



**LEARNING UDI
COMMUNITY**



AHRMM

Association for Healthcare
Resource & Materials Management

Advancing the Healthcare Supply Chain

A professional membership group of the
American Hospital Association

The Business Case for the UDI Work Group Report



LEARNING UDI
COMMUNITY

WWW.AHRMM.ORG / LUC

BUSINESS CASE FOR THE UDI REPORT

TABLE OF CONTENTS

INTRODUCTION	3
GLOSSARY OF TERMS	4
COMMON ASSUMPTIONS	5
WORKFLOWS	
• COMMODITY INVENTORY MANAGEMENT	6
• SPECIALTY INVENTORY (“TRUNK STOCK”)	11
• EHR TO REGISTRY	15
• ADVERSE EVENT REPORTING	19
• PRODUCT RECALLS	23
CONCLUSION	27
SUB GROUP MEMBERS	28

BUSINESS CASE FOR THE UDI REPORT

INTRODUCTION

On September 24, 2013, the FDA issued the final Unique Device Identifier (UDI) rule intended to adequately identify medical devices through their distribution and use. UDI includes a series of numeric or alpha numeric characters that have been assigned to a product as a Device Identifier (DI). UDI also requires a Production Identifier (PI) (lot, expiry, etc.) be included along with the DI on the medical device packaging label or on the device itself in a barcode and in a human readable format. There are also requirements on submitting product data attributes into the Global Unique Device Identification Database (GUDID) and to use UDI across the device lifecycle. Please refer to the FDA UDI regulation for complete details at <https://www.gpo.gov/fdsys/pkg/FR-2013-09-24/pdf/2013-23059.pdf>.

The Business Case for the UDI work group, a formal work group of the Association for Healthcare Resource & Materials Management's (AHRMM) Learning UDI Community (LUC) is comprised of more than 75 members representing the association, manufacturing/supplier, hospital, regulatory, consulting, group purchasing organizations (GPOs), and solution provider communities. Within this group are five sub groups that are addressing one of five process flows that could potentially change following healthcare organizations' adoption of the UDI. The five typical workflow processes are:

- Commodity Inventory Management
- Specialty Inventory ("Trunk Stock")
- EHR to Registry
- Adverse Event Reporting
- Product Recalls

For each workflow process, the sub group has analyzed how it currently operates without UDI and then identified how these systems will change with UDI adoption. Descriptions of workflow processes highlight the redundancies in today's environment and where changes using UDI will lead to streamlined future operations and potential savings opportunities. The groups have also made recommendations on what hospitals need to do to effectively adopt UDI and incorporate it into ongoing clinical and supply chain operations.

This work is intended to close the knowledge gap between the current realities of supply chain workflow processes, and offer a vision for how UDI adoption will allow for a smoothly functioning supply chain based upon reliable product information.

BUSINESS CASE FOR THE UDI REPORT

GLOSSARY OF TERMS

*Indicates an existing entity or role that will be required to support the future workflows.

- *Typical Healthcare Organization (HCO)*: HCOs serving 80 percent of the U.S. population.
- *Electronic Health Record (EHR)*: An electronic version of a patient's medical history that is maintained by the provider and may include all of the key administrative clinical data relevant to that person's care under a particular provider, including demographics, progress notes, problems, medication, etc.
- *Enterprise Resource Planning (ERP)*: The integrated management of core business processes, often in real-time and mediated by software and technology. These business activities can include: purchasing, receiving, inventory management, accounts payable, and financial management.
- *Medical Device*: All medical supplies meeting FDA Classification I, II, or III (Exceptions: biomedical equipment, software).
- *Device Identifier (DI)*: A mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device.
- *Production Identifier (PI)*: A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:
 - the lot or batch number within which a device was manufactured;
 - the serial number of a specific device;
 - the expiration date of a specific device;
 - the date a specific device was manufactured;
 - the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.
- *Global Location Number (GLN)*: The GLN is a globally unique GS1 Identification Number that is used to identify any location in the supply chain that needs to be uniquely identified. The GLN may be used to identify both physical locations and legal entities.
- *The U.S. Food and Drug Administration's (FDA) Global Unique Device Identification Database (GUDID)*: Contains key device identification information submitted to the FDA about medical devices that have UDIs.
- *Electronic Data Interchange (EDI)*: Globally standardized transaction sets used for electronic business exchange.
- **Clean Item Master (CIM)*: A future state where item masters are refreshed with UDI identifiers regularly updated from GUDID and overlaid with HCO pricing. Possible in the future from globally accessible unique device identifiers.
- **Virtual Item Master (VIM)*: A future state where a Clean Item Master (CIM) is maintained by 3rd party entities for HCOs not maintaining their own. Function partially filled by business exchange organizations today.

BUSINESS CASE FOR THE UDI REPORT

- *HCO Medical Device Data Management Function: A future HCO Medical Device Data Management function that will assure device data quality entering the HCO from outside entities as well as device data moved within/between clinical and business HCO systems (similar to the HCO item master maintenance function today).
- *3rd Party Submitters: A future augmented role for agencies meeting FDA guidelines providing documentation for adverse events occurring in HCOs.
- *3rd Party Recall Management Organization: A future augmented role for organizations providing timely recall information to HCOs.

COMMON ASSUMPTIONS

Below are common assumptions made for both the current state and future state workflows for UDI adoption.

CURRENT STATE

- Workflow represents activities in a typical HCO.
- HCO has implemented an electronic health record (EHR) system-wide.
- HCO has implemented an enterprise resource planning (ERP) system.
- No interface exists between EHR and ERP.
- HCO has no consistent barcode scanning system for use with medical devices.
- HCO uses limited electronic data interchange (EDI) transaction sets with fewer than 20 vendors.

FUTURE STATE WITH UDI

- HCO scanning of the UDI (both DI, and PI if required).
- HCO access to accurate and timely data from GUDID.
- Interoperability between clinical and business systems within an HCO (including EHR and ERP systems).
- HCO uses EDI for purchase orders (PO), advanced ship notices (ASN), and accounts payable (AP) for 95% of business transactions involving medical devices.
- Ongoing supplier and HCO commitment to system updates and training protocols.

BUSINESS CASE FOR THE UDI REPORT

COMMODITY INVENTORY MANAGEMENT

Workflow Definition

The Commodity Inventory Management Workflow outlines actions limited to the physical movement of consumable medical supply commodity products that flow through and are used by an HCO. Commodity products are mostly Class I and non-implantable Class II devices. These devices are considered “routine” in hospitals and usually purchased in large quantities.

Workflow Stakeholders

- HCO Purchasing Department
- Distributors
- Manufacturers
- HCO Receiving and Distribution Departments
- HCO Clinical Departments

Assumptions

The following items are excluded from the workflow:

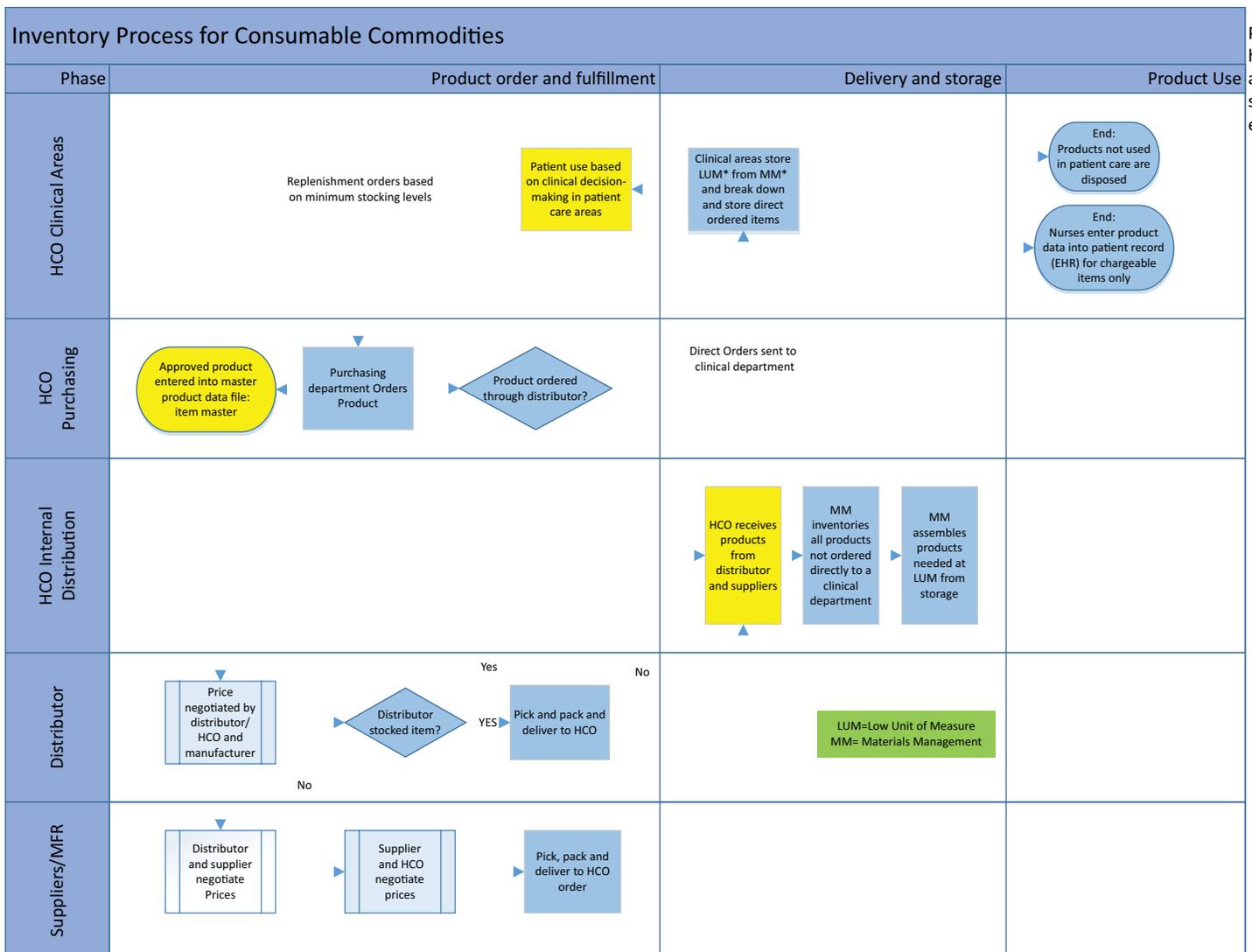
- Implantables
- Custom devices
- Loaner sets
- Vendor owned/consigned devices
- Capital equipment
- Instruments and instrument sets

All product described have been evaluated and approved

Challenges to Healthcare with Current Workflow

The item master has been referred to as the “center of the universe” for HCOs since its data drives many different business and clinical functions (e.g. inventory management, procure-to-pay, patient billing, etc.). It is the first place where product data can reside and be maintained. The challenge today is that a number of HCOs do not invest in a master data management strategy whereby they establish an item master with clean and complete data, and then have processes in place to maintain its integrity over time. As a result, most item masters contain inaccurate, incomplete and/or duplicative data. This negatively impacts all downstream systems and functions that rely on product data from this “source of truth.”

BUSINESS CASE FOR THE UDI REPORT



Workflow Color Key

- *Blue*: indicates a process
- *Yellow*: indicates a process strongly impacted by UDI
- *Green*: indicates a pertinent definition or note

BUSINESS CASE FOR THE UDI REPORT

Where UDI Adoption Can Make a Difference

The work group recommends that HCOs standardize product identification in the item master using the DI (device identifier) portion of the UDIs from the U.S. Food and Drug Administration's Global UDI Database (GUDID), and regularly update this information to ensure it is accurate and complete. During the receiving or stocking processes, the HCO can capture the DI (device identifier) and PI (production identifier) portions of the UDI when they scan the barcodes on these products into the enterprise resource planning (ERP) system. Lastly, when the product is used at the point of care, clinicians can scan the barcode to capture both the DI and PI portions of the UDI in the patient's electronic medical record. This would enable all parties in the supply chain to use a single product identifier (UDI) from the point of manufacture to the stock location and finally at the point of use to facilitate better inventory management. Scanning versus manual data entry has the potential to reduce errors and improve process efficiency.

- **Task 1:** Establish a master data management strategy whereby the HCO updates the DI portion of the UDI in their item master from the GUDID for consumable medical supply commodity products that flow through and are used. As part of this strategy, the HCO must also have in place a process by which it regularly updates the DI information within its item master by syncing it with the data in the GUDID.

In order to maintain clean data within its item master, the HCO should support a limited team of key stakeholders who are constantly monitoring the quality of data that is entered into the systems. This function will become even more necessary as the data passes between the ERP system and clinical systems (e.g. EHR, clinical systems in the OR, Cath Lab, etc.). Data management is a standard function in many distribution businesses, and HCOs need to adopt this practice as well. Since UDI data will enter through the supply chain, it is recommended that master data management resides there as well.

Benefits: Use of a standard identifier (UDI) improves the accuracy of inventory management since all parties are speaking the same language when it comes to the product (e.g. HCO, manufacturer, distributor), and enables all parties in the supply chain to better track products from manufacture through use. Clean, standardized data improves HCO staff efficiency by reducing resource time currently allocated to errors and rework.

Investment: If the HCO's ERP system cannot store and use the DI portion of the UDI, the HCO should consider configuring/updating its system using internal IT resources or a third party to perform this function, upgrade/transition to a new ERP system that has this capability, or utilize an existing unused data field to capture and maintain the DI and PI information – all three of these options will require an investment in IT staff and technology resources. We discuss transitional solutions at the end of this document.

The HCO will need a technology infrastructure/process in place that allows it to update its item master with data from the GUDID. It can either use internal staff resources to accomplish this, or leverage a third party solutions provider.

- **Task 2:** Some manufacturers and distributors send to the HCO an advance ship notice (ASN) via electronic data interchange (EDI) that contains details on the products being shipped, including the DI and PI portions of the UDI, which the HCO can store within its ERP system. But in many

BUSINESS CASE FOR THE UDI REPORT

cases, the only way for the HCO to capture and store this data within its ERP system is to scan the product's barcode during the receiving process.

Benefits: If the HCO can capture the DI and PI portions of the UDI via barcode scanning, it will have in its ERP system the variable portion of that product's UDI (e.g. lot/batch number, serial number, expiration date, etc.). This information is critical to have in the event of a recall or in adverse event reporting (see the workflows on these topics).

This data capture would also facilitate use of the DI in purchase orders (POs) and invoices. If the DI is used within the ERP system in this way, a review of HCO systems and POs would show confirmation of PO to manufacturer, and a review of requisitions would show a match of recall to HCO records.

Other benefits are data accuracy, since the HCO is avoiding the potential for errors associated with manual data entry of the DIs, as well as the process efficiency that comes with barcode scanning versus manually entering the data.

Investment: Many HCOs already have scanning technology in place in their receiving departments. If an HCO does not have these scanners, they will need to purchase them. These scanners have been used by HCOs for many years and have a long track record of success in the receiving area.

Scanners, like any technology, are constantly evolving with new capabilities and features. The identifiers too will likely change over time with manufacturers implementing new automatic identification and data capture (AIDC) modalities (e.g. linear barcodes, 2D barcodes, RFID). Therefore, HCOs should continue to evaluate their equipment needs and processes to stay current with these changes.

If the HCO's ERP system cannot accommodate the number of digits in both the DI and PI portions of the UDI, which can be a total of 40-48 characters, they will need to consider reconfiguring their systems to accommodate this number or potentially upgrade to a new version or system.

- **Task 3:** At the point of care, the clinician scans the barcodes of products used on a patient to capture the products' DI and PI information in that patient's electronic medical record (see EHR to Registry and Specialty Inventory ("Trunk Stock") workflows in this report for more information).

Future Workflow

In the future Commodity Inventory Management Workflow, the Clean Item Master (CIM) or Virtual Item Master (VIM) uses the GUDID to inform HCO EDI purchase orders (PO), based on actual product use, thereby allowing standard product identification along the entire supply chain continuum. This clear electronic communication promotes manufacturing to fluctuate according to demand. This demand planning is routine in many industries and will be possible for healthcare following adoption of UDI. Advance ship notices (ASN) scanning marries specific PI information DI information in the receiving process. ERP to EHR interoperability brings complete UDI information into the HCO's clinical systems to facilitate point of use scanning and documentation of the UDI in the patient's electronic health record.

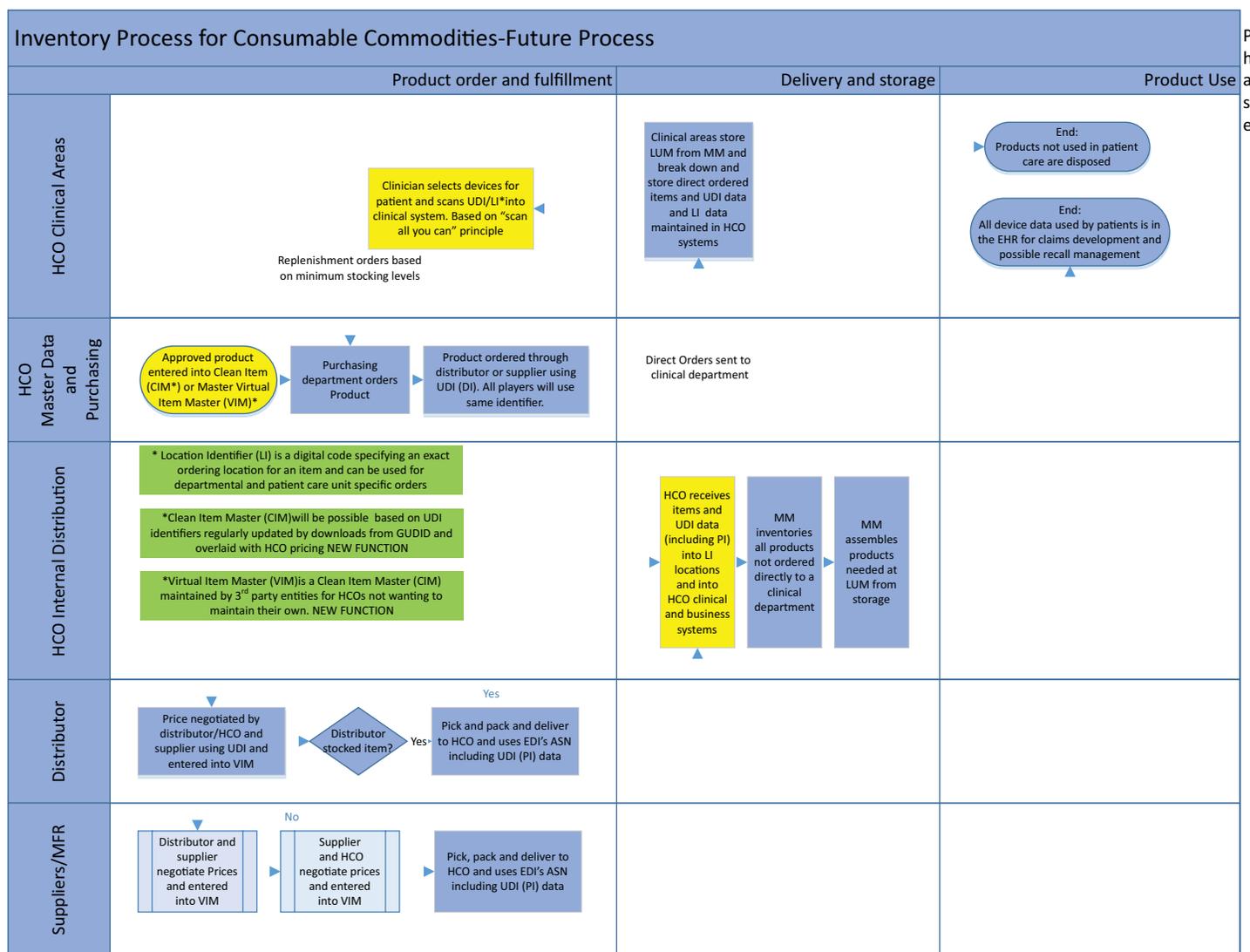
BUSINESS CASE FOR THE UDI REPORT

Savings (as a result of demand planning)

- Labor: HCO item master maintenance and HCO receiving process
- Space: Smaller warehouse spaces and smaller on-site supply storage
- Cost: Lower distribution costs equal reduced handling and inventory for suppliers

Safety

- HCO knowledge of products on site by location, and HCO knowledge of products used by patients



Workflow Color Key

- *Blue*: indicates a process
- *Yellow*: indicates a process strongly impacted by UDI
- *Green*: indicates a pertinent definition or note

BUSINESS CASE FOR THE UDI REPORT

SPECIALTY INVENTORY

Workflow Definition

The Specialty Inventory Workflow outlines how non-stock supplies or implants (owned or consigned) flow through an HCO. These items are only purchased/used when the physician determines that the product is needed for a specific procedure, which may or may not be on the preference card. Initial identification of the item in the hospital most often occurs at point-of-use.

Workflow Stakeholders

- Patients
- Physicians
- Vendors
- OR Materials
- Sterile Processing
- Case Manager
- Scheduling
- Nursing Staff
- OR Billing

Assumptions

People: Staff manually enters device information into clinical and business systems. Vendor brings device(s) into hospital and bypasses typical PO and receiving process.

Process: Connecting device information within hospital clinical and business systems is difficult or is very limited. Barcode scanning is not consistently done at product receipt or at procedure location.

Technology: HCO has an enterprise resource planning (ERP) system and an electronic health record (EHR) however the systems do not interface.

Other: Excludes any products that the FDA has identified as UDI Exceptions, Alternatives and Time Extensions. Tissue products are not addressed. (See the Learning UDI Community Medical Devices Containing Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) Work Group).

Challenges to healthcare with Current Workflow

With non-stock supplies or implants, also referred to as “trunk stock”, the vendor representative typically brings a product or products into the operating room (OR) when it is needed for a case. In the case of an implant, the vendor often brings in a variety of different sizes for the surgeon to choose from based on the patient’s needs. When the surgeon selects that product for use, it is likely the very first time the HCO has seen this UDI because UDI data on that product is most likely not contained within the HCO’s systems (e.g. OR system, ERP, EHR). This is in contrast to commodity products where the device identifier (DI)

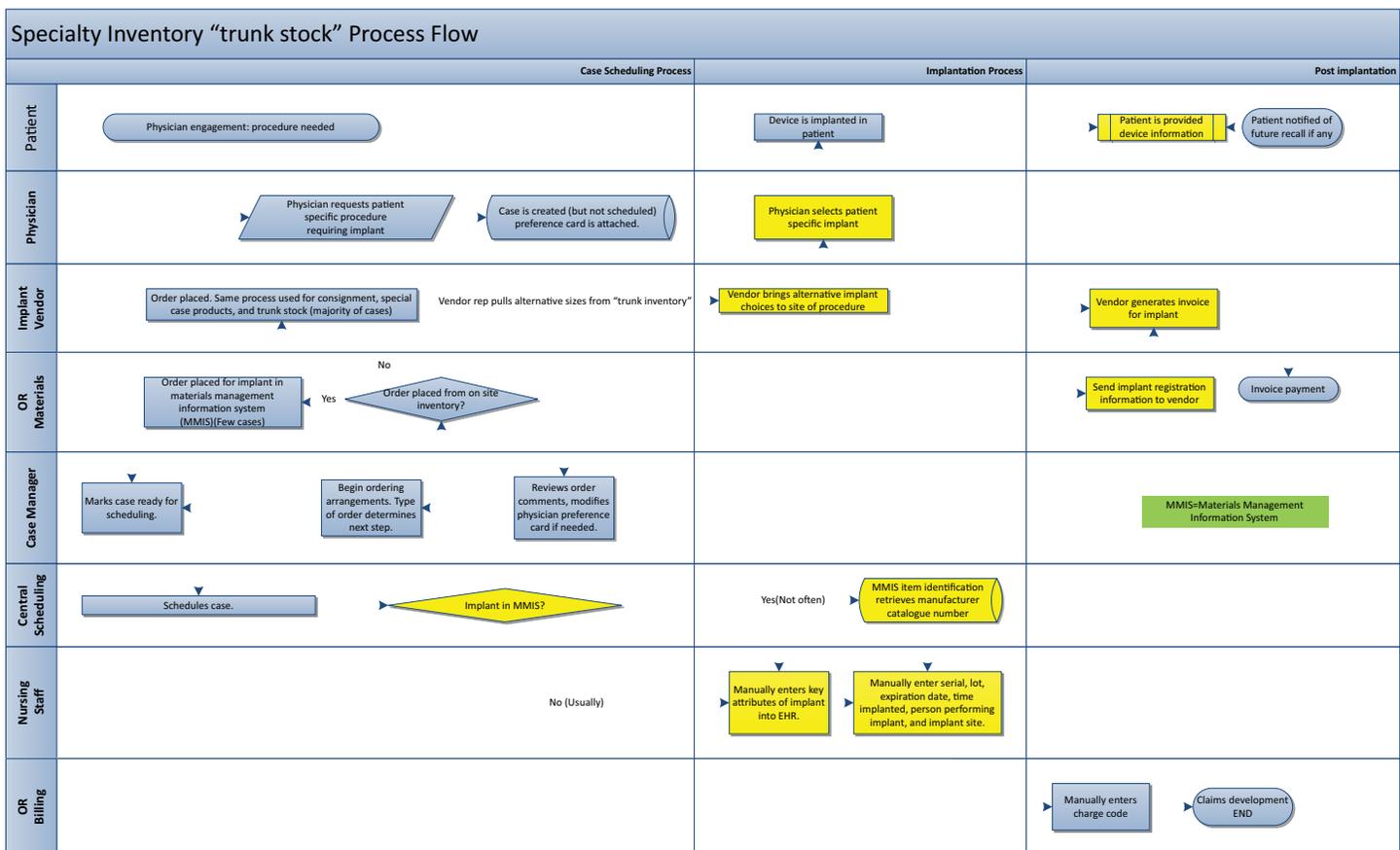
BUSINESS CASE FOR THE UDI REPORT

portion of the UDI can be captured for products during the receiving/stocking processes (see Commodity Inventory Workflow).

Even if the HCO has scanning capabilities in the OR, when an OR staff member scans a product's barcode the UDI is most likely not contained within its systems. This is a break in the process as staff members will need to manually add the missing information into the patient's record creating the risk for errors and missing information within the patient's medical record.

Another challenge with the current process is lack of system interoperability between the ERP system, OR system, and the EHR system. Even if the hospital has the DI and PI portions of a product's UDI in its ERP system, this data typically is not interfaced into the OR system. If there is no interface between the OR system and EHR, OR staff members must manually enter product data into the EHR, increasing the risk for errors and missing information within the patient's medical record.

Within the current processes, the HCO can face a significant challenge in notifying a patient of an adverse event or recall if they have incomplete or missing product data within their systems (see the Product Recalls Workflow in this series for more information). Furthermore, if the product data is not captured, the HCO could miss capture of potential patient billable items.



BUSINESS CASE FOR THE UDI REPORT

Workflow Color Key

- *Blue*: indicates a process
- *Yellow*: indicates a process strongly impacted by UDI
- *Green*: indicates a pertinent definition or note

Where UDI Adoption Can Make a Difference

Through the implementation of barcode scanners in the OR, along with ERP, OR system, and EHR integration and system configurations, an HCO can have an automated way to capture the DI and PI portions of a product's UDI at the point of use. This would improve product data accuracy and inventory management and product usage data, facilitate better adverse event reporting and recall tracking, streamline processes for greater efficiency and OR staff time savings, and facilitate more accurate charge capture and patient billing.

- **Task 1:** When a surgeon selects an item for patient use, OR staff members have the capability to scan the product's barcode in order to capture the PI portion of the UDI in the OR system. The assumption here is that the product's DI is already contained within the HCO's systems.

Benefits: Barcode scanning would reduce errors from manual data entry. The shift from manual data entry to barcode scanning would improve efficiency and save OR staff time currently dedicated to manual audit processes taking place during and post procedure. The HCO charge master will depend on regular updates from the Clean Item Master (CIM) or Virtual Item Master (VIM) and therefore accurate device information will be available to develop HCO claims for reimbursement. Hospitals will also save staff time currently committed to putting claims together for a procedure.

- **Providing Better Data:** for analytics, clinical variation, product utilization (for physicians, HCO leadership), quality improvement initiatives, for patients discharge summaries, surveillance efforts (e.g., registries).

Investment: Barcode scanning system to capture UDI at point of use, training IT staff to implement scanners, and training OR staff to use scanners.

- **Task 2:** Create an interface between the OR system and EHR system so that UDI data flows into the patient's electronic health record.

Benefits: Product UDIs are captured in the EHR system for better adverse event reporting, recall tracking, and billing. If products can be scanned directly into the patient record and the data can move to the billing system, more items will show up for each case improving identification of clinical variation, standardization of care practices, and patient outcomes. Total cost per case is another meaningful metric in understanding the total cost of care specifically in today's value-based care/alternative payment model environment.

Investment: IT investment to make software connection between the OR system and EHR.

BUSINESS CASE FOR THE UDI REPORT

- **Task 3:** Establish a process by which the OR can continue with a procedure in the event a staff member scans a product and finds the DI portion of the UDI is not contained within the HCO's systems. That way the surgeon, nurses, and other staff can focus on their main priority - caring for the patient – without having to worry about missing product data.

Benefits: Helps ensure data on products used in a case is documented in the patient's electronic medical record. This would improve patient safety by helping facilitate adverse event reporting and recall tracking. It would also aid in capturing the cost per case and facilitate a better understanding around the total cost of care, specifically in today's value-based care/ alternative payment model environment.

Investment: Investment in IT resources for EHR system configuration.

- **Task 4:** Compliance with Meaningful Use 3 requirements.

As of today, the Meaningful Use 3 Final Rule goes into effect January of 2018. Hospitals can attest to MU3 requirements during a consecutive 90 day period any time during 2018 in order to receive the incentives. MU3 covers implantable devices that fall under the UDI ruling.

The Common Clinical Data Set: ONC defined a common Meaningful Use data set that facilitates reporting for all summary of care records, care transitions, discharges, and patient access, allowing for more advanced clinical processes.

CMS MU3 requirements require hospitals to share the UDI for implantable devices as part of the Common Clinical Data Set (CCDS) and to share the CCDS across organizations.

Future Workflow

In the Future Specialty Inventory Workflow, the HCO sends a case-based order for non-stock medical devices which are needed for a specific procedure, and the supplier sends the case-based products to the HCO where they are received like all other orders). The received product is either:

- Opened but not used and scanned as “waste”.
- Used in the procedure and scanned into the EHR.
- Not opened or used in the procedure and returned to supplier.

The supplier accurately invoices the HCO for the used/wasted products and the HCO accurately pays the supplier. Supplier assisted cases remain as needed.

Savings

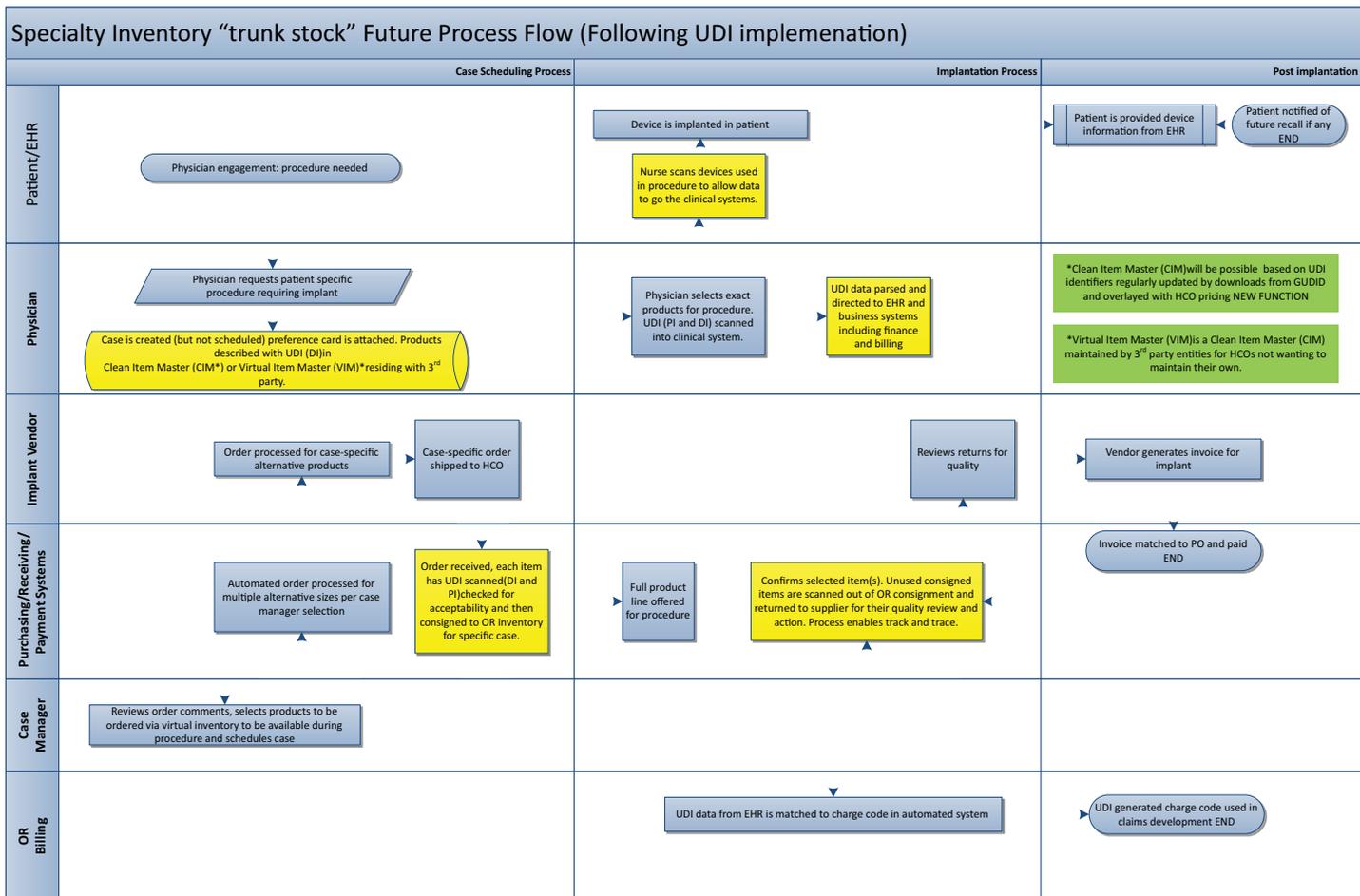
- Cost: Reduced inventory locations for suppliers and reduced overall inventory held by suppliers.

Safety

- HCO knowledge of all products on site permitting identification of expired products and timely response to product recalls. HCO also has knowledge of all products used by patients permitting timely response to product recalls using the EHR.

BUSINESS CASE FOR THE UDI REPORT

Figure: Specialty Inventory “Trunk Stock” Future Process Flow (Following UDI Implementation)



Workflow Color Key

- Blue: indicates a process
- Yellow: indicates a process strongly impacted by UDI
- Green: indicates a pertinent definition or note

EHR TO REGISTRY

Workflow Definition

The EHR to Registry Workflow will demonstrate how product data currently moves from the site of care to the EHR and then to the National Cardiovascular Data Registry (NCDR).

Workflow Stakeholders

- Cath Lab
- Registry Staff
- Physician

BUSINESS CASE FOR THE UDI REPORT

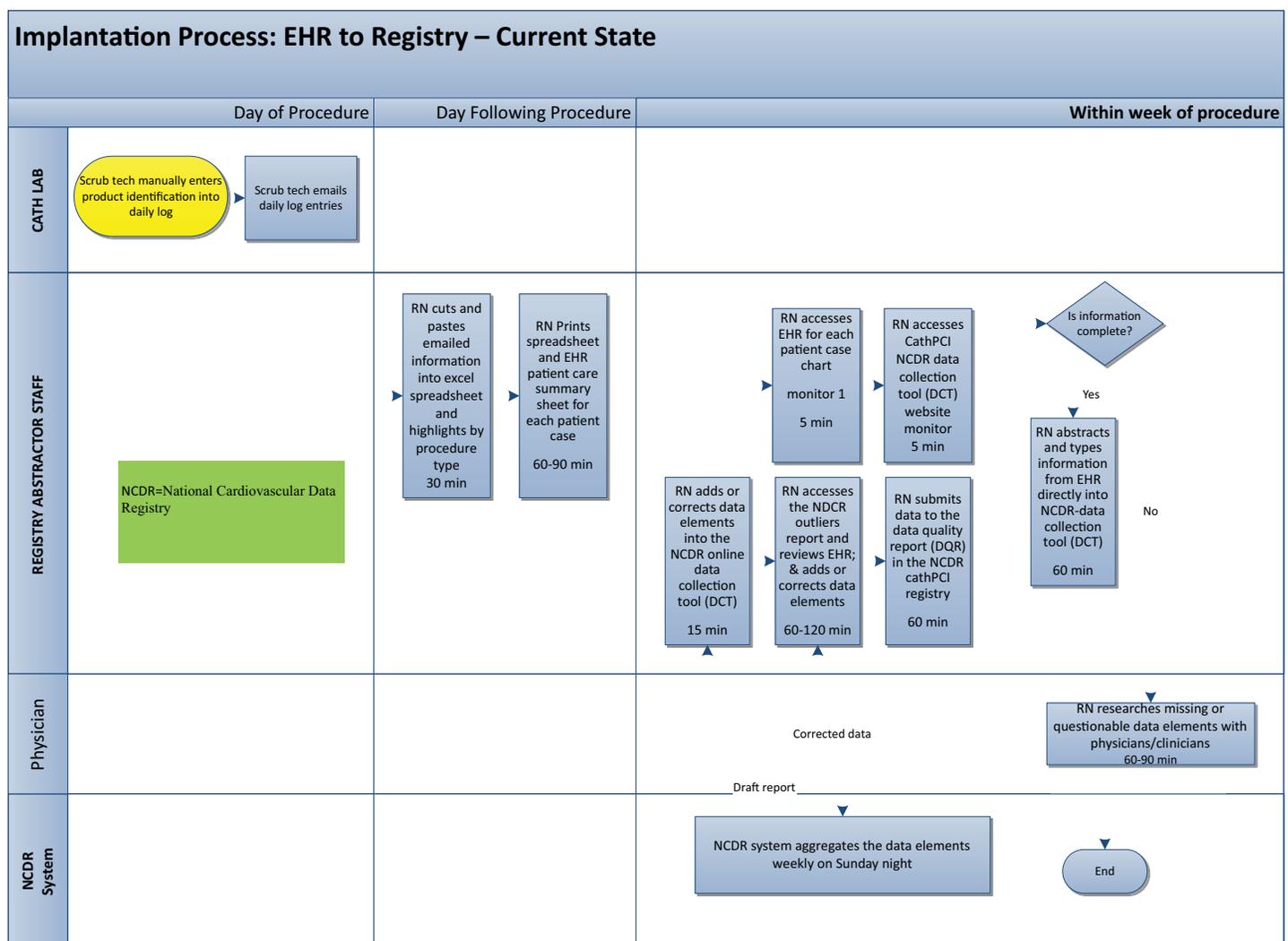
- NCDR System

Assumptions

- The National Cardiovascular Data Registry (NCDR) will have access to product UDIs from the GUDID.
- The DI portion of the UDI has been captured for stock items in the HCO's ERP system during the receiving process (See *Commodity Inventory Workflow* in this report for more information on this process).

Challenges to Healthcare with Current Workflow

Today there are many time-consuming and labor-intensive steps in the process of communicating product usage data from the site of care to the NCDR. Because many of these tasks are manual, they present the risk for inaccurate data capture, and subsequent rework if the HCO must resubmit data to the NCDR. Because of lack of integration between clinical systems (e.g. Cath Lab Clinical Information System, EHR) and the NCDR, staff members must manually enter data into multiple systems, adding additional time and labor to the process.



BUSINESS CASE FOR THE UDI REPORT

Workflow Color Key

- *Blue*: indicates a process
- *Yellow*: indicates a process strongly impacted by UDI
- *Green*: indicates a pertinent definition or note

Where UDI Adoption Can Make a Difference

Replacing manual data entry of product information with scanned data fed from the EHR directly into the NCDR eliminates errors and ensures required fields are completed. Electronically feeding attributes from the GUDID into the NCDR would ensure valuable analytics can be shared, including cost, quality, and outcomes data. Electronic capture of specific data lessens the burden on clinicians and gives them more time with patients.

- **Task 1:** Implement barcode scanners in the Cath Labs so that a staff member can scan a product's barcoded label to record the PI portion of its UDI in the Cath Lab Clinical Information System.

Benefits: Would eliminate manual entry of product data into the Cath Lab system, thereby minimizing the risk of inaccurate data capture or missing information. This would also save staff time currently spent on manual data entry.

Investment: Bedside scanners, as well as training for Cath Lab staff members on how to use the scanners and software.

- **Task 2:** Interface the Cath Lab Clinical Information System with the HCO's EHR so that UDI data flows from the Cath Lab system into the patient's electronic medical record.

Benefits: Would eliminate manual entry of product data into the EHR, thereby minimizing the risk of inaccurate data capture or missing information. This would also save staff time currently spent on manual data entry.

Investment: IT resource investment to interface the Cath Lab Clinical Information System with the EHR.

- **Task 3:** Establish an electronic link from the HCO's EHR to the NCDR so that data flows from the patient's electronic medical record into the registry.

Benefits: This would replace all of the manual steps that staff members must currently complete in order to prepare and submit product usage data to the NCDR, improving accuracy and efficiency, and minimizing labor currently spent on these steps.

Investment: IT resource investment to configure EHR so that it can electronically transmit information to the NCDR.

Future Workflow

In the future EHR to Registry Workflow scanned products at the point of care and system interoperability permit the UDI to inform all clinical systems and registries. Scanning and interoperability saves five steps

BUSINESS CASE FOR THE UDI REPORT

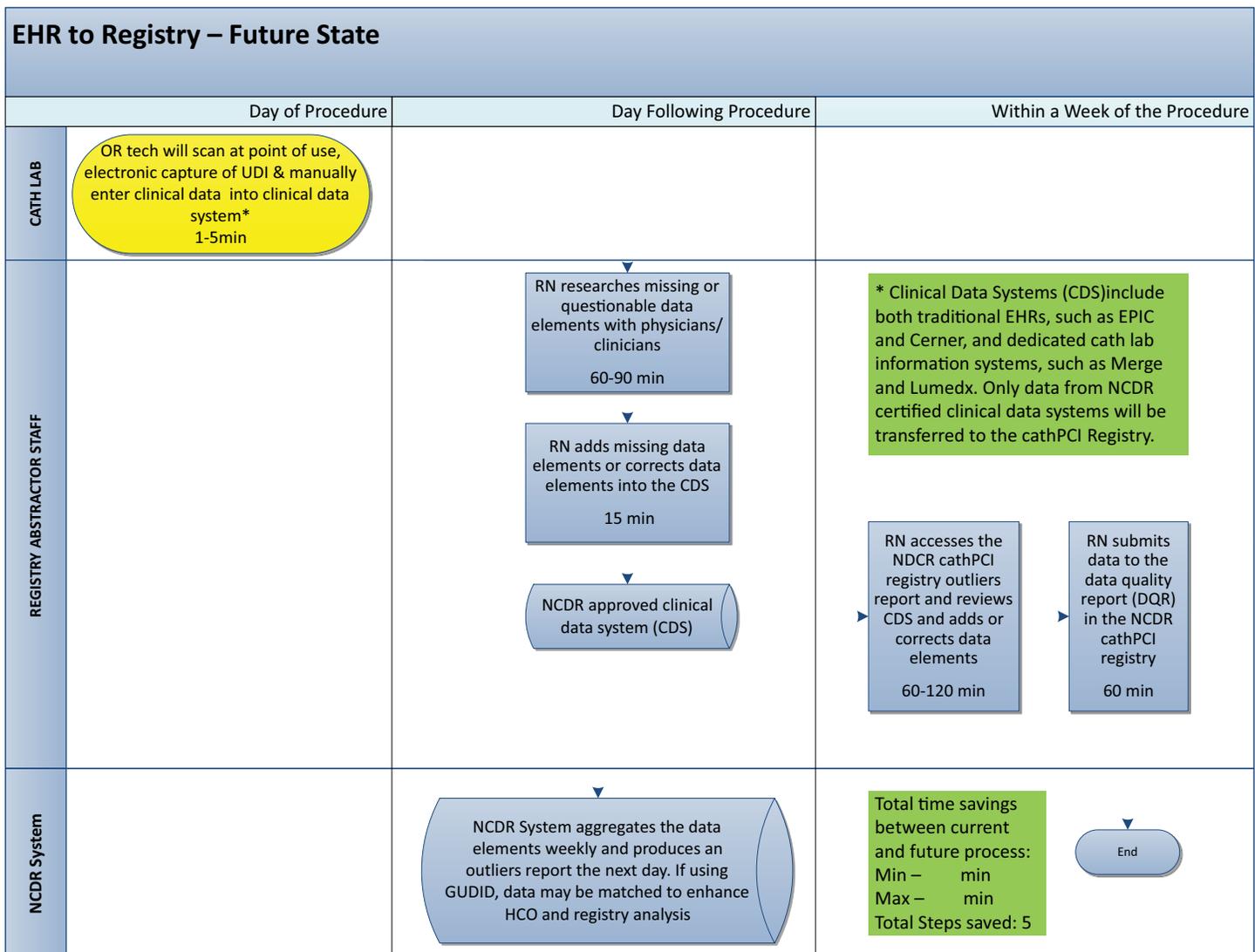
and about 200 minutes when compared to current process. When registries use GUDID as the master file update source, data from the HCO can be easily matched both to registry files as well as to other HCO data gathered by the registry permitting timely product evaluation and reporting.

Savings

Labor – about 200 minutes per case.

Safety

More accurate HCO reporting to the registry. Registry evaluation and reporting is timely and can be immediately integrated into HCO systems as “alerts” if necessary.



Workflow Color Key

- Blue: indicates a process
- Yellow: indicates a process strongly impacted by UDI
- Green: indicates a pertinent definition or note

BUSINESS CASE FOR THE UDI REPORT

ADVERSE EVENT REPORTING

Workflow Definition

The Adverse Event Reporting Workflow describes incidents in patient care involving products when an unexpected negative occurrence may be reportable to the U.S. Food and Drug Administration (FDA) or to other agencies.

Workflow Stakeholders

- HCO Procedure Area
- HCO Risk Management
- HCO Supply Chain
- HCO Clinicians
- Patient EHR
- Supplier
- FDA

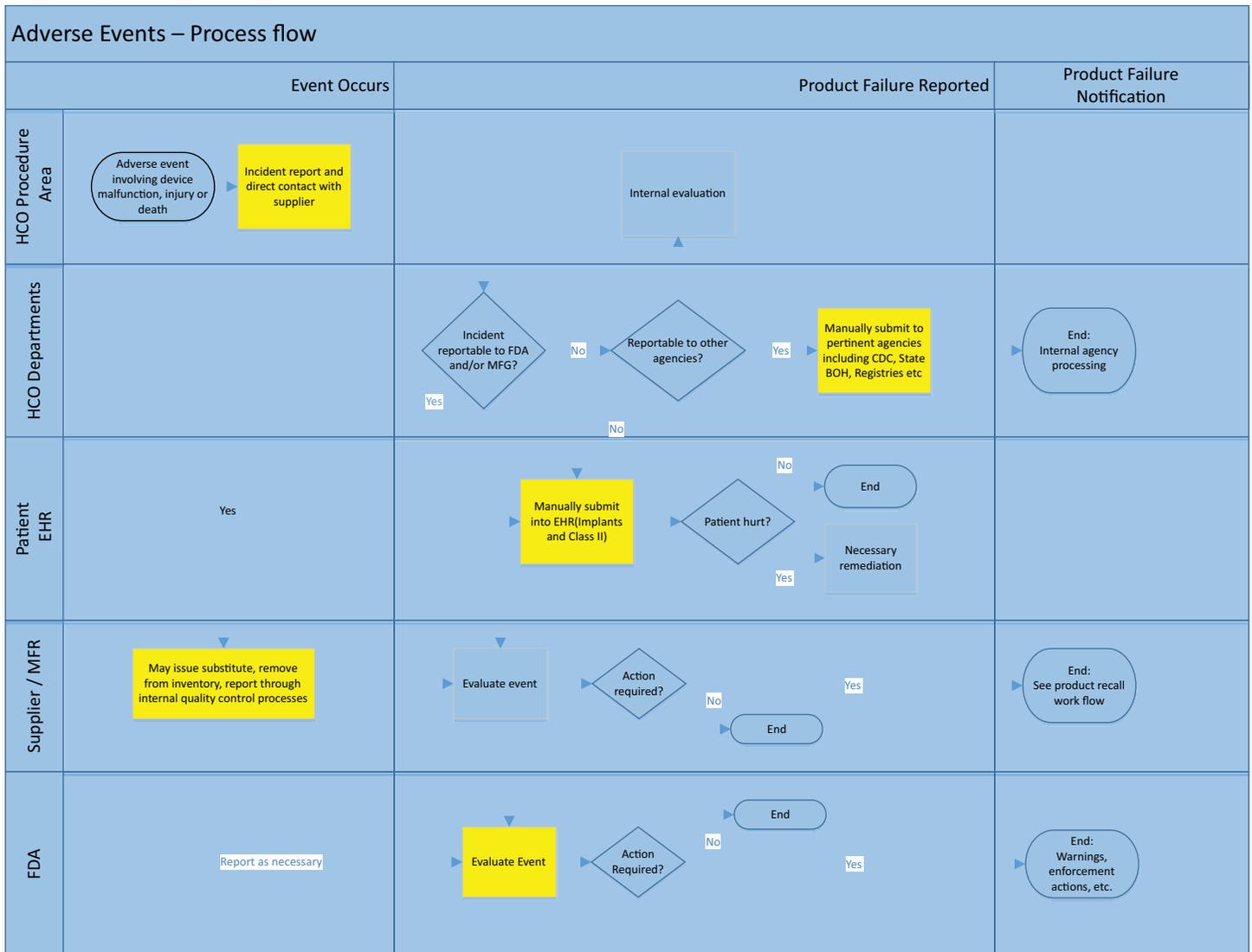
Assumptions

- Explants excluded
- The DI portion of the UDI has been captured in the HCO's ERP system during the receiving process (see Commodity Inventory Workflow in this report for more information on this process).
- The PI portion of the UDI has been captured in the EHR via barcode scanning at the point of use (see the Specialty Inventory Workflow in this report for more information on this process).

Challenges to Healthcare with Current Workflow

Today the process by which an HCO reports an adverse event to the product's supplier and to pertinent agencies (CDC, FDA, State Board of Health, registries) is manual and labor intensive. Furthermore, all of the parties to the process could be using their own product identifier (e.g. manufacturer number, catalog number), making it difficult to accurately and quickly identify the product in question. All of this increases the risk for errors and staff time dedicated to this process (e.g. work, rework). It also reduces the speed at which events are reported, which can jeopardize patient safety and increase liability and compliance risk for the HCO.

BUSINESS CASE FOR THE UDI REPORT



Workflow Color Key

- *Blue*: indicates a process
- *Yellow*: indicates a process strongly impacted by UDI
- *Green*: indicates a pertinent definition or note

Where UDI Adoption Can Make a Difference

By using the UDI to auto-populate the incident reporting system, automatically alerting the supplier and notifying pertinent agencies, an HCO could significantly streamline the adverse event reporting process for greater efficiency and faster reporting. This could save on staff time/costs, reduce the risk for manual data entry and rework, and ultimately improve patient safety through faster and more accurate reporting.

- **Task 1:** Use the UDI to auto-populate the incident reporting system and trigger direct communication with the supplier. This would require system integration between the EHR and the incident reporting system.

BUSINESS CASE FOR THE UDI REPORT

Benefits: Would eliminate manual entry of product data into the EHR and the incident reporting system thereby minimizing the risk of inaccurate data capture or missing information. It would improve communication with the supplier since both the HCO and supplier would be using the same identifier – the UDI – when referring to the impacted product.

Investment: IT resources required to interface EHR and incident reporting system and configure electronic communication to the supplier.

- **Task 2:** Use the UDI to auto-populate adverse event reports to pertinent agencies (FDA, CDC, State Board of Health, registries) and send these reports electronically, versus manually completing and submitting these reports.

Benefits: Electronic data capture versus manual data entry would streamline and improve communication with pertinent agencies.

Investment: IT resources required to interface EHR with appropriate internal system to electronically generate agency reports, as well as system configuration to electronically submit reports to agencies.

Future Workflow Impact Points

In the future Adverse Event Workflow, clinicians will scan the UDI at the point of use with an interface to the HCO's incident reporting system and 3rd party submitter (see glossary). The 3rd party submitter manages all communication between the HCOs, suppliers, manufacturers, and FDA concerning adverse events involving medical devices. The HCO risk management and supply chain teams will have timely access to comparative product information and can respond accordingly. The HCO will pass the event information to other government agencies as required using UDI.

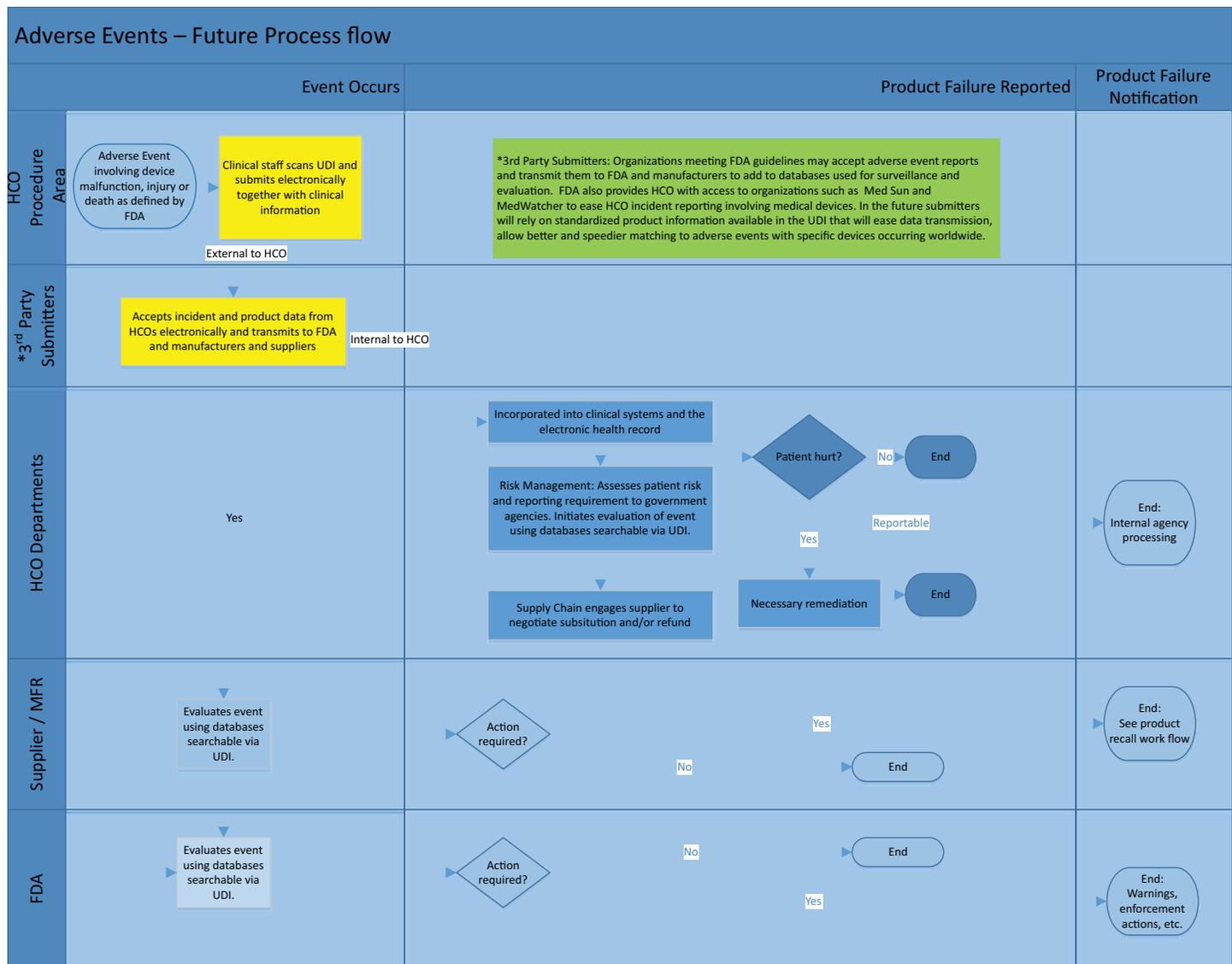
Savings

- Labor savings for clinicians who currently report adverse events to many manufacturers and suppliers and will in future only report to a 3rd party submitter.
- Electronic HCO communications to risk management and supply chain will reduce reporting time.

Safety

- Manufacturers, suppliers, and FDA will get more timely and complete information from HCOs through 3rd party submitters and can respond accordingly.
- Timely reporting can result in more timely recalls, should they be required.
- HCO risk management will have access to product evaluation information to assist with internal evaluation.

BUSINESS CASE FOR THE UDI REPORT



Workflow Color Key

- *Blue*: indicates a process
- *Yellow*: indicates a process strongly impacted by UDI
- *Green*: indicates a pertinent definition or note

BUSINESS CASE FOR THE UDI REPORT

PRODUCT RECALLS

Workflow Definition

The Product Recalls Workflow outlines actions within an HCO that take place in response to notifications from distributors, manufacturers, third party recall services, or the FDA stating that a medical device must be recalled.

Workflow Stakeholders

- FDA/Distributors/3rd Party Recall Services/Manufacturers
- HCO Purchasing Department
- HCO Clinical Departments
- HCO Supply Chain
- HCO Risk Management
- Patients

Assumptions

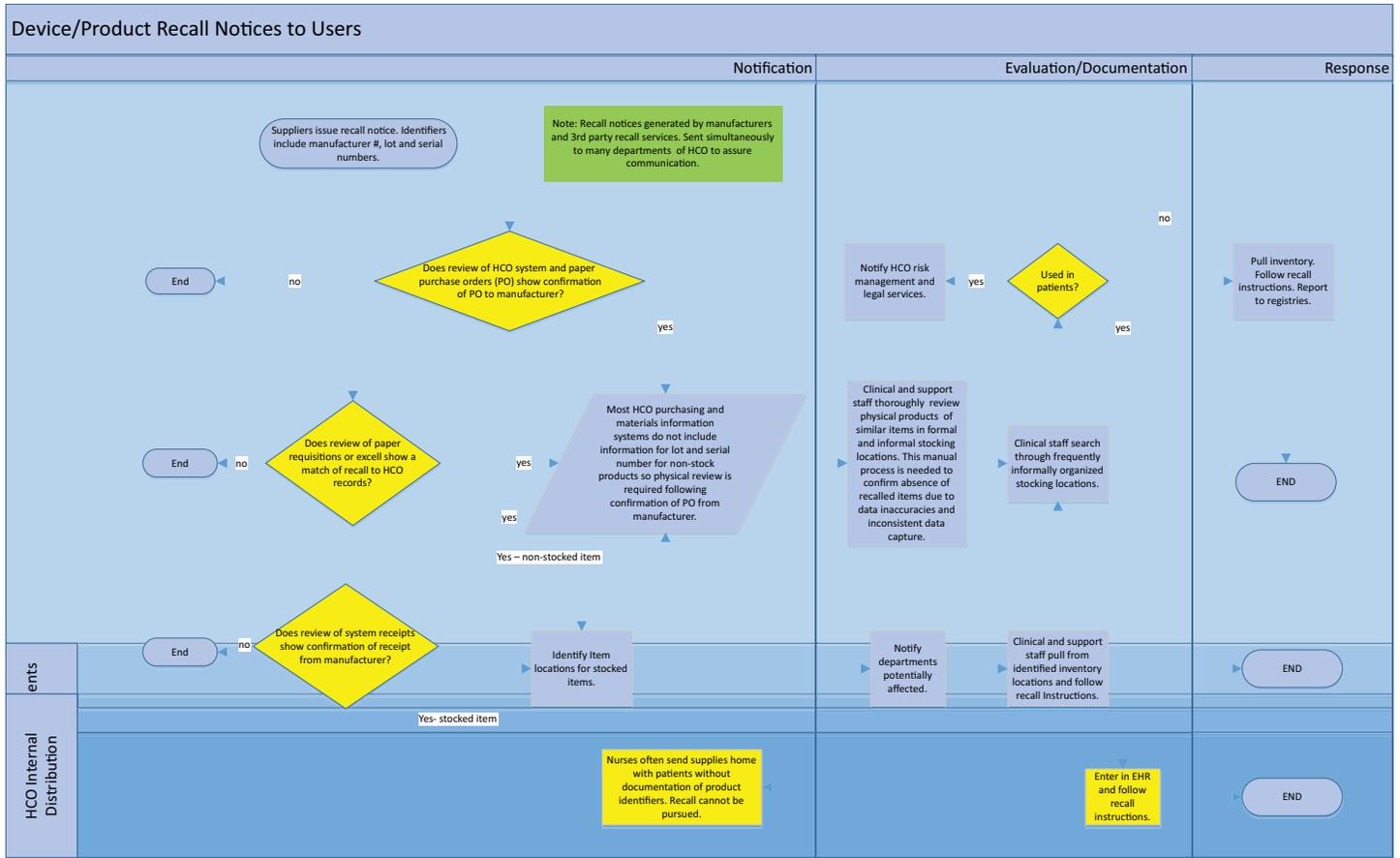
- Bio medical equipment is excluded from workflow
- Consignment inventory is excluded from workflow
- Product substitutions are excluded from workflow

Challenges to Healthcare with Current Workflow

The biggest challenge without product UDIs is the number of isolated work streams occurring – both within the HCO and externally with the suppliers. There are multiple contacts, multiple activities, and multiple resolutions around product use. Tasks that are carried out in isolation are a challenge to HCOs and suppliers when performing a product recall. When a recall is conducted in these silos, it is difficult to determine how complete and successful it has been. The UDI serves as a common identifier to coordinate information and communication among various the stakeholders.

Another challenge is that HCOs tend to store products in multiple locations within their facilities. This is done typically for ease of use so that a nurse has the product on hand when he/she needs it. But this makes it difficult for the HCO and its suppliers to track down these products in the event of a recall.

BUSINESS CASE FOR THE UDI REPORT



Workflow Color Key

- *Blue*: indicates a process
- *Yellow*: indicates a process strongly impacted by UDI
- *Green*: indicates a pertinent definition or note

BUSINESS CASE FOR THE UDI REPORT

Where UDI Adoption Can Make a Difference

Use of product UDIs within the HCO's ERP system and within the EHR would allow the HCO and its suppliers to track products via UDI from the point of manufacture, to point of stock, and through to the point of use. This would help break down silos since all parties would be using the same product identifiers, resulting in better recall tracking, improved patient safety, and greater operational efficiency.

Please refer to the Commodity and Specialty "Trunk Stock" Inventory Workflows, in this report, which outlines the need to build HCO systems relying on the GUDID as the source of truth for product identification. This product identification will be used by various technologies (e.g. barcode scanners), enhance system interoperability (e.g. ERP, EHR, clinical systems, registries), and other tasks required to achieve this future state.

Future Workflow

Use of the Clean Item Master (CIM) or Virtual Item Master (VIM) together with the advance ship notices (ASN) gives the HCO specific knowledge of all products purchased to exact internal locations. Interoperability of the ERP to EHR systems gives the HCO knowledge of all products used with patients. 3rd party recall management organizations can provide timely recall information that the HCO can match to all internal product data, providing the ability to recognize and remove recalled product prior to patient use. The HCO's data management team for medical devices is responsible for sharing information internally to facilitate the recall.

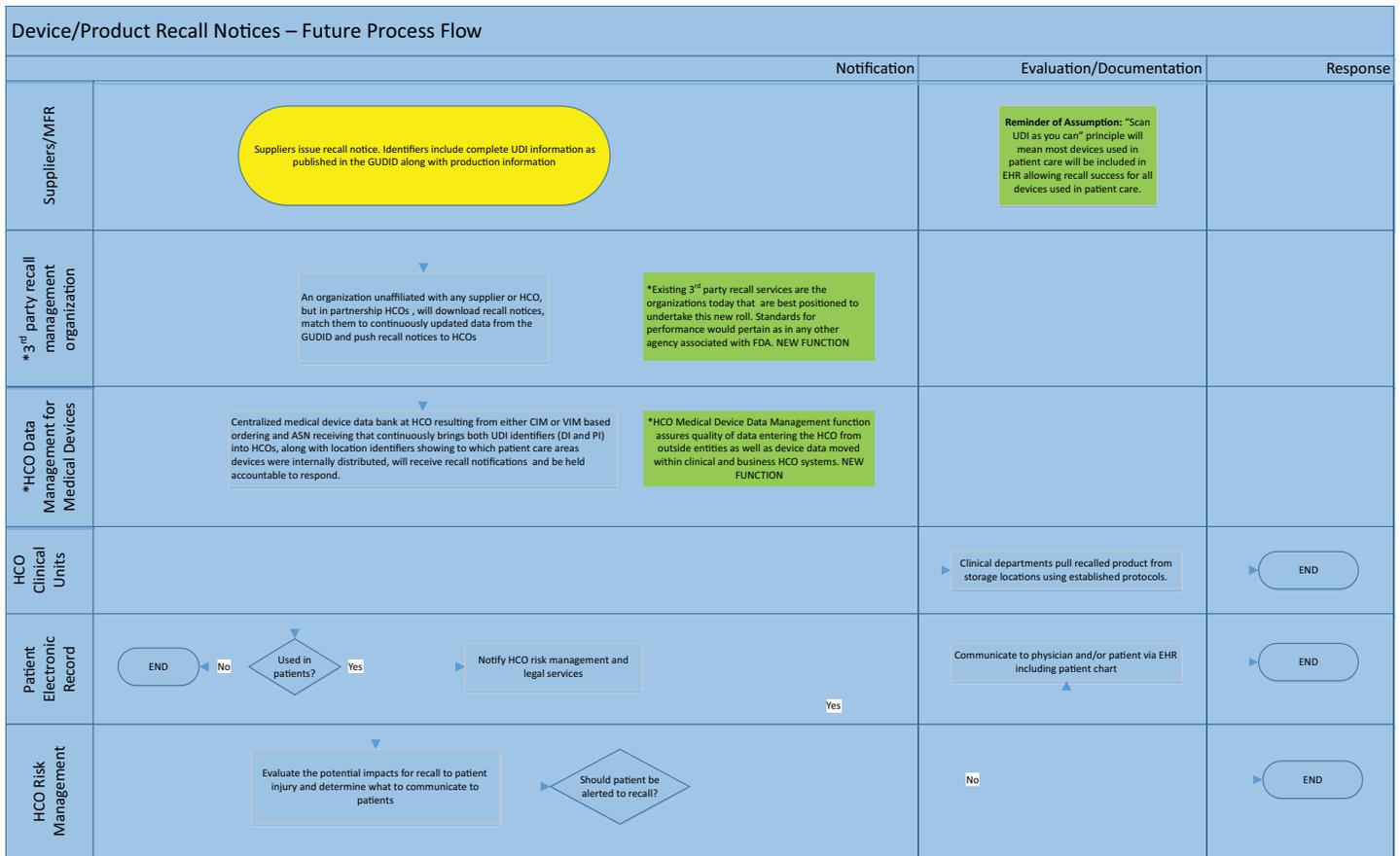
Savings

- Labor now used for "hunting" for recalled product will significantly decline as recalls will be focused specifically on known purchases to exact locations within an HCO.
- Labor now used for identifying patients impacted by the recall.

Safety

- Recalls along supply chain will be successful and recalled products will be unavailable to purchase and removed from all inventories.
- Recalls found in the EHR will allow HCO patient communication as necessary.

BUSINESS CASE FOR THE UDI REPORT



Workflow Color Key

- Blue: indicates a process
- Yellow: indicates a process strongly impacted by UDI
- Green: indicates a pertinent definition or note

The Current State and Interim Solutions

Getting to this future state where automation and integration facilitates seamless recall tracking will not be easy, and it will take some time before HCOs can complete all of the tasks necessary to achieve this. We must consider interim solutions whereby HCOs can begin incorporating UDIs into their systems and processes to better manage the recall process, in parallel with implementing and completing the recommended solutions required to achieve the future, ideal state. Below are some examples:

Maintaining Two Identifiers

Some HCOs are housing in their ERP systems both the UDI and the manufacturer's catalog item number during this transitional period. This allows those aspects of the HCO's system that are dependent upon the manufacturer's catalog number to continue to use it as a bridge or crosswalk until they are ready to transition to the UDI.

BUSINESS CASE FOR THE UDI REPORT

DI Recalls

HCOs can take a lesson from the retail industry where stores may have product identifier information in their systems, but not necessarily production identifier information. If there is a recall on the product identifier, the retailer is alerted to it when it scans that product's Universal Product Code (UPC) barcode. From there they can then check with FDA to determine whether the recall pertains to that specific product's lot, serial number, etc. (the production identifier information).

HCOs that have downloaded product DIs from the GUDID into their ERP systems could configure their systems to engage in a similar process. If they scanned a product and were alerted to a recall based on the DI, then they could check with the FDA to determine if that specific product was affected based on its PI. This brings healthcare one step closer to achieving its goal of improved patient safety.

Recall Databases

U.S. HCOs can also learn from their counterparts in Europe. For example, some European HCOs have a system in place whereby they scan the product's barcode at the point of use to capture its UDI data and this information is matched up against a database of recalled items. That way, the clinician is immediately alerted to the recall before they use that item in patient care.

CONCLUSION

As a result of the U.S. UDI rule, there are already a significant number of products labelled with UDIs, in both machine and human readable form, with data on more than 1.6 million products in the GUDID as of the writing of this report. That number will continue to grow as new products are approved for sale and use in the U.S. and the Class I deadline approaches. But the value of the UDI rule, in terms of better visibility to adverse events, more effective recall management, visibility to real time performance of medical devices in routine clinical practice, and more efficient supply chain practices, will only be realized if UDIs are incorporated into healthcare provider systems and processes.

With significant pressures on hospitals and healthcare systems, it is incumbent upon those who recognize the benefits of UDI to build the business case for UDI adoption in the healthcare delivery environment. As the one discipline that works with operational, clinical, financial and technical leaders, supply chain professionals can help build the business case that documents value for multiple stakeholders. By identifying current and future workflows around key hospital processes, Business Case for UDI workgroup has provided insights that can help identify areas of investment necessary and corresponding benefits. Healthcare systems can take the current state workflows and adjust them as necessary to match their specific processes and also make any necessary adjustments to the future state to align with their vision for UDI adoption.

The AHRMM Learning UDI Community wishes you well on your journey toward UDI adoption and looks forward to hearing how you are successfully using these tools in your organization.

BUSINESS CASE FOR THE UDI REPORT

SUB GROUP MEMBERS

- Commodity Inventory Management Workflow
- Lena Cordie, Owner, Consultant, Qualitas Professional Services
- Alida Hart, Volunteer Consultant
- Corwin Hee, MDM Business Process Program Director, Medtronic
- Michael Hudon, Director of Global Regulatory Affairs, Philips
- Lana Makhanik, Chief Operating Officer, Vuemed
- Ellenmary Martin, Chief Strategy Officer, Duka
- Brian Murray, MBA, CMRP, Director, Supply Chain Systems, NorthShore University Health System
- Mike Nolan, President, Automatic Identification Systems
- Libye Nuernberg, CMRP, Materials Management, Christus Santa Rosa
- Virginia O'Connell, PS Business Analyst II, MedStar Health
- James Phillips, Consulting Manager, DSI, Franciscan Missionaries of Our Lady Health System (FMOLHS)
- Joann Robertson, MBA, CMRP, Division Director, Baylor Scott & White
- Erin Salbilla, Quality Manager, Label Development, Vyaire
- Thomas Stenger, Director, AP and Purchasing, Baptist Health System
- Steven Zogelman, Inventory Manager, George E. Wahlen Department of Veterans Affairs Medical Center

Specialty Inventory (“Trunk Stock”) Management Workflow

- John Doub, MBA, CMRP, Manager, Supply Chain Operations, Erlanger Health System
- Jeff Dunkel, Vice President of Strategic Partnering, Titan Spine
- Kelly Fischer, Director, Global Reporting & Accounting Operations, Cook Medical
- Corwin Hee, MDM Business Process Program Director, Medtronic
- Dale Jacques, Data Scientist, Procured Health
- Tom Jones, Project Director, UDI, Supply Chain, J&J
- Allen Ledbetter, Assistant Vice President, Supply Chain Solutions, Healthtrust Purchasing Group
- Keith Lohkamp, Director, Industry Strategy, Workday

BUSINESS CASE FOR THE UDI REPORT

- Erich Lukas, Senior Manager, RA/QA Technical Communications, Olympus
- Tom Maughan, Principal Engineer, J&J
- Denise Maxwell-Downing, RN, MS, CNOR, Informatics Nurse Specialist, Association of periOperative Registered Nurses (AORN)
- Mike Nolan, President, Automatic Identification Systems
- Darrell Padilla, Manager, N.A. Consulting, GHX
- Cynthia Shumway, Director, Supply Chain Business Applications, Intermountain Healthcare
- Julie Suko, PharmD, Senior Director, Editorial Services, First Databank
- Ricki Wilson, Director, Standards Implementation, Vizient

EHR to Registry Workflow

- Joe Drozda, MD, FACC, Director of Outcomes Research, Mercy
- Douglas Dumont, PhD, Office of Surveillance and Biometrics, U.S. Food and Drug Administration (FDA)
- Kade Etter, PhD, Medical Device Epidemiology Postdoctoral Fellow, J&J
- Beth Kaylor, RN, RPIAC, Director, Clinical Innovation, DeRoyal Industries
- Sandi Michel, LSSBB, MPMP, ITIL, System Director, Systems & Quality, Franciscan Missionaries of Our Lady Health System (FMOLHS)
- Caroline Morgan, Program Manager PVI Registry, American College of Cardiology
- Karen Ramsey, Strategist, Cerner
- Terrie Reed, MSIE, Senior Advisor for UDI Adoption, U.S. Food and Drug Administration (FDA)
- Jim Roach, Manager, Data Engineering & Analytics, Mercy Technology Services

Adverse Event Reporting Workflow

- Ethan Abernathey, Director of Business Operations, Procured Health
- Tandi Bagian, MSE, Program Analysis Officer, VA National Center for Patient Safety
- Thomas Bauld, CCE, Biomedical Engineer, VA National Center for Patient Safety
- Susan Broyles, RN, Patient Representative, American Nursing Association
- Douglas Dumont, PhD, Office of Surveillance and Biometrics, U.S. Food and Drug Administration (FDA)
- Beth Gore, Patient Safety/Advocate

BUSINESS CASE FOR THE UDI REPORT

- William Howard, CMRP, Medical Sales and Marketing, W.A. Howard & Associates
- Katrina Jacobs, MS, Biomedical Engineer, VA National Center for Patient Safety
- Bob Matthews, CMRP, Assistant Vice President, Supply Chain, Albany Medical Center
- Kevin Neuman, Vice President of Marketing and Operations, Innovative Healthcare Corporation
- Lee Phillips, Officer, Bodenheim Properties
- Michael Tanner, Director, Clinical Technology Management, Beaumont Health
- Madris Tomes, MBA, Founder and Chief Executive Officer, Device Events
- Rayneisha Watson, Manager, Translational Medicine, Deloitte
- Elizabeth Willson, MHA, Senior Director, Health Policy and Quality, Society of Interventional Radiology

Product Recalls Workflow

- Ethan Abernathy, Director of Business Operations, Procured Health
- Ronald Brown, MS, Recall Team Director, Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration (FDA)
- Chris Chandler, PharmD, Strategist, Franciscan Missionaries of Our Lady Health System (FMOLHS)
- Jay Crowley, VP and Practice Lead, UDI Services and Solutions, USDM Life Sciences
- Carl Gomberg, Lead Solution Analyst, Portfolio Strategy & Design, Premier
- Mary Gray, RAC, Policy Implementation Manager, J&J
- Melanie Hadlock, Regulatory Affairs Specialist, C.R. Bard
- Jodi King, UDI Program Director, Certified Project Manager, Philips
- Patrick Lupinetti, Senior Vice President, First Databank
- Rosalind Parkinson, MPH, President, Parkinson Logistics Associate
- Frank Pokrop, Director, Regulatory Affairs, Becton Dickenson
- Ron Prybella, Senior Director of Marketing, Medegen Medical Products
- Guillermo Ramas, Chief Executive Officer, Genesis Automation
- Melanie Raska, Director, Regulatory Affairs, Boston Scientific Corporation
- Mike Schiller, Senior Director of Supply Chain, Association for Healthcare Resource & Materials Management (AHRMM)
- David Tinker, Regulatory Compliance Specialist, Musculoskeletal Transplant Foundation

BUSINESS CASE FOR THE UDI REPORT

- April Veoukas, Director, Regulatory Affairs, Abbott
- Ricki Wilson, Director, Standards Implementation, Vizient

AHRMM also wishes to thank the following individuals for their insight and guidance in initiating and helping bring to fruition the Business Case for UDI Workgroup: Karen Conway, Curtis Dudley, Myoung Kim, Rosalind Parkinson, Dick Perrin, and Mike Schiller.