general headings and format each time regardless of the Class of the Device Recall to enable the provider organization to readily complete recommended actions.

### FDA

- Improve timely posting of FDA–CDRH workflow problems, patterning what other divisions post immediately such as the posting processes used by the Center for Drug Evaluation and Research (CDER) and Center for Food Safety and Applied Nutrition (CFSAN).
- Need active advocacy to change FDA processes to include:
  a. Timely responses
     i. From FDA to providers and manufacturers
     ii. From manufacturers to providers in a retrievable format
  b. Revise current recall notification from a manual process to an electronic process.

### Health Care Stakeholder Professional Organizations

- The cost calculator tool should be promoted by AHRMM, AHVAP, AdvaMed, SMI and other health care professional organizations and be made available to users.
- The task force is advocating working with professional health care organizations such as but not limited to AHVAP (Association Healthcare of Value Analysis Professionals) and AHRMM (Association of Health Care Resource Materials Managers) as a platform to educate and promote UDI awareness to providers. This could occur with joint educational sessions at conferences, publications, email blasts, blogs and other avenues of communication.

## Recall Management Sample Policy and Procedure

The Provider Task Force developed the following Recall Management Sample Policy document for provider organizations to use as a base for developing a comparable policy document for individual organizations.

## Recalls Management: Product/Medical Device, Hazards Notices or Alerts Procedure

**Scope**
Applies to all personnel involved in the notification identifying a product/medical device recall, hazard notice or alert, for all products with the exception of pharmaceuticals and food.

**Purpose**
To provide direction for managing notification of all product/medical device recalls, hazard notices or alerts to ensure appropriate and timely response.

**Procedure**

| Responsible Position | Activity |
|---|---|
| Supply Chain Management Staff, and/or other Departments | 1. Route the following received correspondence to the Recall Coordinator if any of the following key words appear.<br>• Key words: Product Recall, Recall Notification, Hazard Notice, Alert, Urgent Medical Device Recall or Removal, Product Notification, Important Product Advisory Notice, Mayo Clinic Internal Recall Notification, or other wording that suggests a product/medical device recall, hazard notice, or alert |
| Supply Chain Management Staff | 2. Date/time stamp the notification, scan, and send via e-mail to _____ |
| Recall Coordinator | 3. Enter the following into the Product Recall Management System Database<br>a. Notice information<br>b. Response priority: Follow the appropriate response times - FDA Class I: within 1 business day; - FDA Class II: within 3 business days; - FDA Class III: within 5 business days.<br>**For FDA Class I**<br>a. Notify Directors of Supply Chain Operations, Director of Value Analysis/Value Analysis Coordinators, Recall Coordinators, and/or their designees of any.<br>4. Search Supply Chain Management Information System for recalled product purchases and \or potential product purchases.<br>5. Send recall notification to affected or potential areas.<br>6. Document all actions taken and search results.<br>7. Product Recall Management Database System sends notice dependent upon the type of Recall. Purchase history defined and documented in the recall notice.<br>8. If patient or employee safety risk identified, Recall Notification Form is distributed to the Medical Product/Device Recall Response Team Executive Team which include Clinical MD, Administrative Leader & Patient Safety Officer. |

| Responsible Position | Activity |
|---|---|
| Recall Response Team | 9. Medical Product/Device Recall Response Executive Team accesses the need to activate Recall Response Team<br><br>**Membership:** Clinical and administrative leadership of departments and divisions affected by the recall, Legal, Risk Management, site and enterprise CPC liaisons, Public Affairs, subject matter experts of the risk to patients (e.g., Infection Prevention and Control, Radiation Safety Officer, Patient Safety), subject matter experts of the risk to employees (eg.HR, Occupational Health), Recall Coordinator and depending upon scope of recall a Management Engineering and Internal Consulting resource.<br><br>**Responsibilities**<br>a. Develop guidance for management of patients or employees.<br>b. Develop communications to be sent to patients or employees.<br>c. Oversee execution of recall to plan.<br>d. Document the following:<br>i. Recalled products or devices at all sites,<br>ii. Communications to affected patients or employees,<br>iii. Management of patients or employees to plan,<br>iv. Submit documents to Recall Coordinator for attachment to the recall within the Recall Management tool, and<br>e. Write a summary of the recall and distribute to the facility and enterprise departments or divisions that supplied the recalled product or device and enterprise Clinical Practice Committee. |
| Recall Coordinator | 10. Confirm and document responses to recall notification by affected user(s).<br><br>11. If no response to Recall notification after three attempts, provide Clinical Practice Committee (CPC) Secretary with list of non-responders. |
| Clinical Practice Committee (CPC) | 12. CPC notifies non-responders to complete requested web base recall response. |
| Recall Coordinator | 13. Notify CPC that the notification is being closed due to all responses received. |
| Recall Coordinator and/or End Users | 14. Provide, if required, written verification of actions taken as requested by manufacturer. |

## Definitions

**External Recall:** A product or medical device that is subject to a recall or safety notice from the Manufacturer or FDA.

**FDA Recall:** The FDA guidelines classify all recalls into one of three classes according to the level of hazard involved:

**FDA Recall Types:** The FDA guidelines classify all recalls into one of three classes according to the level of hazard involved:

- **Class I:** Dangerous or defective products that predictably could cause serious health problems or death. Examples include food found to contain botulinum toxin, food with undeclared allergens, a label mix-up on a lifesaving drug, or a defective artificial heart valve.
- **Class II:** Products that might cause a temporary health problem or pose only a slight threat of a serious nature. Example: a drug that is under-strength but that is not used to treat life-threatening situations.
- **Class III:** Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws. Examples include a minor container defect and lack of English labeling in a retail food.

**Internal Recall:** A product or medical device that is being recalled or pulled for evaluation due to issues arising in the <organization's> practice.

**Medical Device:** An instrument, apparatus, machine, contrivance, implant, in vitro reagent, or similar or related article, including any component, part, or accessory, that is:

- Recognized in the official National Formulary, or in the United States Pharmacopoeia, or any supplement to them,
- Intended for use in the diagnosis of disease or other conditions, or the cure mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of man or other animals, and that does not achieve its primary intended purpose through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its intended principal purposes.
- Examples include, but are not limited to, CT scanners, infusion pumps, hospital beds, patient restraints, sutures, defibrillators, wheelchairs, intravenous (IV) administration sets, in vitro diagnostics, tongue depressors, etc.

**Purchase History:** The results from an internal search of previously purchased products.

**Recall:** Procedure initiated by the product/medical device manufacturer or FDA, to either remove hazardous devices from the marketplace, or to supply users with additional information on the safe use of their products/devices. Mayo Clinic experience may warrant an internal product/medical device recall. In the event of a product/medical device related incident, Mayo Clinic will initiate corrective action to prevent or minimize the occurrence of

similar incidents and will comply with the reporting requirements of the Federal Food, Drug and Cosmetic Act and Food and Drug Administration (FDA) regulations.

**Recall Coordinator:** Defined as any person assigned responsibility for recall notification process. Official title may vary by site

## Recall Coordinator Key Job Responsibilities

The following graphic represents the key job responsibilities to be completed by the organization's recall process coordinator. Please note the following:

- The graphic is provided as a base for organizations to develop for their own organizations as guidance to the overall management of activities by a 'recall coordinator.'
- Organizations should also incorporate requirements and methods for tracking non-purchased devices that may be provided and used in patient care during evaluations and are thus not evident from purchase history reports.

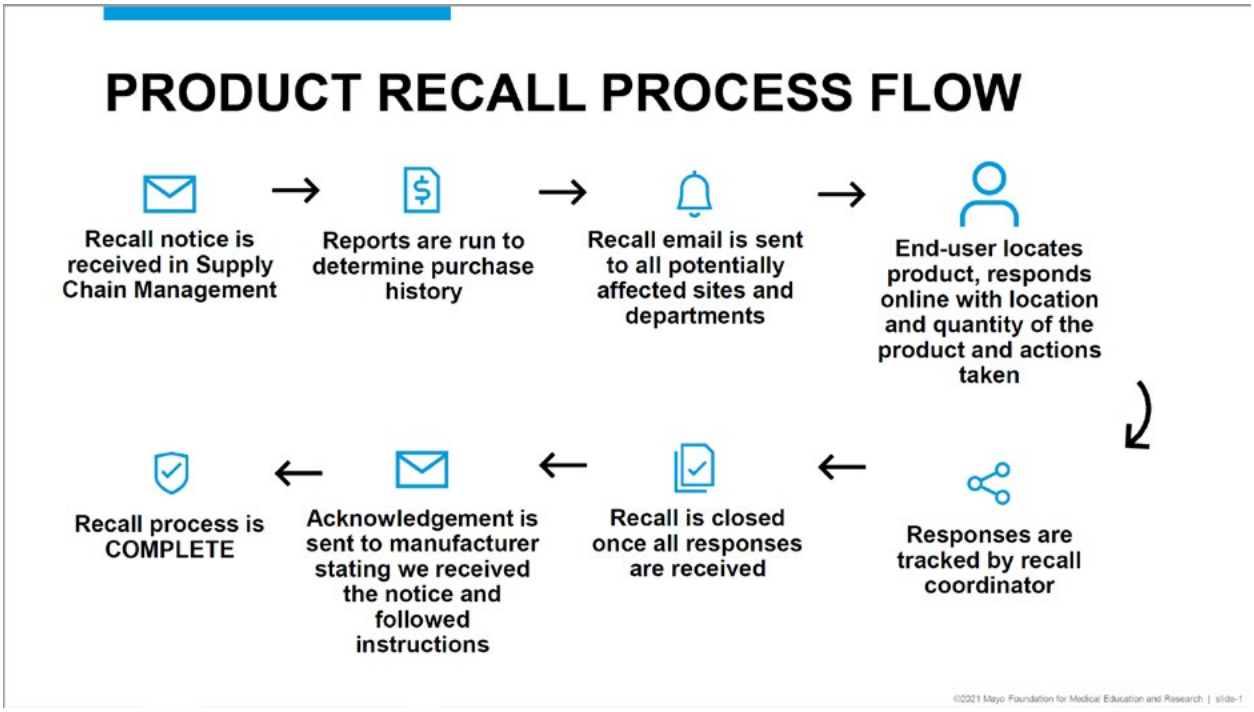



Figure: High-level Overview of Product Recall Process Flow

## APPENDIX I – PROVIDERS TASK FORCE SURVEY RESULTS

This Appendix presents the results collected from the survey tool on UDI Impacts developed and distributed by the Providers Task Force. Q1 was a request for responder's email address and is not included here.

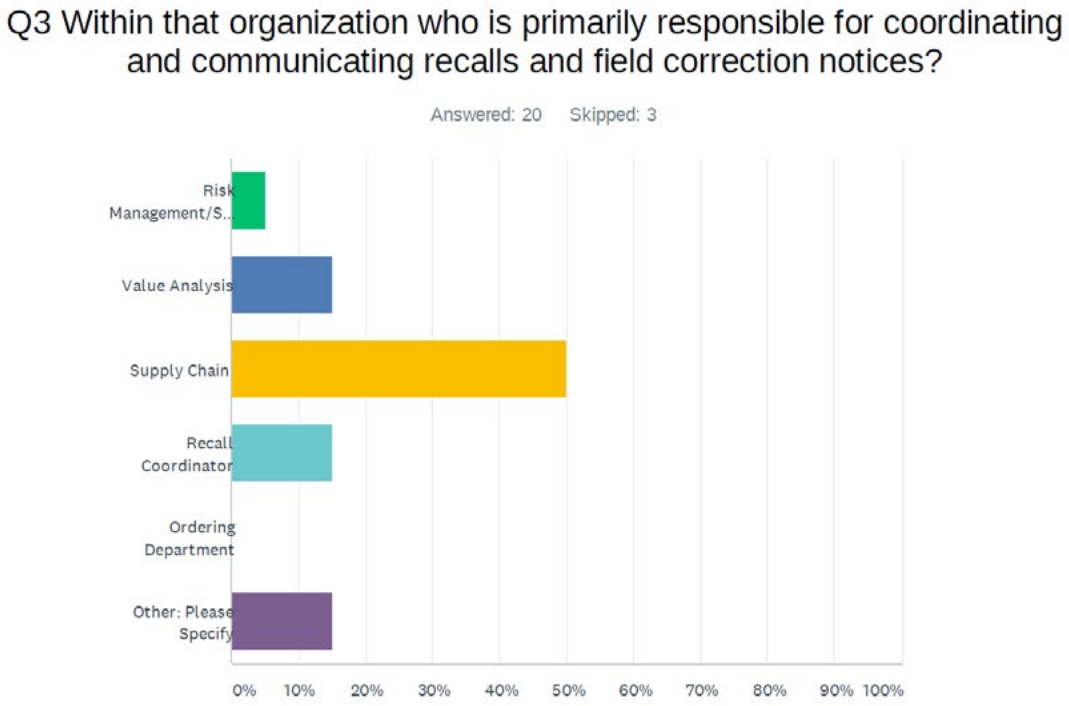
Note: The survey was completed in the 3rd and 4th quarter of 2020.

### Providers Task Force Survey Results


| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Corporate/Enterprise level | 60.00% | 12 |
| Individual Healthcare Facility level e.g. a hospital | 25.00% | 5 |
| Other: Please Specify | 15.00% | 3 |
| TOTAL | | 20 |

| # | OTHER: PLEASE SPECIFY | DATE |
|---|---|---|
| 1 | prefer Enterprise level, but they could be received at a facility/dept level | 10/29/2020 4:20 PM |
| 2 | multiple areas receive | 10/16/2020 3:00 PM |
| 3 | Both at a Enterprise level as well as a | 10/15/2020 3:43 PM |

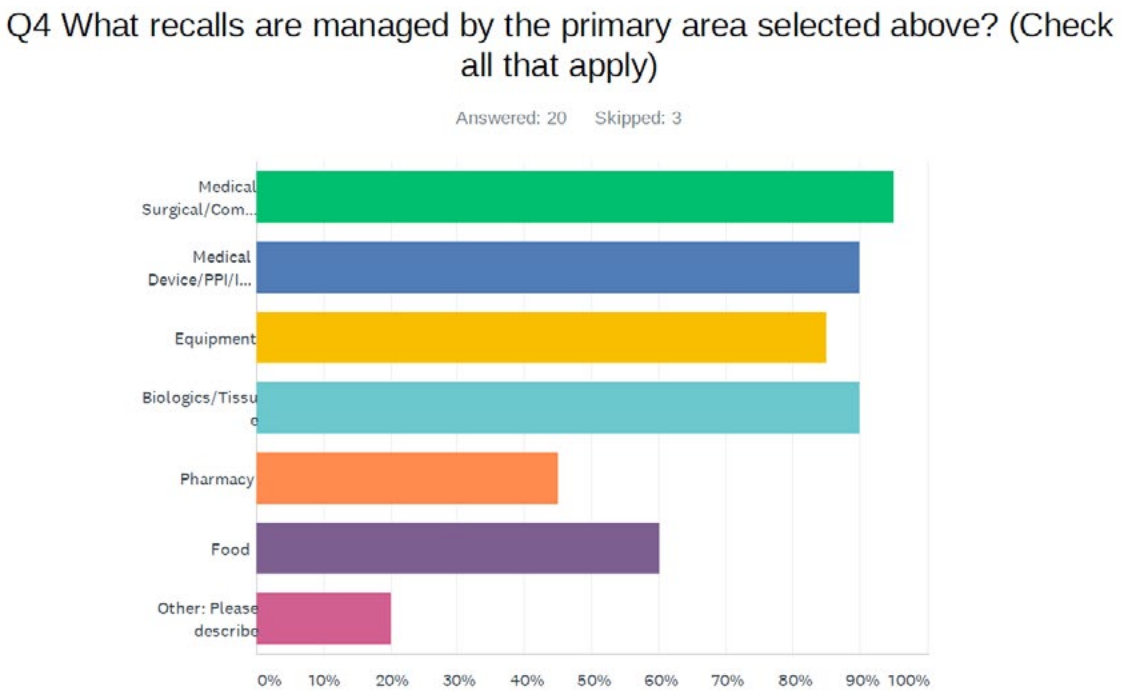
## Providers Task Force Survey Results




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Risk Management/Safety | 5.00% | 1 |
| Value Analysis | 15.00% | 3 |
| Supply Chain | 50.00% | 10 |
| Recall Coordinator | 15.00% | 3 |
| Ordering Department | 0.00% | 0 |
| Other: Please Specify | 15.00% | 3 |
| TOTAL | | 20 |

| # | OTHER: PLEASE SPECIFY | DATE |
|---|---|---|
| 1 | All have a part I. This though and if recall was not entered into RASMAS, the person who received the notice would be managing it | 10/19/2020 11:43 AM |
| 2 | Health System Distribution Manager | 10/16/2020 3:57 PM |
| 3 | procurement & supply chain | 10/2/2020 3:28 PM |

## Providers Task Force Survey Results



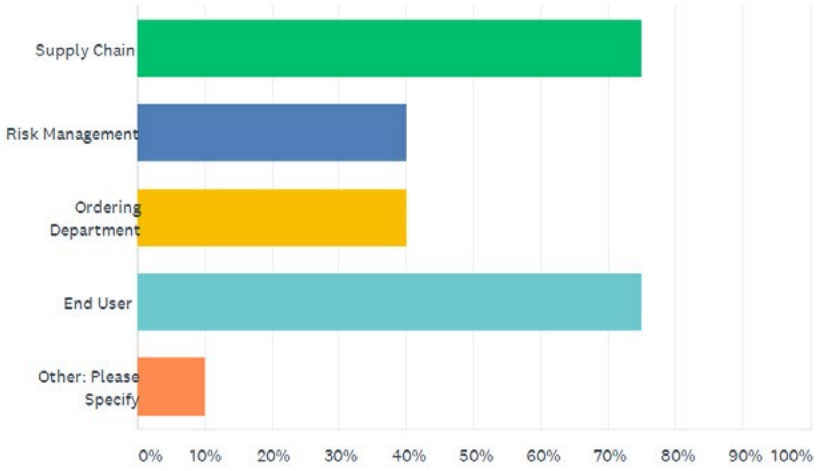

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Medical Surgical/Commodity | 95.00% | 19 |
| Medical Device/PPI/Implants | 90.00% | 18 |
| Equipment | 85.00% | 17 |
| Biologics/Tissue | 90.00% | 18 |
| Pharmacy | 45.00% | 9 |
| Food | 60.00% | 12 |
| Other: Please describe | 20.00% | 4 |
| Total Respondents: 20 | | |

| # | OTHER: PLEASE DESCRIBE | DATE |
|---|---|---|
| 1 | pharmacy has their own recall coordinator | 10/29/2020 4:20 PM |
| 2 | Facilities, IT, Cath Lab, Imaging, Child | 10/16/2020 7:23 AM |
| 3 | VA coordinates with specific staff in each area listed to resolve recalls | 10/15/2020 1:22 PM |
| 4 | toys, facilities (E&O), OR, Cardiology | 10/2/2020 3:28 PM |

## Providers Task Force Survey Results

Q5 Who else in your organization is involved in completing the recall process? e.g. disposition of product? (check that all apply)

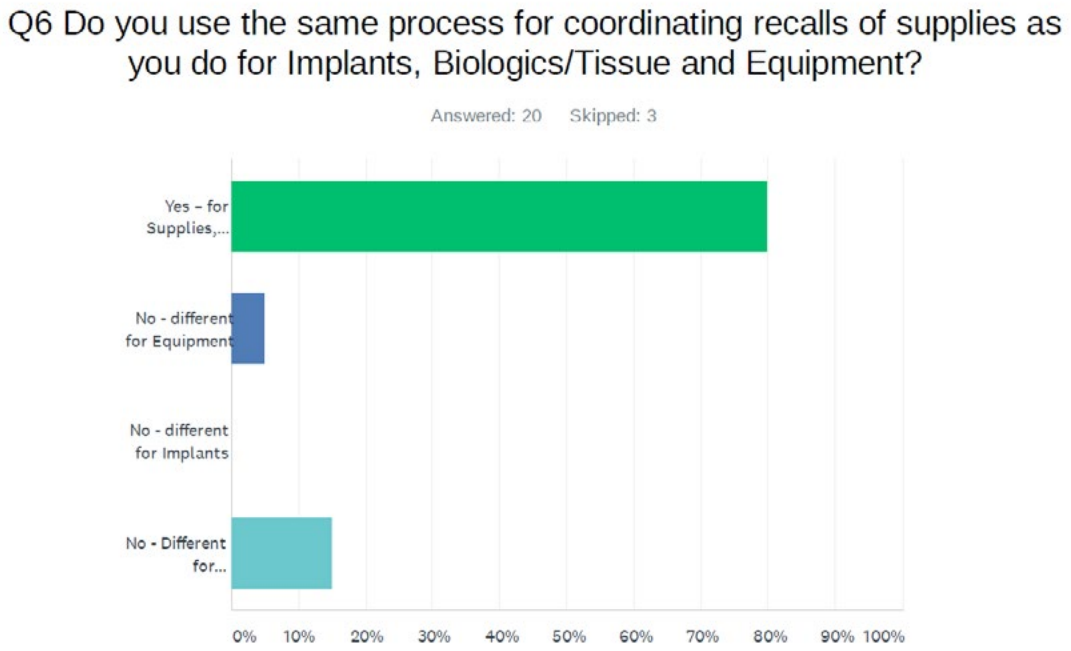
Answered: 20 Skipped: 3




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Supply Chain | 75.00% | 15 |
| Risk Management | 40.00% | 8 |
| Ordering Department | 40.00% | 8 |
| End User | 75.00% | 15 |
| Other: Please Specify | 10.00% | 2 |
| Total Respondents: 20 | | |

| # | OTHER: PLEASE SPECIFY | DATE |
|---|---|---|
| 1 | Biomed | 10/16/2020 9:48 AM |
| 2 | If ordered direct, not through SC, the ordering person is notified of the recall and is the responder who removes the item. | 10/2/2020 3:28 PM |

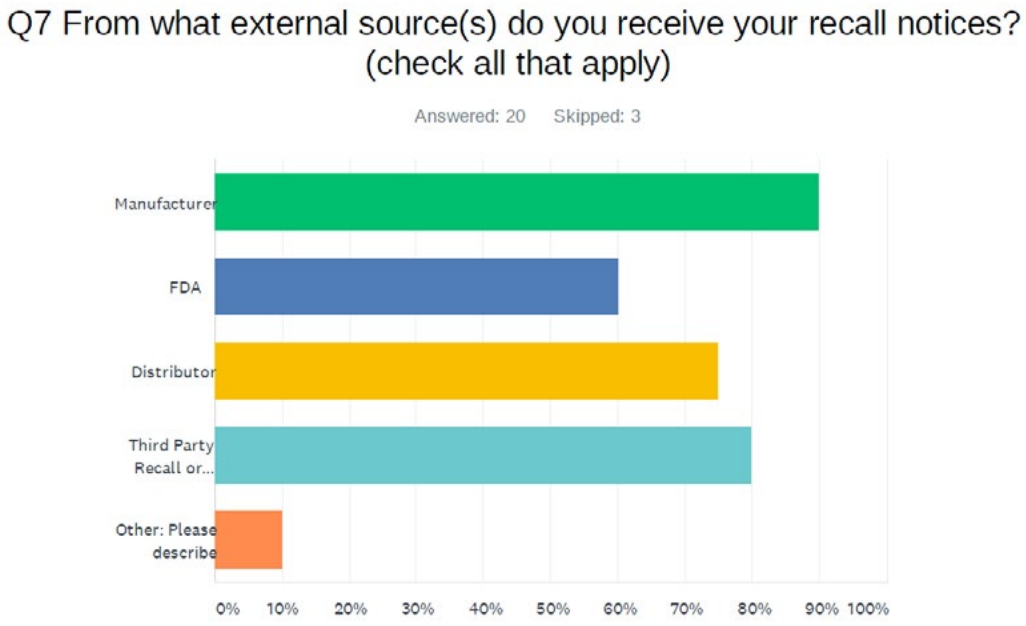
## Providers Task Force Survey Results




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes – for Supplies, Equipment, Implants and Biologics/Tissue | 80.00% | 16 |
| No - different for Equipment | 5.00% | 1 |
| No - different for Implants | 0.00% | 0 |
| No - Different for Biologics/Tissue | 15.00% | 3 |
| TOTAL | | 20 |

| # | IF YOU CHOSE ONE OF THE "NO" OPTIONS ABOVE, PLEASE LIST WHO BY ROLE AND PROCESS DIFFERENCES. | DATE |
|---|---|---|
| 1 | I've never seen a Biologics/ Tissue Recall. I do not know. | 10/13/2020 11:21 AM |
| 2 | Biologics / Tissue is managed by the ORs. | 10/12/2020 2:24 PM |

## Providers Task Force Survey Results



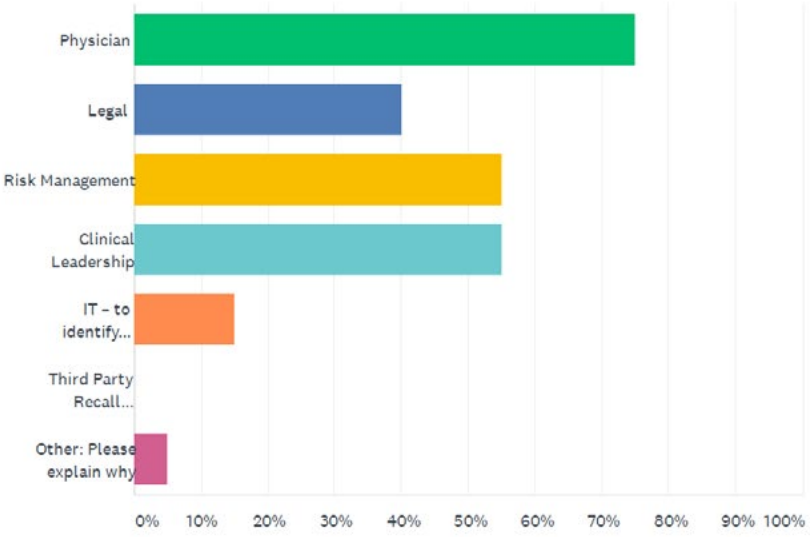

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Manufacturer | 90.00% | 18 |
| FDA | 60.00% | 12 |
| Distributor | 75.00% | 15 |
| Third Party Recall or Alerting Service | 80.00% | 16 |
| Other: Please describe | 10.00% | 2 |
| Total Respondents: 20 | | |

| # | OTHER: PLEASE DESCRIBE | DATE |
|---|---|---|
| 1 | ManageRecalls hosted service and application | 10/16/2020 10:05 AM |
| 2 | RASMAS/Inmar | 10/6/2020 10:25 AM |

## Providers Task Force Survey Results

Q8 If notification of a patient is a requirement of the recall who is involved in this process? (Check all that apply)

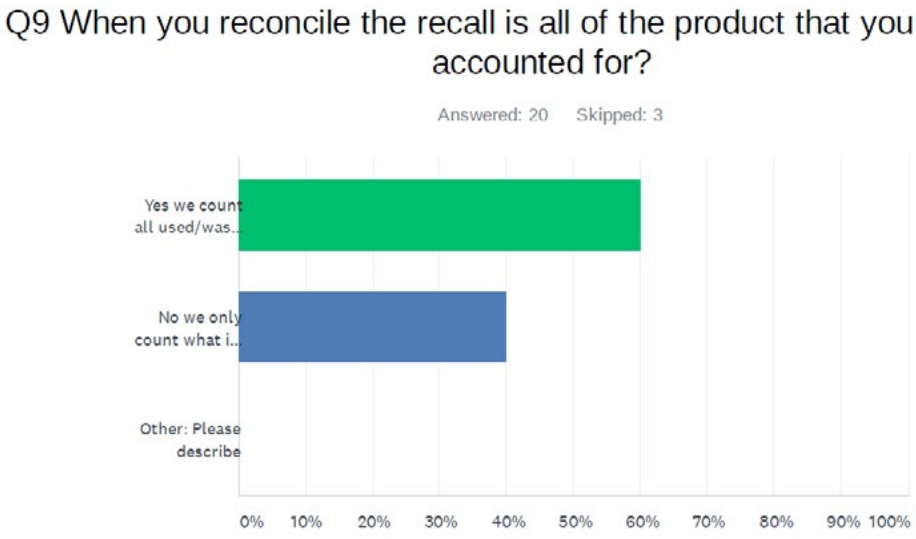
Answered: 20 Skipped: 3




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Physician | 75.00% | 15 |
| Legal | 40.00% | 8 |
| Risk Management | 55.00% | 11 |
| Clinical Leadership | 55.00% | 11 |
| IT – to identify patients | 15.00% | 3 |
| Third Party Recall Management Notifies Patient | 0.00% | 0 |
| Other: Please explain why | 5.00% | 1 |
| Total Respondents: 20 | | |

| # | OTHER: PLEASE EXPLAIN WHY | DATE |
|---|---|---|
| 1 | Senior Recall & Response Team. (CMOs, CNO, RM, Chief of Staff, VP procurement, medical affairs, myself | 10/2/2020 3:28 PM |

## Providers Task Force Survey Results



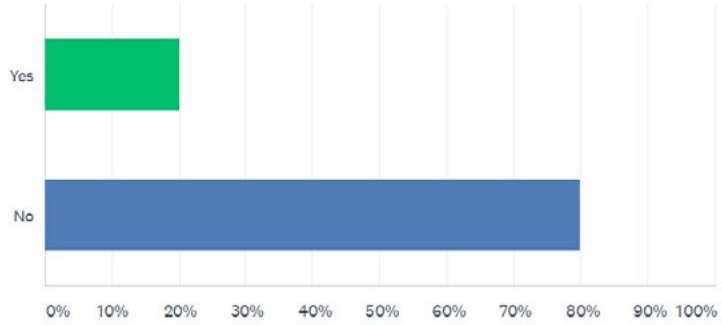

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes we count all used/wasted or implanted devices, what is on the shelf and expired that may be waiting on disposition | 60.00% | 12 |
| No we only count what is on the shelf | 40.00% | 8 |
| Other: Please describe | 0.00% | 0 |
| TOTAL | | 20 |

| # | OTHER: PLEASE DESCRIBE | DATE |
|---|---|---|
| | There are no responses. | |

## Providers Task Force Survey Results

Q10 Does your organization currently use the UDI when provided in the recall notice? (Refer to Certified Electronic Health Record Technology requirements for information2)

Answered: 20 Skipped: 3

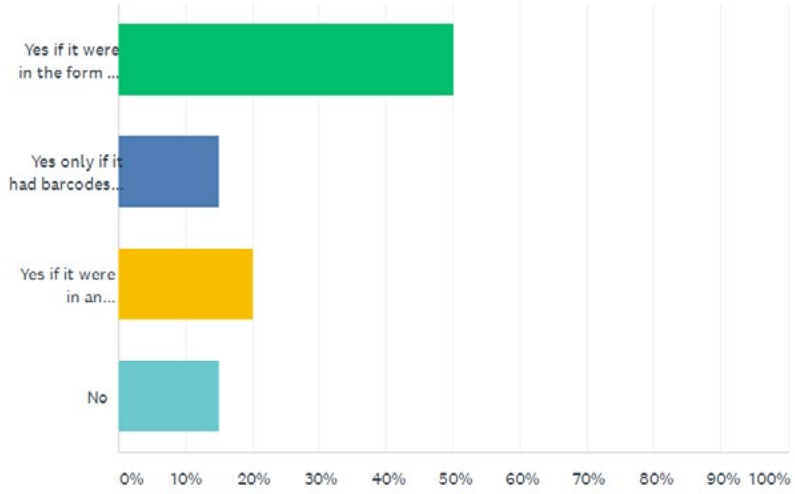



| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes | 20.00% | 4 |
| No | 80.00% | 16 |
| TOTAL | | 20 |

## Providers Task Force Survey Results

Q11 If the UDI DI (device identifier(s)) and/or the UDI PI (production identifier(s)) were included in the recall notice would your organization use it? (check all that apply)

Answered: 20 Skipped: 3



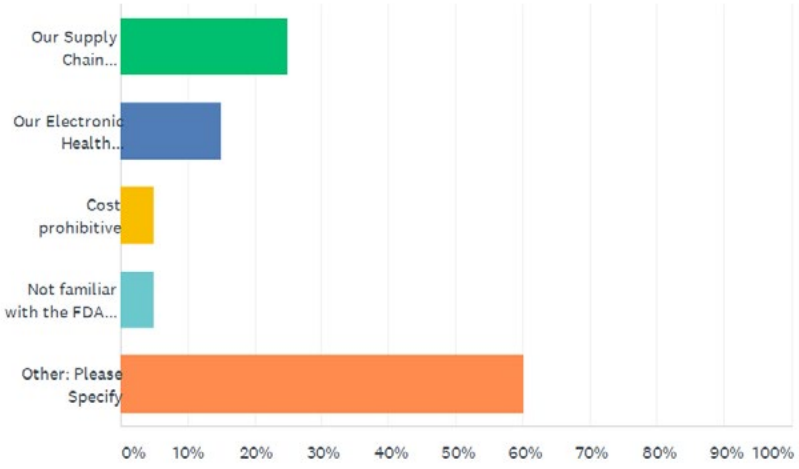

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Yes if it were in the form of a scannable bar code or | 50.00% | 10 |
| Yes only if it had barcodes with human readable identifiers or | 15.00% | 3 |
| Yes if it were in an electronic readable format that could be downloaded | 20.00% | 4 |
| No | 15.00% | 3 |
| TOTAL | | 20 |

| # | IF NO: PLEASE SPECIFY | DATE |
|---|---|---|
| 1 | We currently do not have the technology in place to track UDI's | 10/15/2020 3:43 PM |
| 2 | Manual process | 10/6/2020 10:25 AM |
| 3 | UDI field in SAP, but not in use yet. FYI - you can't check more than 1 answer despite the instruction to check all that apply. | 10/2/2020 3:28 PM |

## Providers Task Force Survey Results

Q12 If you answered No to question 11 what is the reason? (Check all that apply)If you answered yes, please skip to question 13.

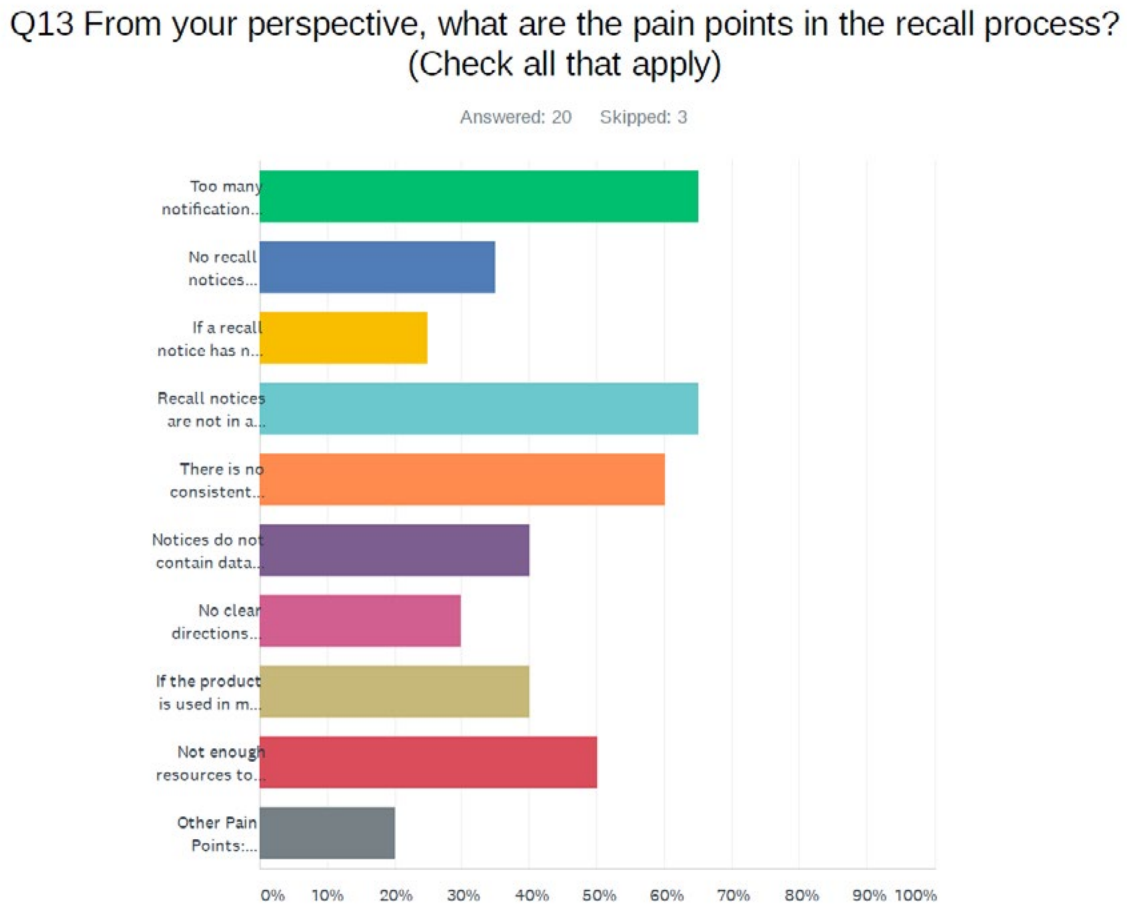
Answered: 20 Skipped: 3




| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Our Supply Chain Technology/ERP does not have functionality to capture UDI | 25.00% | 5 |
| Our Electronic Health Record/Ancillary Clinical Systems have not enabled or use the functionality to capture UDI | 15.00% | 3 |
| Cost prohibitive | 5.00% | 1 |
| Not familiar with the FDA, ONC or CMS UDI regulations and guidelines | 5.00% | 1 |
| Other: Please Specify | 60.00% | 12 |
| Total Respondents: 20 | | |

| # | OTHER: PLEASE SPECIFY | DATE |
|---|---|---|
| 1 | Did not answer no - not able to skip this question | 10/30/2020 2:11 PM |
| 2 | I didn't answer no, but it required an answer | 10/29/2020 4:20 PM |
| 3 | I would really need to pull my s upply chain partners in to see if this was an Interest | 10/19/2020 11:43 AM |
| 4 | N/A | 10/16/2020 3:57 PM |
| 5 | If you answered yes, please skip to question 13. | 10/16/2020 10:05 AM |
| 6 | n/a | 10/16/2020 9:48 AM |
| 7 | Responded yes to question 11 and was told to skip | 10/16/2020 7:23 AM |
| 8 | na | 10/8/2020 7:32 AM |
| 9 | Answered yes to 11, should have been able to skip | 10/7/2020 5:22 PM |
| 10 | skip | 10/7/2020 3:08 PM |
| 11 | i answered yes to question 11, so i skipped to 13. | 10/2/2020 3:28 PM |
| 12 | Answer- yes to question 13 so skipping this one... | 10/2/2020 3:19 PM |

## Providers Task Force Survey Results

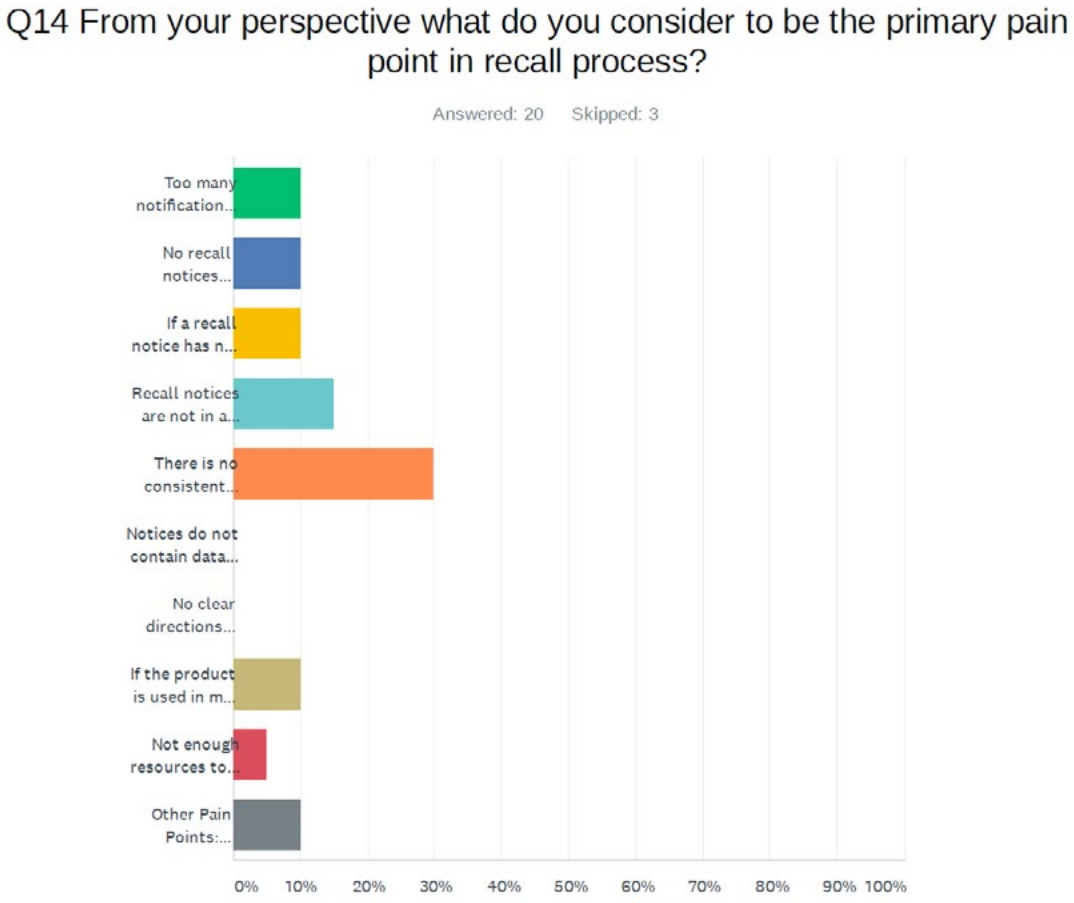


## Providers Task Force Survey Results

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Too many notifications of the same recall are received by my organization | 65.00% | 13 |
| No recall notices received | 35.00% | 7 |
| If a recall notice has not been received it takes too much time for the manufacturer to respond | 25.00% | 5 |
| Recall notices are not in a standard format | 65.00% | 13 |
| There is no consistent manner describing the product, e.g. catalog number, product number, item numbers, order number, UDI | 60.00% | 12 |
| Notices do not contain data elements in a usable, discrete searchable format | 40.00% | 8 |
| No clear directions provided for product reconciliation | 30.00% | 6 |
| If the product is used in many departments or locations there is no option to provide a response from one organization | 40.00% | 8 |
| Not enough resources to address the number of recalls received | 50.00% | 10 |
| Other Pain Points: Describe | 20.00% | 4 |
| Total Respondents: 20 | | |

| # | OTHER PAIN POINTS: DESCRIBE | DATE |
|---|---|---|
| 1 | believe that mfgs have more tracking info that what is provided e.g. lot that went to a specific ship to address | 10/29/2020 4:20 PM |
| 2 | concern with not receiving recall notices | 10/16/2020 9:48 AM |
| 3 | Repeated comliance checks from SteriCycle, even after all forms have been submitted. | 10/15/2020 3:43 PM |
| 4 | many calls from stericycle or the mfr after paperwork is sent. I have to resend paperwork about 30 percent of the time. | 10/2/2020 3:28 PM |

## Providers Task Force Survey Results



## Providers Task Force Survey Results

| ANSWER CHOICES | RESPONSES | |
|---|---|---|
| Too many notifications of the same recall are received by my organization | 10.00% | 2 |
| No recall notices received | 10.00% | 2 |
| If a recall notice has not been received it takes too much time for them to respond | 10.00% | 2 |
| Recall notices are not in a standard format | 15.00% | 3 |
| There is no consistent manner describing the product, e.g. catalog number, product number, item numbers, order number, UDI | 30.00% | 6 |
| Notices do not contain data elements in a usable, discrete searchable format | 0.00% | 0 |
| No clear directions provided for product reconciliation | 0.00% | 0 |
| If the product is used in many departments or locations there is no option to provide a response from one organization | 10.00% | 2 |
| Not enough resources to address the number of recalls received | 5.00% | 1 |
| Other Pain Points: Describe | 10.00% | 2 |
| TOTAL | | 20 |

| # | OTHER PAIN POINTS: DESCRIBE | DATE |
|---|---|---|
| 1 | concern with not receiving recall notices | 10/16/2020 9:48 AM |
| 2 | Voluntary vs. manditory care left up to discression | 10/6/2020 10:25 AM |

## APPENDIX J – REGULATORY GLOSSARY TASK FORCE SUMMARY REPORT

The Regulatory and Glossary Task Force Co-Leads were Terrie Reed, Director Partner Relations, Symmetric Health Solutions, and Barbara Strain, MA, CVAHP, Principal, Barbara Strain Consulting LLC.

The Regulatory Task Force was comprised of representatives from manufacturers, distributors, and software application providers. The task force members examined manufacturers' recall process, workflows through distributors and providers, and identified pain points and areas of opportunity.

### Background and Analysis

The goal of the AHRMM LUC UDI Impacts on Recalls Work Group Regulatory and Glossary Task Force was to assist in reducing the confusion and misunderstanding of current FDA recall guidelines, regulations and terms that were evident during the initial Work Group member calls.

The Task Force first met in March 2020 and identified the following objectives that would be used to drive the activities of the group. These were to:

- Review current guidance documents for recalls and field corrections,
- Summarize recommendations for enhancement and educational needs/methods to share best practices and enhance recall processes,
- Develop a glossary of commonly used terms, and
- Support the other Work Group task forces through education.

The primary deliverable was a Regulatory Task Force 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 Center for Devices and Radiological Health (CDRH).

### Current Situation

The task force reviewed the Resource Document to identify gaps between recall requirements and the policy and data requirements of manufacturers, distributors, and providers to effectively manage a recall.

A major concern is that current references to Unique Device Identifier (UDI) in recall guidance and policy manuals do not indicate that UDI is required when the device is required to have UDI on the label (i.e., UDI compliance date for the product has passed, referring to UDI as one of many ways to identify UDI in manufacturer recall submissions and public reporting of recalls.

A related concern is that even when UDI is included in a recall, the capture and access to

the UDI is done inconsistently and in an unstructured format ( e.g., grouped as a string with other identifiers, represented as UDI-DI (Device Identifier) or other labels specified by issuing agencies, made accessible via a website or a PDF or in a physically mailed letter).

The concerns of the Regulatory and Glossary Task Force were in line with those of the other UDI Recall WG task forces. It was in cross-task force discussions that it became clear that while the major focus of the regulatory task force was the representation of UDI, the lack of clear data element definitions and submission requirements for all recall data (e.g., a data element reference table) has significant negative impact on the health care supply chain at the National, regional, and local level.

### Regulatory and Glossary Task Force Key Finding and Concerns

The key findings and concerns identified by this task force in completing its review of regulatory documents included the following:

- The UDI-DI and UDI-PI (Production Identifier) should be represented in the proper UDI format as required key data elements in future regulations.
- When a device is required to have a UDI and the device manufacturer is required to submit data to GUDID per the UDI rule.
- An additional concern, especially considering COVID-19 and highlights on health care supply chain, there is an opportunity for the FDA to evaluate the device recall submission process to move from a process based upon text, PDFs, and manual processing to one that digitizes the key data elements in a recall and links that data automatically to AccessGUDID.
- Improve the accuracy and efficiency of recall processes for all medical devices containing UDI.
- Reduce supply chain costs.
- Most importantly improve patient safety by significantly reducing the risk of patient exposure to recalled products.

### Recommended Practices

A key finding of the Regulatory and Glossary Task Force is that the UDI-DI and UDI-PI (Production Identifier) should be represented in the proper UDI format as required key data elements in future regulations when a device is required to have a UDI and the device manufacturer is required to submit data to GUDID per the UDI rule.

In addition, the Regulatory and Glossary Task Force believes that, especially considering COVID-19 and the highlight on health care supply chain, there is an opportunity for the FDA to evaluate the device recall submission process to move from a process based upon text, PDFs, and manual processing to one that digitizes the key data elements in a recall and links that data automatically to AccessGUDID. This action would not only support health systems that are scanning UDI to meet Office of National Coordinator of Health Information Technology (ONC) regulatory requirements for tracking implants but would improve the accuracy and efficiency of recall processes for all medical devices containing UDI, reduce supply chain costs and most importantly improve patient safety by significantly reducing the risk of patient exposure to

recalled products.

The Regulatory and Glossary Task force provided these recommendations as well as references to all current FDA recall data submission requirements to the IT, Manufacturers and Provider Task Forces. The IT Task Force took the lead on developing a Data Field table to represent the needs of all stakeholder groups further supporting these summary findings.

## APPENDIX K – WORKFLOWS AND SWIM LANES FOR UDI USE

The following is a high-level overview of workflows and swim lanes developed from reviews completed the Task Forces.

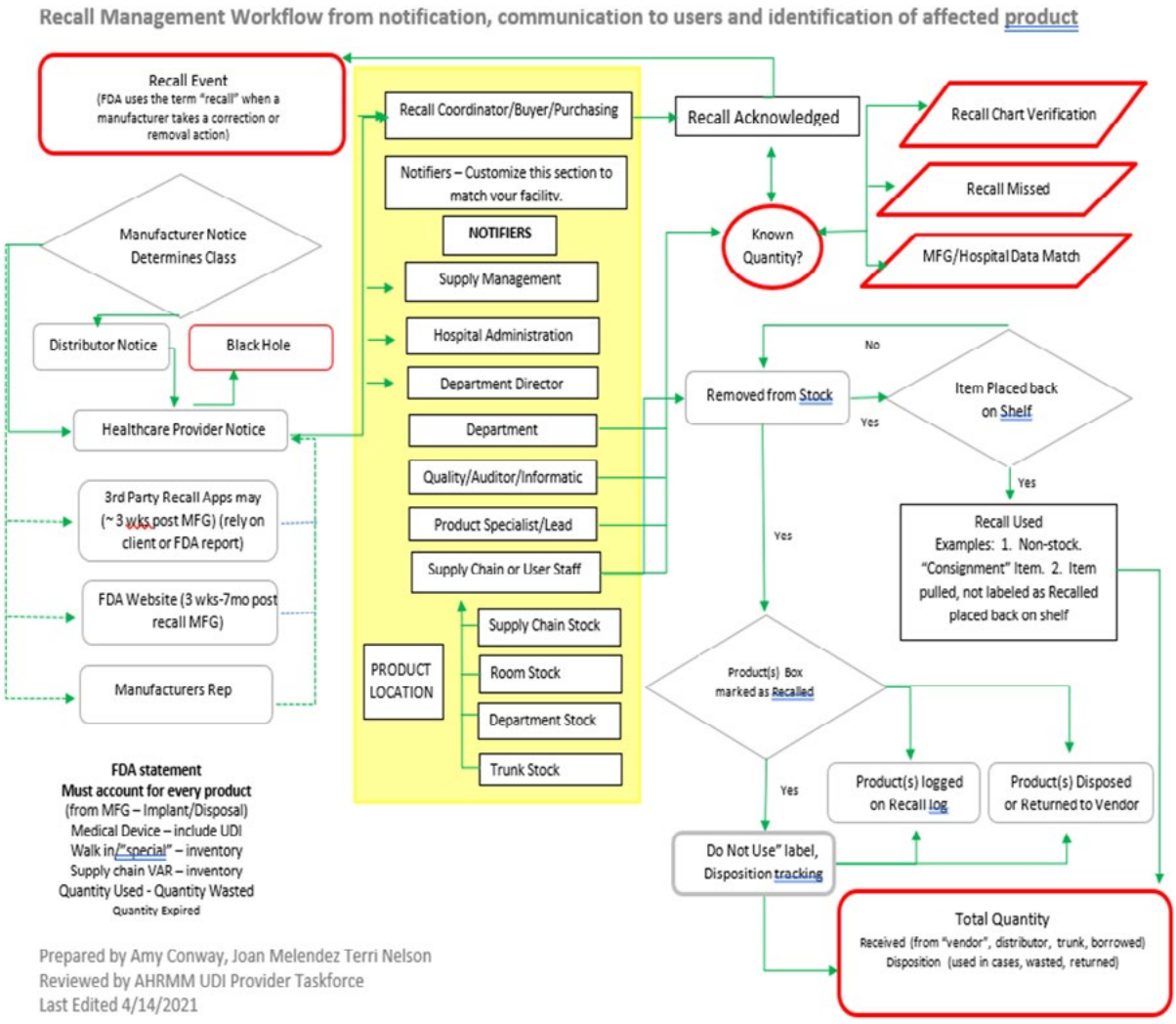



FIGURE: RECALL MANAGEMENT WORKFLOW

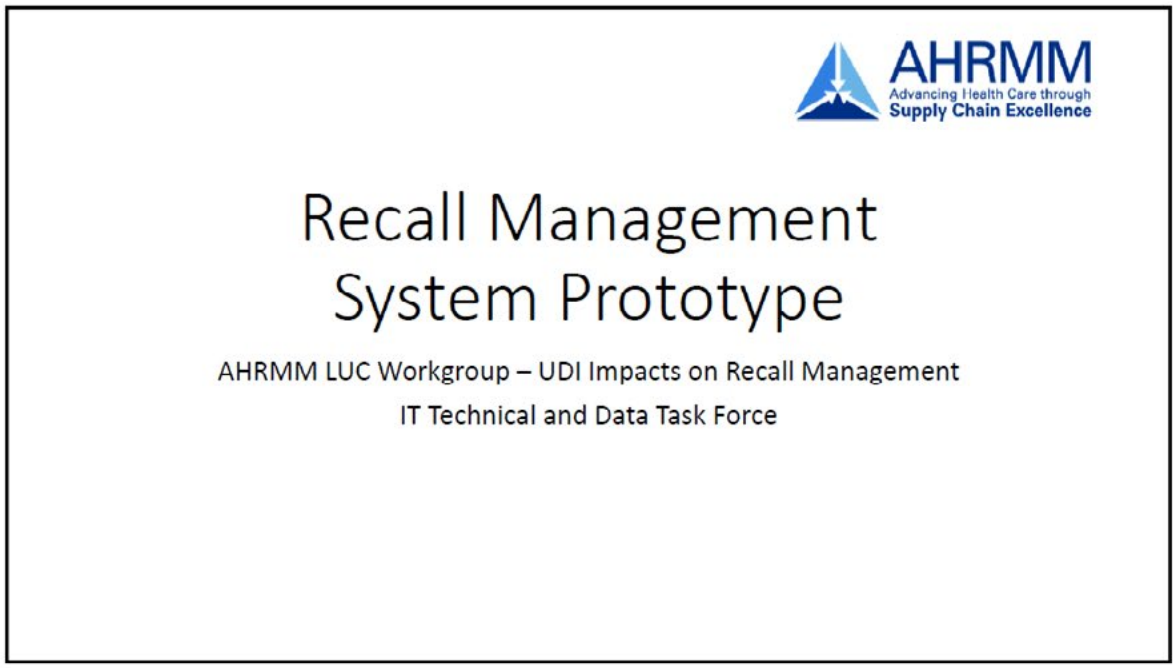
## APPENDIX L – MEDICAL DEVICE RECALL SYSTEM PROTOTYPE

The IT Technology and Data Task Force developed a model for enhancing recall activities using UDIs.

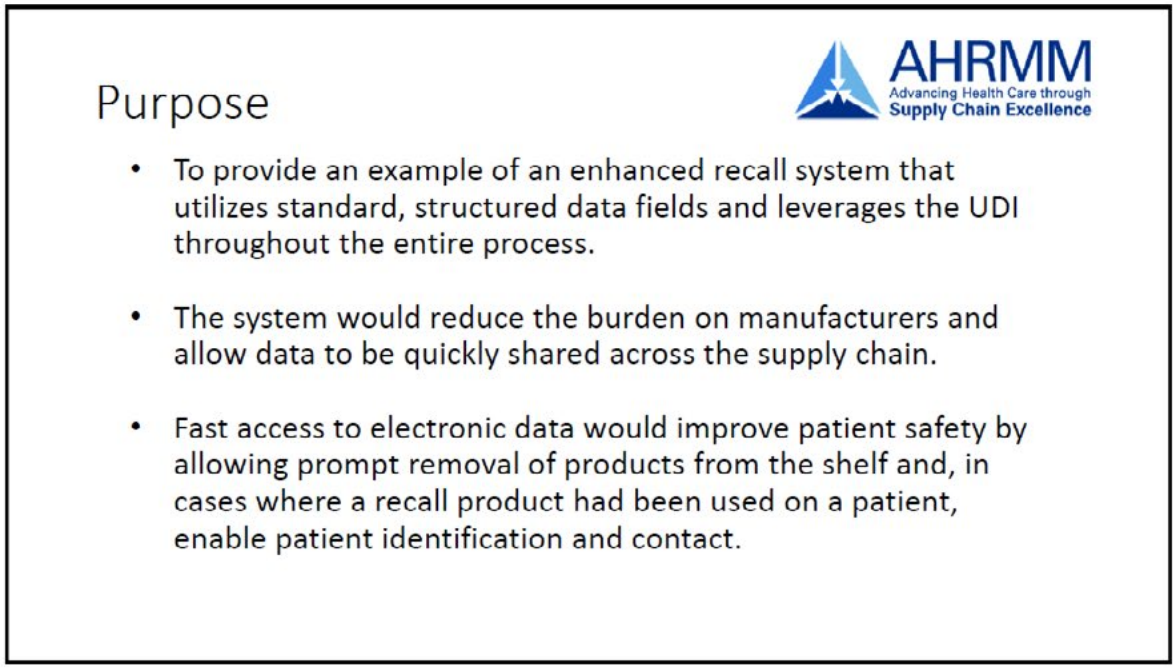
The foundation for this tool was previously described in the Appendix G on the IT Technology and Data Task Force. The Task Force worked with the provider and distributor task forces to determine the data elements each stakeholder needed to effectively identify and remove recalled products. In addition, manufacturer survey results were reviewed to identify pain points for manufacturers submitting recall information to the FDA.

They combined this input to create a prototype electronic recall submission data base that would use the UDI-DI to access information in the GUDID and auto populate the initial recall form. The database would allow providers and distributors electronic access to the recall information so that they could query internal systems to quickly determine if they were in possession of recalled products and where those products were located.

Highlights of the Recall Management System Prototype are provided on the following pages.




1




2

## Current State

- Several methods to submit a recall to the FDA – E-Submitter, PDF Forms, Emails, and Snail Mail.
- Not specific to healthcare – Too many fields and complex forms.
- Requires manual entry and processes in downstream systems
- Back and Forth communication between FDA and Manufacturer
- Manual Keying Errors


3

## Proposed Solution Key Components

- Cloud based application
- Large scale database to retain history of all medical device recalls
- Easy access for authenticated users
- Specific to medical device products
- Unique Device Identifier is used to identify product data
- Include UDI-DI and UDI-PI throughout entire recall process
- Use data from the GUDID database to minimize hand-key errors
- Standard export options for downstream supply chain systems
- Closed loop returns process

4

## System Security

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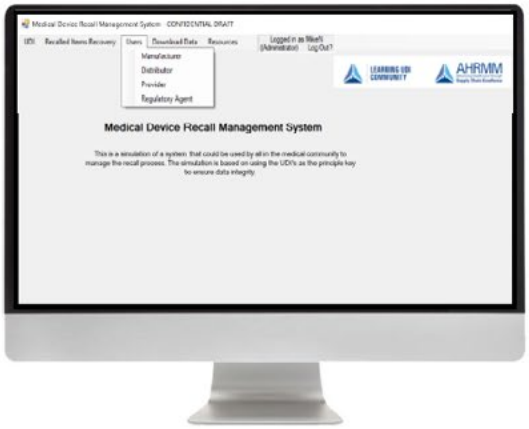
System will need to have security for the following:

- Inquiry/Search of recalls
- Initiating Recalls
- Returning/Recovery of Products
- Uploading & Downloading Data

Could use same security as GUDID

User Types:
- Manufacturer
- Distributor
- Provider
- Regulatory Agent




5

## Initiating a Recall

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1st Select Initiate a Recall from the UDI Menu


6

## Initiating a Recall

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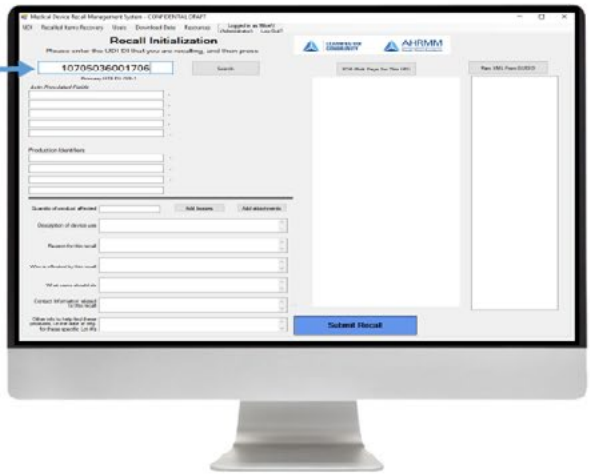
**2nd**
Enter the Primary UDI DI Click SEARCH




7

## Initiating a Recall Example - Echelon Flex Endopath

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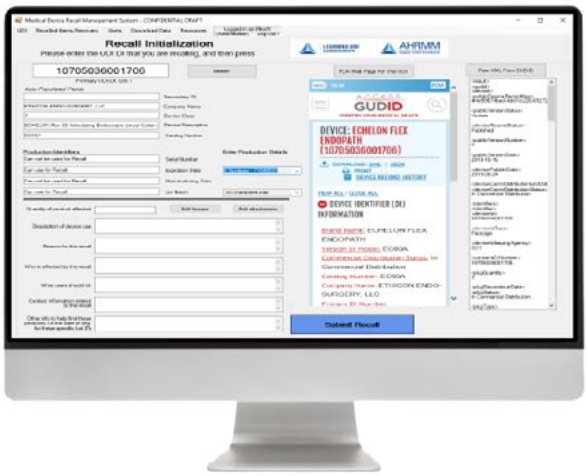
**3rd**
Enter UDI PI(s) information for the Recall




***Note:*** *The system will indicate the production identifiers (PI) required according to the GUDID.*

*Ex. This product is tracked by lot and expiration date. Serial Number and Manufacturing Date are not used.*

***Note:*** *If the UDI-DI was found, the data from the GUDID will be viewable on the right hand of the screen. The XML will also be displayed.*

8

## Initiating a Recall
### Natrelle Silicone-Filled Breast Implant

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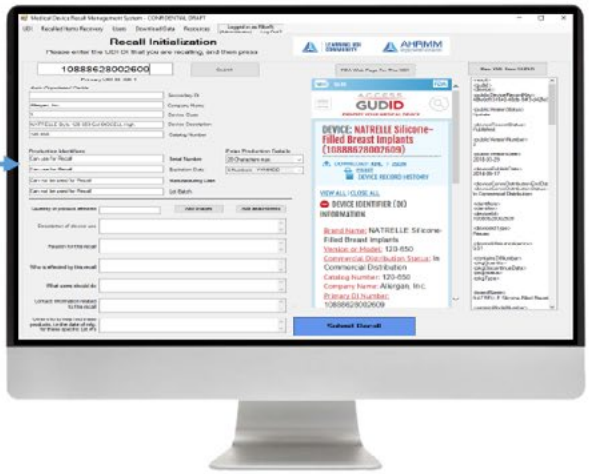
**3rd** Enter UDI PI(s) information for the Recall




***Note:*** *The system will indicate the physical identifiers (PI) required according to the GUDID.*

*Ex. This product is tracked by Serial Number and Expiration Date. Lot Number and Manufacturing Date are not used.*

***Note:*** *If the UDI DI was found, the data from the GUDID will be viewable on the right hand of the screen. The XML will also be displayed.*

9

## Initiating a Recall
### Swan-Ganz True Size

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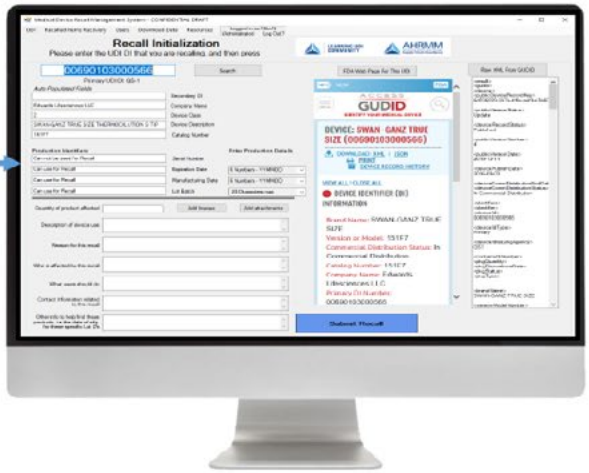
**3rd** Enter UDI PI(s) information for the Recall




***Note:*** *The system will indicate the physical identifiers (PI) required according to the GUDID.*

*Ex. This product is tracked by Lot Number, Expiration Date, and Manufacturing Date . Serial Number is not used.*

***Note:*** *If the UDI DI was found, the data from the GUDID will be viewable on the right hand of the screen. The XML will also be displayed.*

10

## Initiating a Recall
### Alaris

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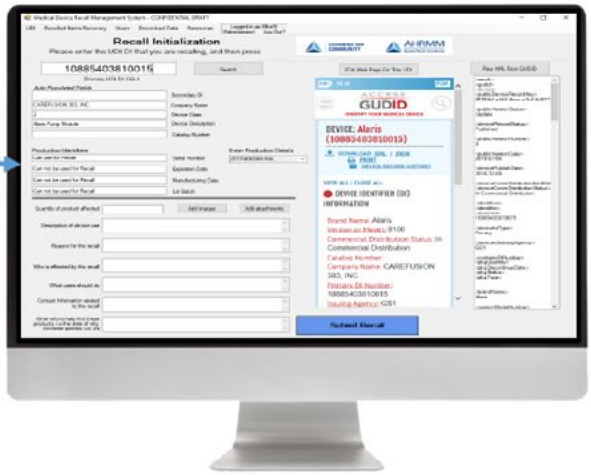
**3rd** Enter UDI PI(s) information for the Recall




***Note:*** *The system will indicate the physical identifiers (PI) required according to the GUDID.*

*Ex. This product is tracked by Serial Number only.*

***Note:*** *If the UDI DI was found, the data from the GUDID will be viewable on the right hand of the screen. The XML will also be displayed.*

11

## Initiating a Recall
### Panda

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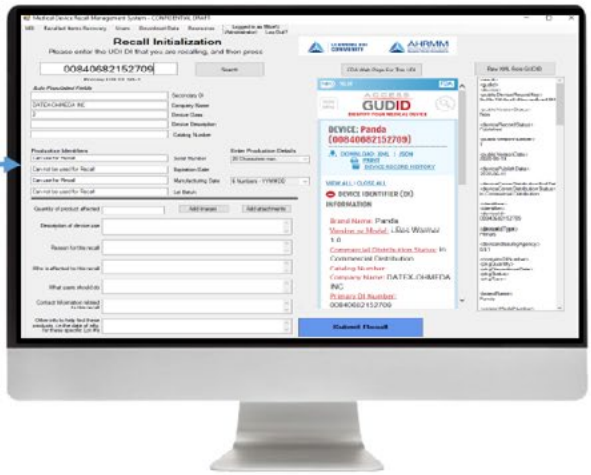
**3rd** Enter UDI PI(s) information for the Recall




***Note:*** *The system will indicate the physical identifiers (PI) required according to the GUDID.*

*Ex. This product is tracked by Serial Number and Manufacturing Date . Expiration Date and Lot Number are not used.*

***Note:*** *If the UDI DI was found, the data from the GUDID will be viewable on the right hand of the screen. The XMI will also be displayed.*

12

## Initiating a Recall

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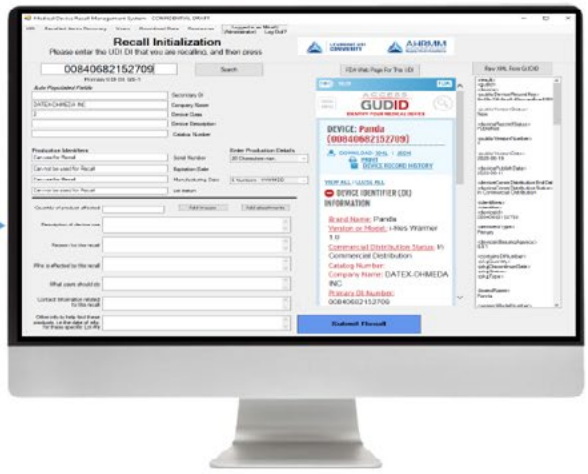
**4th**
Enter additional information




***Note:*** *Use the Add Images and Add Attachments to include other documents related to the recall.*

13

## Initiating a Recall

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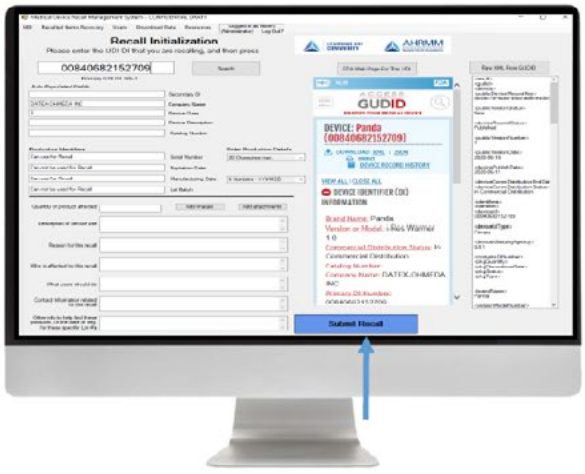
**5th**
Submit Recall




***Note:*** *Once submitted, data is available in recall database for downstream systems to access.*

*The user can update recall with additional information by selecting edit from UDI Menu.*

14

## Recalled Items Recovery Menu

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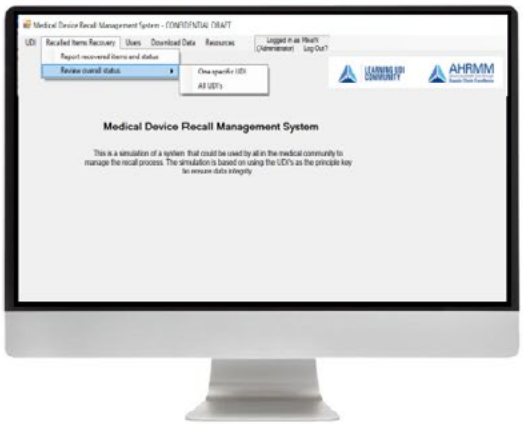
- Report Recovered Items and Status Option - will allow the user to report the disposition of the recalled product.
- Review Overall Status – will provide a detail status of a recall for one specific UDI or for multiple UDI's.

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## Download Data Menu

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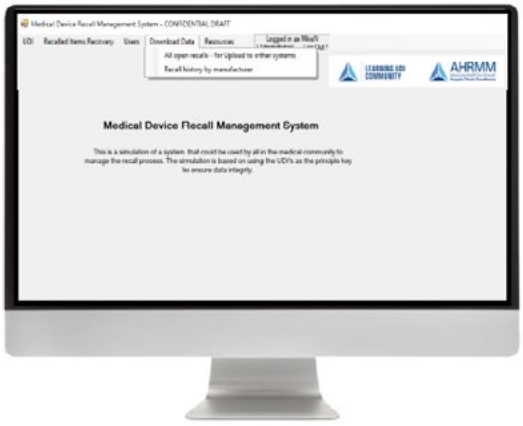
- Download All Open Recalls – Used to upload recall data to other systems. Will use standard file format
- Recall History by Manufacturer – Download historical recall information.

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## Resource Menu

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Links to popular standards sites and other related information to help navigate the recall process. Sites include:

- FDA
- GS1
- HIBCC
- ICCBBA
- Recall System Manual
- Learning UDI – Charter


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## Conclusion

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Using the prototype system as a model, the FDA should create a robust system that utilizes the UDI to automate the recall process and allow data to be shared across the supply chain allowing a quick response to remove product from the shelf and eliminate the risk to patients and caregivers.

Creation of this robust system will:

- Use the UDI to automate the recall process
- Allow authorized end-users quick access to electronic information
- Will improve patient safety, enhance efficiency and reduce costs for all stakeholders

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## APPENDIX M – 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.

| First Name | Last Name | Organization |
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| Joyce | Trese | Roche Diabetes Care |
| Nam | Trinh | Securisyn Medical |
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