Achieving Unique Device Identifiers in Real World Data Sources: A Playbook for Health System Unique Device Identifier Implementation at the Point of Care

Posted Date: November 15, 2022

Comments Due: December 15, 2022

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Objective: To develop a Playbook for health system stakeholders in order to support unique device identifier (UDI) implementation at the point of care, therefore ensuring data integrity and scalability to support real-world evidence generation about medical devices.

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Funding for this report was made possible, in part, by the Food and Drug Administration through grant U01 FD 006292. Views expressed in written materials or publications and by speakers and moderators regarding this report do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government. In addition, this publication reflects the views of the authors and should not be construed to represent the views or policies of the FDA or any of the authors' employers.

ADDITIONAL INFORMATION

For more on the UDI Adoption and Application project, view the NESTcc Collaborative Community page or contact Sanket Dhruva, sanket.dhruva@ucsf.edu or Natalia Wilson, natalia.wilson@asu.edu.

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Preamble

The United States Food and Drug Administration (FDA) Unique Device Identifier (UDI) is a system to identify medical devices sold in the United States from manufacturing through supply chain to patient use. Specification of the system has been accomplished through both legislation and FDA rulemaking. A UDI is now available on essentially all moderate and high-risk devices, and implementation and use of the UDI is expanding across the world. Significant investments have been made to label devices with the UDI, which identifies device manufacturer, device-specific information (e.g., model), and production-specific information (e.g., lot number). Use of the UDI provides many benefits to improve the safety and delivery of patient care through applications in clinical decision-making, in recall management, and in health system operational functions that underpin safe and high-quality clinical care. Availability of the UDI advances device surveillance and other assessments of the safety and effectiveness of medical devices through real-world data (RWD) sources, for which the National Evaluation System for health Technology Coordinating Center (NESTcc) has been created.

Optimizing the potential for this multitude of benefits requires that the UDI be captured at the point of care (POC) by health system information technology (IT) systems. To date, however, only a limited number of health systems have taken steps to capture UDI data electronically at the POC and use that data as the single "source of truth" regarding medical device utilization in patient care. A burgeoning literature and body of expertise have developed from the limited "end-to-end" UDI implementations that provide critical insights to describe and guide the specifics for health system UDI implementation at scale.

In this setting, the UDI Playbook was created for NESTcc health system research network collaborators (and more broadly, for all health systems) to advance UDI implementation at the POC and UDI availability in RWD sources in their respective health systems. This will serve to augment real-world evidence (RWE) generation about medical devices for improved patient care and safety. The Playbook is divided into the following sections: Introduction, Defining Steps, Implementation Planning, Implementation Development, Implementation, Sustainability and Advancement, UDI Use, Conclusion, References, and Appendix.

I. Introduction

<u>UDI System</u>

Despite a wealth of information documented in health IT systems, the lack of a standard device identifier has significantly hampered the ability to link device data to clinical care processes and patient outcomes for studying the safety and effectiveness of medical devices and identify and correct safety issues in a timely fashion.[1,2] The UDI system was prompted by this gap, notable for several high-profile medical device failures,[2] to address concerns about the ability to track medical device performance and protect patient safety.[3] A 2011 Institute of Medicine Report

called for a robust system for postmarket medical device evaluation.[4] Subsequent FDA reports focused on strengthening medical device postmarket surveillance[5,6] that included establishing a UDI system and incorporating UDIs into electronic health information data sources.

Legislative and Policy Impetus

The 2013 Unique Device Identification System Rule mandated the labeling of medical devices with a UDI by medical device manufacturers.[7] The Rule was preceded by the FDA Amendments Act of 2007[8] and the FDA Safety and Innovation Act of 2012,[9] which called on the FDA to develop a UDI system.

Over the past decade, the UDI requirement has been phased in and the UDI is now on the vast majority of moderate- and high-risk medical devices as well as increasingly on lower-risk medical devices.[10]

Basics of the UDI[11]

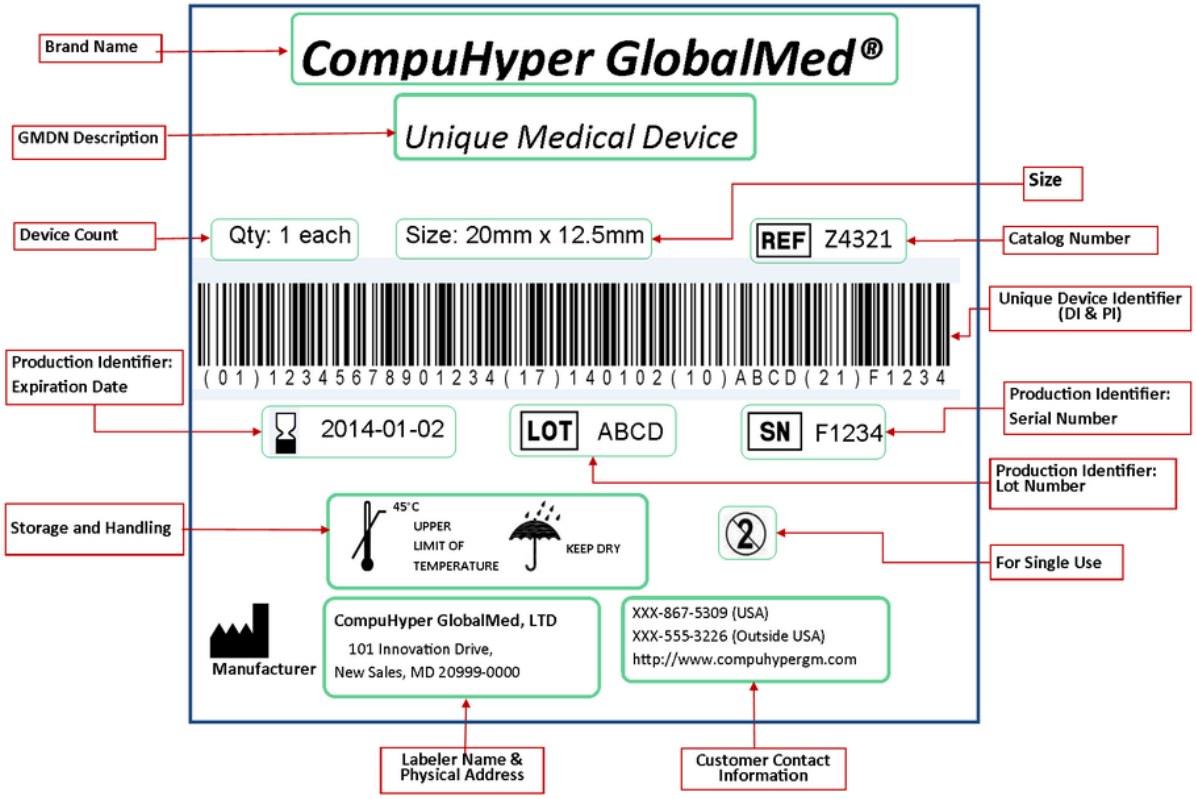
The UDI is a unique code that must be in both human-readable and machine-readable forms on the label and packaging of medical devices.

There are two components of the UDI:

A) Device Identifier (DI), which identifies the device's manufacturer and model

B) Production Identifier (PI) which identifies the manufacture date, expiration date, lot number, and/or serial number. The specific available components of the PI may differ for different devices.

Figure: Example of a device label with the UDI



Necessity of UDIs in Health System Data to Support the Generation of RWE

Integration of the UDI into health system IT systems when devices are used in patient care is a critical element for generating RWE about medical devices, including their safety and effectiveness. The UDI both enables accurate identification of medical devices used in patients as well as tracking of associated clinical outcomes, supporting both exposure and clinical outcomes ascertainment.

Despite being a nascent area, in early adopter health systems where UDIs are available and have been used in RWE studies, medical devices can be accurately identified and linked to specific patients in whose care they are used, which enables evaluation of clinical outcomes. The Building UDI into Longitudinal Data for Medical Device Evaluation Initiative (BUILD) demonstrated the ability to leverage UDIs to create research databases at three different health systems employing a common data model and to examine clinical outcomes of coronary stents using a distributed analytics approach.[12] Similarly, research as part of the NESTcc ThermoCool® Phase II Project, which studied the safety and effectiveness of cardiac ablation catheters for treatment of two different cardiac arrhythmias, leveraged UDIs for device identification.[13-15]

Gaps in UDI Implementation in Health Systems

The status of UDI implementation and electronic capture of UDIs at the POC in U.S. health systems is limited,[16,17] including in NESTcc health system research network collaborators. As of 2021, more than 50% of the NESTcc-affiliated health systems evaluated had not integrated

electronic capture of the UDI at the POC into routine workflow processes, precluding UDI availability for use in RWE studies.[18]

Multiple barriers to UDI implementation have been identified. First is a lack of knowledge about what the UDI is, its benefits, and the status of implementation within a given health system. Second are challenges within health systems, including a lack of leadership and collaboration across functional areas for UDI implementation, perceived lack of return on investment (ROI), and lack of a health system level approach to information technologies and technology integration. The third set of barriers relates to a lack of coordinated external support, particularly the intersection of vendor technologies and policy mandates.[18] Even when UDI implementation has been approved to commence in a health system, barriers are faced both internally and externally. These include long-term organizational support, IT limitations (both needed functionalities and vendor support), clinical resistance, manufacturer support, and gaps in the needed reference data.[17,19]

RWE Generation Without UDI

Without UDI implementation at the POC in health systems, UDIs are not reliably available for use in RWE studies about medical devices. Consequently, research on medical devices faces limitations.[20] In the current state, medical device research studies rely on broad administrative codes, which usually encompass multiple different devices. Device-specific RWE studies must be performed through manual extraction of data, which is both time- and resource-intensive.[18,20] Given these challenges, RWE studies about medical devices to inform patients, physicians, payors, regulators, and other stakeholders within the medical device ecosystem are stymied and a significant barrier is imposed for achieving goals expressed in the FDA UDI Rule and by the NESTcc.

Motivation and Goals for this UDI Playbook

Despite the challenges, some health systems have successfully implemented UDIs into their IT systems at the POC. In order to achieve this implementation, they have built awareness about the UDI as well as cross-functional collaboration within their health system, have delineated expected ROI, and have navigated the external support needed and collaborative opportunities available that support UDI implementation. Researchers in these health systems, as evidenced in the examples provided earlier,[12,15] have heightened opportunities to conduct RWE research evaluating and comparing medical device performance and to inform best practices in patient care.

While there is a body of valuable published research and reports about health system UDI adoption, the information has not been aggregated. Research has illuminated the value of the UDI through the eyes of physicians, nurses, hospital personnel, patients, and researchers; the necessary steps for health system UDI implementation at the POC; how the UDI is being used; and how UDI availability augments RWE studies. Very importantly, research has also illuminated the critical role health systems must play to advance the availability of RWD enriched with UDIs and a broader UDI-enabled system for medical devices in health care.

Accordingly, the UDI Playbook was generated to guide NESTcc health system research network collaborators in advancing UDI adoption in their respective health systems as well as serve as a

guide for any health system. The goal is to support achieving UDI availability in RWD sources for RWE generation about medical devices for improved patient care and safety.

Methods

An Advisory Group of 10 individuals with long-standing expertise in UDI implementation, including leaders of implementation at the POC within their health systems, was created. The Advisory Group was tasked with reviewing and providing input on an initial UDI Playbook outline and literature list, providing targeted feedback on gap areas during development of the draft UDI Playbook, and performing a final review of the UDI Playbook prior to submission to NESTcc for public comment.

The approach of the author team was to aggregate literature about UDI implementation at the POC and UDI use from peer-reviewed original research publications and commentaries; reports from government, think tanks, academia, and industry; and industry case studies, and create a project literature list. Fifty-six research papers and other publications were identified (Appendix: Literature List). Preliminary review of these sources, findings from ongoing NESTcc-supported research on UDI implementation[18] as well as review of the FDA UDI regulation,[7] FDA UDI webpages,[3,10,11,21] and the NESTcc UDI Center[22] informed development of the UDI Playbook outline. This outline guided the author team in writing the UDI Playbook, which involved an in-depth review of the literature sources, internal discussion, iterative revisions between the authors, and incorporation of input from the Advisory Group.

The major areas identified to guide UDI implementation at the POC, which are discussed in detail below, are Defining Steps for UDI implementation, Implementation Planning, Implementation Development, Implementation, and Sustainability and Advancement. Also discussed are benefits of UDI and use of UDI, focused on RWE generation.

II. Benefits of UDI

Benefits of UDI availability and use across several areas within health systems have been discussed and studied over the past decade.[1,2,12,13,16-19,23-29] Benefits accrue in clinical care, supply chain management, finance and revenue, and use in the broader medical device ecosystem for research and evaluations of postmarket device performance for patient safety. Critical to achieve leadership buy-in at the health system for UDI implementation at the POC is articulation of the clinical and operational benefits. This, rather than the ability to pursue RWE studies, is the primary motivation to operationalize UDI adoption.

Clinical Care

Information needed for Clinical Decision-making

Should a patient require a revision surgery for an implanted device, it is essential to know which specific device had been initially implanted; this both informs procedural strategies and identifies the requisite replacement devices.[29,30] UDI provides the granular information to identify the initial device. Without it, the process to obtain identifying device information is not only time-consuming and cumbersome, but not always successful.[30,31] In some clinical contexts, magnetic resonance imaging (MRI) is the best diagnostic modality. Some devices are not compatible with

MRI, which is essential knowledge before performing this test; this information is available in the FDA AccessGUDID database, where information about MRI compatibility, among other variables, is listed by the device UDI-DI.[32] Documentation of the UDI in the implant log in a patient's electronic health record (EHR) provides information that can be accessed in the case of a recall as well as providing information for physicians who may be new to a patient's care, including in an emergency when this information may be critical for clinical decision-making. Shared in a quote from an OR nurse about their implant barcode scanning process at the POC, "I think all of us now realize how important it is for patient safety."[33]

Improving Clinical Workflow

UDI implementation at the POC reduces the documentation burden for clinical staff and reduces transcription errors.[16,19] Barcode scanning is felt to be easier than manual entry[34] and has been shown to save staff documentation time.[19] Nurses have perceived barcode scanning of medical devices to be more accurate and supportive of patient safety and have reported overall high satisfaction levels with barcode scanning.[33] Shared by OR nurses about their health system's implant barcode scanning process at the POC, "Should make it easier…faster" and "I would definitely trust a scan versus writing."[33]

Recalls

Recall management in health systems has historically been a manual, labor-intensive, and inefficient process, characterized by a level of uncertainty as to whether all impacted patients have been identified and all unused recalled inventory has been removed. Use of UDIs in recalls has been consistently recommended in order to transition to an automated process using UDIs that is quicker and more definitive.[23,35] As described by a health system staff member, "Recall was primary. ... three recalls where they had to like go in and manually chart review hundreds and hundreds and hundreds of records and find all the pieces and then contact the people, and so that was a very painful thing."[18]

Patients also desire a comprehensive system for recalls and patient notification and have indicated their surprise and frustration that this is lacking.[36] After UDI implementation in the cardiac catheterization lab (cath lab) and electrophysiology (EP) lab at Duke University Health System, UDI has been used to manage the recall of two pacemaker leads.[19,37] "The process is a five minute query, 'Find all records where this specific pacemaker lead UDI is documented.' It has taken just a couple of minutes to write the query and data is returned almost immediately."[37] Use of UDI enabled an accurate, quicker, and efficient process, requiring much less staff time.[37]

Providing Information to Patients About Their Devices

Patients desire information about their implanted devices. They perceive benefit in their clinical care and reduction of their health risk. They acknowledge the value of device information including the UDI being available, to share as needed for their care and for research that has the potential to benefit other people.[36] Shared in quotes by patients with implanted devices, " I am thinking this will be useful down the road. I may be moving…" When discussing tracking devices that had been used in their care, "I like research, to help learn about the possibility of creating better health."[36] At Duke University Health System, entry of implant information into the EHR's implant log has facilitated patient access to their device information.[19]

Supply Chain Management

Inventory Management

The UDI enables standardized and automated device documentation for inventory management, thereby significantly improving consistency, accuracy, and visibility of data.[16,19] Benefits include tighter management of periodic automatic replenishment (PAR) levels,[19] replenishment based on actual device usage and pre-determined inventory levels, use of devices prior to their expiration date,[25] fewer stock outs,[38] and overall reduction of device data issues.[19] These have helped prevent procedural delays, improve efficiency and reduce revenue leakage.[19] UDI implementation is also important to support more accurate prediction of demand.[23,25] As shared by a leader in process engineering at Geisinger Health, "The combination of capturing information with a barcode scan and having a system that can use and act on that captured information has allowed Geisinger to turn the tide on managing expirations in our procedural areas."[39]

Recall Management

As detailed above, recall management in health systems has historically been a manual, labor-intensive, and inefficient process. Critical for supply chain management is removal of recalled devices from inventory, thereby reducing risk to patients and the health system from use of these devices. Use of UDIs in recalls has been consistently recommended to achieve an automated process that is quicker and more definitive.[23,35] As shared by a supply chain management leader from Mercy, "In addition to improving the efficiency of the healthcare supply chain, data standards play a significant role in ensuring patient safety through improved product recall management. With data standards in place, hospitals can rely upon the uniqueness of the packaged barcode and use it to drive critical processes."[38]

Procurement and Contracting

The UDI provides a reliable standard for contracting and purchasing medical devices. It enables traceability, can help prevent counterfeiting and diversion, and can assist in preparation for medical emergencies[21,23]. The American Hospital Association has recommended the use of UDIs to reduce/eliminate counterfeited devices and to strengthen the healthcare supply chain.[40]

Finance and Revenue

The UDI provides a reliable standard for charge capture. Both accurate and timely charge capture is supported, with logic and edit checks identifying potential data errors, by allowing automatic transmission of charges as soon as data aggregation has been completed.[19] The UDI can also enable reliable comparative effectiveness and value assessment of medical devices, which can inform value-based purchasing decisions.[16,23]

Benefits of UDI Implementation at the POC Beyond the Health System

RWE Generation

UDI availability in health data systems enables linkage of datasets, including electronic health records, administrative claims, registries and others which contain meaningful, real-world patient-centered data elements and device data.[1,2,26,27,29,41-46]As a result of these linkages, device

safety and performance, effectiveness, comparative effectiveness, and differences across various patient sub-populations and device indications can be studied, supporting a robust, reliable postmarket surveillance system.[12-15,47] UDI implementation in health systems supports the generation of RWE that can inform clinical, regulatory, payer, manufacturer, and patient decisions.[20,34,46,48]

Improved Adverse Event Reporting

Adverse event reports to the FDA are mandatory for certain device-related adverse events and problems (this includes by user facilities, such as hospitals) but device malfunctions can be filed voluntarily by anyone.[49] Inclusion of UDIs in adverse event reports is an essential step to identify the exact device affected.[41,50] This would provide greater accuracy in reports, and the counts and frequencies of adverse events would be more reliably determined, thus supporting more timely analysis, identification, and correction of device-related safety concerns.[21] Further, UDI integration would enable a reliable standard in FDA and manufacturer safety alerts and recall communications, thereby offering standardized information for recall management from manufacturers to distributors to healthcare facilities and ultimately to patients.[15]

III. Defining Steps for UDI Implementation

Detailed here are areas that are critical to engage interest in the UDI and spur health system willingness to move forward to implement electronic capture of UDIs at the POC. Four specific steps are included: Awareness of the UDI and its Benefits for the Health System, the ROI and Economic Case for UDI Adoption, UDI Champion(s), and Leadership Buy-in.

A. Awareness of the UDI and its Benefits

A key gap for POC UDI implementation is lack of individual and organizational awareness about what the UDI is, and the operational and clinical benefits accrued through real-time availability of UDI data. This lack of awareness about the UDI hinders buy-in and approval to start implementation, as well as imposing barriers for those that have approval and are already moving forward.[17,18]

1. What the UDI Is

Although the UDI has been extensively written about, health system leaders, clinicians, and staff across units in a health system are usually not well-versed in what the UDI is. They may not have heard of UDIs, may assume that they have implemented electronic capture of UDIs at the POC by the clinical team since they have some methods through supply chain management for tracking devices, are often unclear how the UDI benefits their work, patients, or the overall health system, and in cases where the UDI has been implemented are often unclear about its availability.[17-19,33] As described in one quote, "We have to talk to a lot of different people that have a say about this. We have the clinicians. We have the supply chain people. We have the IT people. We have the business managers. And of all those people, well maybe only the supply chain person really knows what a UDI is."[18]

2. Benefits to Health Systems of UDI Implementation

As indicated in Section II, benefits of UDI availability and use across several areas within health systems have been discussed and studied over the past several years.[1,2,12,13,16-19,23-29] Benefits accrue in clinical care, supply chain management, finance and revenue, and use in the broader medical device ecosystem for research and evaluations of postmarket device performance for patient safety. Leadership buy-in for the clinical and operational benefits is key. It is imperative to succinctly and in context describe the UDI and its benefits for patients, clinicians, and the health system.

B. ROI and the Economic Case for UDI Adoption

A key barrier to UDI implementation at the POC in health systems is lack of awareness of the ROI and the economic case, resulting in a lack of buy-in and support for the initial investment to implement UDIs.[18] Despite this barrier, some health systems have developed their own internal projections of ROI as well as the clinical and the operational case for UDI implementation at the POC within their organization. These data have been used to obtain leadership buy-in and support to proceed forward with UDI implementation.[16,50-52]

What is the clinical case?

The clinical case refers to the purpose of UDI implementation for improving patient care. This is motivated by providing safe, high-quality care to patients when medical devices are used.[16,28] Electronically capturing UDIs during patient care provides the foundation for accurate, consistent, and accessible device information that can be retrieved when needed. This includes identification of devices prior to a revision procedure, an MRI, in an emergency, or when a patient establishes care with a new physician; support of efficiency and accuracy in identifying patients affected by device recalls; support for patient engagement in their care by providing patients information about their devices; and availability of data for postmarket surveillance and research to ultimately inform clinical decision-making on device safety and effectiveness, enabling choice of the most optimal device for a patient.[22,23,25,29,30,36,41] At Mayo Clinic the case for UDI adoption was the clinical case for patient safety. It then became a decision on how to best accomplish this.[53]

What is the operational case?

The operational case refers to the purpose of UDI implementation for the financial and transactional functions in the health system as well as the functions that underpin the ability of healthcare teams to provide safe and high-quality clinical care. This is grounded in accuracy, efficiency, and achieving value for the health system.[16] Standard electronic device documentation with UDIs strengthens the processes and provides greater transparency in inventory management, device tracking, and recall management, when removal of recalled devices not yet used in patients is a critical function. UDI use in contracts, purchasing and electronic data interchange (EDI) ensures a common language for the multitude of stakeholders involved in procurement and distribution of medical devices in the health care supply chain. UDI use augments outcomes analysis to inform operational decision-making on issues of variability, cost, and value within the health system.[22,25]

The holistic goal is to develop an “end-to-end” infrastructure for UDI implementation within the health system that links clinical care, supply chain management, and billing in a coordinated fashion for optimized information sharing, information retrieval, and value achievement across

organizational units. This "clinically integrated supply chain"[19] replaces the current manual, error-prone, and duplicative processes characterized by revenue leakage, workflow inefficiencies, and lack of coordination within a health system.[13,16]

What data are available in the literature about the clinical case, operational case, and ROI?
Clinical Case: A national survey of orthopedic surgeons specializing in total hip and knee arthroplasty provided insights on clinical repercussions stemming from challenges with identification of failed implants before revision surgeries. Over 50% of the surgeons reported needing to regularly use five or more methods for implant identification, including review of patient x-rays, operative reports, clinic notes, and/or implant sheets; consulting with the manufacturer representative; ordering additional imaging; or relying on visualization at surgery. Median surgeon time/case spent was 20min; median staff time/case spent was 30min. Despite this, 10% of the time the failed implant could not be identified pre-operatively and 2% of the time it could not be identified intraoperatively.[31] The surgeons' perceived impact was that patients faced increased procedure time, more complex surgery, more implant components replaced, more blood and bone loss, and/or longer recovery time.[31] National projections based on study data suggested that failed implants that cannot be identified may number more than 50,000 pre-operatively and 25,000 intraoperatively in 2030.[30] Surgeons indicated that the UDI in the electronic medical record and the UDI in the total joint arthroplasty registry would be most helpful to identify failed implants and patients in a recall, significantly reducing the time spent.[31]

Operational Case: In a Mercy-Becton Dickinson (BD) collaboration, the organizations integrated the UDI-DI utilizing the Global Standards 1 (GS1) standard from manufacturer to POC. Outcomes included a 30% reduction in outstanding days payable and a 73% reduction in discrepancies in transactions between the organizations.[38]

In the UDI Demonstration Project at Mercy, after a barcode scanning inventory management system was implemented in their cath labs, Mercy was able to ascertain that inventory value in one of the cath labs was over $1.9 million - rather than $800,000, which had been the last value assessment from a physical inventory. In the first six months after implementation, inventory was reduced to $1.56 million with resultant cost savings related to reduction of excess inventory.[25] The automated system also provided visibility into expiration dates of devices on the shelves, allowing movement of products near expiration between hospitals to avoid waste.[23,54] Also enabled was automation of the charging process, replacing manual entry done by a unit secretary for each case.[54]

At Duke University Health System, UDI implementation in the cath labs and EP labs supported tighter management of PAR levels and consistency in charge capture, resulting in over $600,000 of revenue recognition in the first year. In the EP labs, replacement of manual entry with electronically interfaced data with UDI saves 15-20 minutes of staff time/case. Capital costs for the project were less than $20,000 with approximately 500 person-hours of effort.[19]

At Eskenazi Health, UDI implementation in their minimally invasive procedure areas resulted in an average increase of $3000 in per-case charge.[51]

An assessment by the Association for Healthcare Resource & Materials Management (AHRMM) UDI Impacts on Recall Process Management workgroup
estimated labor when responding to a recall, ranges from 16-104 hours, depending on the type and extent of recall. One provider in the workgroup indicated they processed 42 Class I recalls during a 12-month period, with an estimated cost of $20,166.[35]

ROI:
Mercy projected $13 million savings across their 26 ORs when they went live with UDI implementation.[55]

UDI implementation at Duke University Health System, as discussed above, required less than $20,000 of capital costs and 500 person-hours of effort. The ROI, recognized in under one year, included over $600,000 of revenue recognition for the cath and EP labs and 15-20 minutes of staff time/case in the EP labs.[19] Additionally, although not quantified in terms of labor costs, opportunity costs, clinical efficiency, and/or patient and staff satisfaction, other ROI included reduction of clinical documentation errors to a negligible level, reduction of supply chain management device and data issues to a negligible level, elimination of rejected charges due to incorrect device information, clinician and patient access to implant information, and availability of device data in the enterprise data warehouse that can be queried for use in recalls, quality assessment and process improvement projects, and research.

Boston Medical Center estimated an ROI of 400% for their first year when they adopted a standard master data set with UDIs.[56]

In support of the ROI for UDI adoption, a tool is available for health systems to calculate costs of a recall, comparing current process to future process with UDIs.[35]

The Policy Landscape
There is no regulatory mandate requiring health systems to document and use UDIs.[17] This admittedly reduces the impetus for UDI implementation at the POC in some health systems. However, for other health systems, awareness of ongoing policy efforts and anticipation of future regulatory requirements is a key purpose that has driven their UDI implementation and supported their operational case.[16] These health systems are motivated to invest in the needed infrastructure now and be prepared as an organization to meet policy requirements, rather than face penalties or loss of revenue.

Examples include the:

- UDI-DI in claims, where the proposed updated claim form will have a designated field for DI that can be populated in the claim form and included in the health system-payer exchange[34,46]
- Inclusion of UDI as a data element in the United State Core Data for Interoperability (USCDI)[57] and future anticipated requirements by CMS[58] for patients' electronic access to their health information
- No Surprises Act of 2022[59] which may require health systems to provide good faith estimates of cost for non-emergency care to uninsured or self-pay patients.

C. The UDI Champion(s)

Research has emphasized the critical importance of the health system UDI champion(s).[16] Successful implementations at the POC generally have an overall champion but there may be a team of champions including a clinician, representation from supply chain management, administration, and/or clinical research.

The clinical champion, generally a physician with cross-disciplinary involvement (supply chain, IT, and/or research) along with patient care, is central to the effort for UDI implementation at the POC. The clinical champion is knowledgeable about UDI, passionate about the benefits of use for clinical and operational purposes, well-versed in the collaborative and interdisciplinary work required for implementation, and able to engage colleagues, leaders, and staff well as they move between organizational siloes. They may also have the added benefit of being clinically active at a POC site for UDI implementation.[16,28]

- At Mercy, the overall champion was a cardiologist and clinical researcher engaged in sponsored UDI implementation research projects.[25]
- At Duke University Health System, the overall champion was an interventional cardiologist-informatician and researcher with administrative roles as well as active engagement in patient care.[19]
- At Intermountain Healthcare, the clinical champion was a cardiologist and clinical researcher.[12]
- At Vanderbilt University Medical Center, the champion was a medical informatician, researcher and internist.[60]

The supply chain UDI champion is often a leader that brought the concept of UDI to the organization, is engaged externally with interdisciplinary partners and groups, often in advocacy, and in collaborative engagement across organizational siloes within the health system.[16,28]

- At Mercy, supply chain leadership played significant roles as champions for UDI implementation[25,38]
- At Duke University Health System, the Vice President for Supply Chain was part of the UDI champion team[19]
- Geisinger has had significant leadership for UDI implementation and advancement by their director of supply chain informatics and process engineering[39]

Administrative champions may be C-suite or procedural area leaders.[16]

- At Duke University Health System, the Health System Vice President for the Heart Center and Health System Administrative Director for Cardiac Catheterization and Electrophysiology Laboratories were both part of the UDI champion team.[19]
- At Mercy, the Chief Nursing Officer has had significant involvement in their UDI adoption.

The above provides important examples of UDI champions; however, there are others – physicians from different clinical specialties, health services researchers, professionals in informatics, inventory management, performance optimization, etc., whose work, roles and titles have not necessarily been published or broadly documented outside of their respective health systems.

D. Leadership Buy-in

A gap exists in health system leadership engagement and buy-in for UDI implementation, which poses a significant barrier, as senior leaders are key to prioritizing implementation.[18,23] A publicly available roadmap for health system UDI implementation at the POC outlines critical elements to gain support.[16] First is determination of who in the health system leadership would approve and provide support for UDI implementation at the POC. It is likely that approval from more than one health system committee will be necessary.[19] Second is development of a formal presentation for this leader(s) including:

- The Purpose of UDI implementation (including clinical, operational, regulatory, and/or research)
- Benefits of the UDI and its use for the organization
- Supporting Data
    - Current problems or gaps that UDI implementation is anticipated to improve, with estimated costs of these issues
- The vision
- Outline of the project plan
    - Consideration if UDI implementation at the POC can be included in another initiative, e.g., research project, IT system update
    - Recommendations for a POC pilot site
- Anticipated necessary resources
    - Funding
    - In-kind work

IV. Implementation Planning

Once a health system has deemed UDI implementation at the POC as a priority initiative, the implementation planning process, which can take several months, is critical for success.[16,19] Planning includes delineation of initial strategy, a governance structure, project plans and requirements, identification of the necessary expertise to accomplish the work, initiative mapping, and outlining a plan for education and training. Implementation planning is not generally a linear process. Rather it is one where different aspects of planning may occur simultaneously and may be closely related. Required is stakeholder collaboration, organization, patience, and realization that this will be an iterative process.

1. Governance Structure

The establishment of an interprofessional committee to oversee the UDI implementation initiative is critical. This committee should be guided by formal project documents including a charter and timeline. Included individuals should be 1) multi-disciplinary leadership (e.g., clinical site, supply chain), whose support will ensure necessary resources are available, 2) UDI champion(s), 3) representatives from supply chain, IT, financial management, and the POC site.[19,25]

2. Necessary Expertise

Engaging stakeholders with the necessary expertise to plan and perform the work for implementation is crucial. The following groups must be involved[16,19,25]:

- Supply chain management: This group is central to driving and supporting UDI implementation at the POC. Upgrades and changes in process, inventory management, IT, databases, and connectivity between different units necessitate resources and significant effort from supply chain teams across multiple areas.[16]
- Information technology: Capabilities of available IT systems must be assessed, followed by the development, testing, and deployment of changes as needed for UDI implementation at the POC.[16] In some cases, new IT systems need to be introduced or upgrades need to occur. Internal IT teams are critical, ideally including individuals who had previously implemented new point of use systems.[25] External IT vendors also need to be engaged, for necessary upgrades and especially if new technological solutions are necessary to build the requisite IT infrastructure for UDI implementation.[16]
- Clinical POC: Clinicians at the POC play a critical role in sharing their expertise on the clinical workflow, clinical culture, and how to best address the necessary change with implementation. They communicate/liaison with other clinicians on-the-ground at the POC and provide invaluable support with clinical buy-in.[16]
- Other: Other personnel provide targeted and health system-specific expertise that helps organize and support UDI implementation at the POC so UDIs are available for use. These may include a dedicated project manager, charge capture personnel focused on device reconciliation[19] and individuals in recall management, performance improvement, or risk management who will have a vested interest in use of UDIs.[28]

3. Initiative Mapping

An important initial consideration is which clinical POC area should be the first for UDI implementation. Most initial UDI implementations at the POC in health systems have begun in single procedural area, generally the cath lab.[12,16,19,25] Reasoning for this has been the controlled and smaller size of the site, less complexity in terms of numbers and types of procedures and devices, the presence of a UDI on the packaging of all supplies and devices, fewer roles for staff, the frequent presence of a clinical UDI champion, and less overall complexity compared with the operating room (OR)[16,19] Some health systems have started in the OR, but generally with a limited, specialty-based "roll out" so they can iterate and optimize in one specialty area within the OR before advancing to others.[33]

Initiative mapping includes a gap analysis with identification of the current vs. projected state across the various processes and touchpoints within three domains for the chosen clinical POC area(s): a) data capture, exchange, and usage of supply/implant product data, b) staff and clinician workflows, and c) financial opportunities.[37] In the OR environment, a specific dilemma is the presence of two different product classes with different packaging and labeling approaches, specifically sterile pre-packaged products vs. "non-sterile" products that are repackaged and sterilized on-site in organized trays specific to a given procedure.[37] This is important so that a plan and map for integration of information flow with workflow can be developed, laying the foundation for the technical build[19] and addressing the potential impact of UDI implementation on personnel and other stakeholders.[16]

This stage also includes development of formal project documents, goals, and metrics along with identification of necessary relationships. Metrics for UDI implementation at the POC have included IT personnel time for builds and implementation and expected impacts on staff

(including inventory management personnel, clinical staff, physicians, and coding and billing personnel).[37] There must also be financial consideration of initial capital investment as well as projections of revenue recovery.

4. Needed Education

Succinct, high-quality, convenient education and training is necessary that details the purpose and motivation for UDI implementation at the POC site as well as logistics for the process change. Supply chain staff require education because of the change to inventory management systems.[37] Clinical end-users (e.g., OR nurses, cath lab technicians) are a key group because they must buy-in to the new process and scan UDIs at the POC. Additionally, organizational leaders, clinicians (e.g., physicians, nurse managers), and staff from the different areas involved in UDI implementation all derive benefit and motivation from education and training. During implementation planning, identifying who will deliver this education and in what format must be determined. Peer-peer education is highly effective as well as availability of durable materials for initial, maintenance, and new staff training. Some health systems have successfully used already established education teams, particularly with clinical education.[16,17,28]

V. Implementation Development

The Technical Build

Critical for the technical build is a clear plan to transition from multiple supply chain, clinical, and operational processes and data sources to an aligned, unified, data-driven approach using the UDI as the "single source of truth". This facilitates the electronic capture of UDIs at the POC.

The capabilities and gaps of current IT systems need to be determined within the context of UDI implementation. Frequently, this leads to the realization that to support the requirements of data exchange, a current IT system needs to be replaced or undergo significant upgrade.[16,19,25] Which IT systems will be data sources, and which will be data recipients must be delineated.[19] A database to support POC UDI scanning and documentation must be designated, built, and maintained. New interfaces to support dataflows and changes to user interfaces are generally necessary. Detailed meetings with external vendors and internal IT teams are imperative throughout.[16,19]

The technical build requires time, coordination, and extensive end-to-end testing.[16,17,19] Whereas different health systems typically do not utilize identical IT systems, they do share the common goal of achieving interfaced and aligned IT systems that can store and transmit UDIs,[16,17] and facilitate the electronic capture of UDIs at the POC.

Examples in the literature of the Technical Build for Health System UDI Implementation at the POC

Mercy's UDI implementation in their cath labs was accomplished as an FDA-funded UDI Demonstration Project and executed via the BUILD Initiative.[12,25] IT system integration included the:

- Enterprise Resource Planning (ERP) system (Infor Lawson) which supported automation of supply chain management and included the item master

- POC Inventory Management system (Omnicell OptiFlex CL) which tracked inventory, ordering, and billing
- Cardiovascular Procedure Documentation system (Merge Hemo) which stored clinical and device information
- EHR (Epic) which stored clinical and billing data

Mercy established processes for barcode scanning to capture the UDIs in the ERP supply chain database, the POC inventory management system, and the EHR.[54] Whereas the Infor Lawson ERP system, Merge Hemo, and Epic were already established IT systems at Mercy, a transition was made from a manual inventory management process at the POC to an automated process with Omnicell OptiFlex CL so coronary stent UDIs could be incorporated into Mercy IT systems.[25]

As an early investigator of the feasibility of UDI implementation and challenges faced, Mercy did experience and document IT challenges including the inability of Optiflex CL and Merge Hemo to accept electronically captured UDIs and the lack of communication of Merge Hemo with other clinical systems.[25] As Mercy has moved forward, they have worked with vendors and leveraged IT systems to best support capture of data including UDIs generated during patient care.

Duke University Health System's UDI implementation in the cath and EP labs required coordinated data flow involving the:

- ERP system (SAP) where inventory management, the item master list with UDI, and supply ordering processes were orchestrated
- POC Inventory Management system (CareFusion Pyxis) which accepted UDI scans at the POC
- Cardiovascular Procedure Documentation system (Lumedx) which managed the creation of procedure documentation, procedure report, and UDI data
- EHR (Epic) which stored patient data, UDI data, procedural documents, and charge capture information
- Integration Broker (HealthShare) which handled data messaging, exchange, and cross-systems integration

Whereas the SAP ERP system, Lumedx, Epic, and HealthShare were already established systems at Duke University Health System, a transition was made from a standalone inventory management system to CareFusion Pyxis in order to achieve data exchange requirements for UDI implementation.[19]

Geisinger's UDI implementation has been long-standing in clinical sites such as the cath and EP labs and interventional radiology (IR), and has been progressively advancing to now over 25 installations.[39,61] IT systems involved include[12,34]:

- ERP system (Infor/Lawson)
- POC Inventory Management system (QSight), where the item master is managed, devices are scanned upon receipt in inventory and again when the device is used at the POC. QSight manages the full UDI in all stocking and usage transactions

- Cardiovascular Procedure Documentation system (Lumedx) where the procedure report, implant documentation, and UDIs are stored
- EHR (Epic) where patient data, UDIs of implanted devices, procedural documents, and charge capture are stored

Qsight is interfaced to the ERP system, Lumedx, and the EHR.

Intermountain Healthcare's UDI implementation in the cath labs, which was accomplished during the BUILD Initiative,[12] involves:

- ERP system (PeopleSoft) where the item master is managed, and devices are scanned upon receipt
- Cardiovascular Procedure Documentation system (Lumedx) where the device is scanned when used at the POC, creating the link between the patient and device
- EHR (Cerner/iCentra)

Mayo Clinic's UDI implementation in the cath labs, OR, and interventional radiology involves[14]:

- ERP system (Infor/Lawson) where the item master is managed
- POC Inventory Management system (Cardinal Wavemark) where the device is scanned upon receipt in the POC inventory, and which receives UDI-linked device data, through an interface with the EHR, when the device is used
- EHR (Epic) where the device is scanned when used at the POC, creating the link between the patient and device

Mayo Clinic is planning implementation of Oracle Cloud in 2023 at which time the item master in ERP will no longer be used. Rather, product master data including UDIs will be maintained in Mayo's product information management/PIM system (Innovit Solution) and fed to internal systems as needed. Product data obtained from manufacturers, their group purchasing organization (GPO), and the GUDID is entered into a staging table; the data is cleansed; and internal attributes are added for a gold copy master data record for each product.[53]

Other research studies have explored commonalities in UDI implementation across health systems.[16,18,28] The majority of health systems studied used Epic as the EHR and Infor Lawson, PeopleSoft, or SAP as the ERP system. Greater diversity has existed with the POC IT systems accepting the UDI scan. POC IT systems used in studied health systems have included Qsight, Pyxis Carefusion, Omnicell, Lumedx, Cupid, Wavemark, and Epic in the cath lab and the EHR, TECSYS, Qsight, Champion, and Oplogix in the OR.[16,18]

The technical build for UDI implementation can be complex yet highly possible as evidenced by the various examples from health systems. In addition, IT vendor capabilities, innovation, and partnerships in support of UDI adoption have been advancing. However, health systems operating on older software platforms/versions continues to be a barrier as is health system overall knowledge of the IT landscape for UDI adoption. Whereas the detail shared in the examples from different health systems is not exhaustive, it does provide insights into successful IT decision-making and processes for UDI implementation at the POC.

Relationships and Collaborative Work

UDI implementation requires engagement and collaborative work by personnel from different professional areas within a health system. Generally, these personnel do not work together on a routine basis and have different training, expertise, priorities, and perspectives. However, their collaborative efforts are integral to a successful UDI implementation at the POC. Leaders, champions, clinicians, and staff from all these units play important roles.[16,17,19,28]

As discussed previously, UDI availability and its use benefit different areas in a health system, particularly clinical care, supply chain management, finance and revenue, and research on device performance. Important in the collaborative work for UDI implementation is appreciation of the value of UDI availability across all of these areas, rather than focusing on value for a single stakeholder. Good communication, respect, receptivity to different ideas, and the ability to move beyond a siloed perspective are required.[28] Relationships facilitate the necessary coordination across different units and disciplines within the health system as well as addressing resistance and barriers to change. Without this, UDI implementation to facilitate the electronic capture of UDIs at the POC stalls.[17,19]

Leadership relationships are particularly important at the genesis of the initiative. Initial discussions among health system, supply chain management, IT, and clinical leaders are important to address funding, resource coordination, and responsibilities.[16,19] These leadership relationships also underscore the necessity for other personnel to embrace the organizational buy-in and support for UDI implementation.

Supply chain management leadership and staff play a sizeable role in UDI implementation, which includes broad relationship-building, mobilization of interdisciplinary teams and workgroups, and significant collaboration with clinical POC and IT personnel. Knowledge of the clinical workflow, priorities, and perspectives builds the *supply chain management-clinical relationship*. This is facilitated by supply chain management site visits to the POC to meet staff, observe the workflow, engage in dialogue, and share knowledge about UDI and its benefits to clinical personnel and for patient care. As described by a health system staff member, "This is one of the few things that brings everybody together."[16]

The *supply chain management-IT relationship* is necessary for the technical build. This often extends to those external to a health system including IT vendors and solutions providers.[19,28] The *supply chain-manufacturer relationship* is important to identify challenges such as inconsistency in labelling (multiple barcodes, different formats, different locations on the label) which pose significant problems for clinical personnel tasked with scanning the UDIs at the POC.[16,17,28]

UDI champions, as discussed earlier, are critical for effective engagement within and between organizational siloes. *Clinician-clinician relationships* are critical and are often fostered by UDI clinical champions at POC sites. Clinical champions can share UDI knowledge and its benefit with peers in a trusted and respected environment.[16,28] As described by a health system member, "Our cath lab director from our largest hospital helped champion the effort and saw the long-term benefit of doing this, then the others … were very accommodating."[16]

Interdisciplinary personnel come together in meetings or workgroups to address workflow revisions, site priorities, and change management.[19,28] Stakeholders who will work to align IT systems must be engaged in the mapping of the information flow and delineation of roles, responsibilities, and details of this critical task. At Duke University Health System, personnel from supply chain, IT, inventory management, coding and billing, as well as IT vendors were involved.[19] In the Mercy-led UDI Demonstration Project, implementation of the POC IT system was a collaborative effort involving personnel from the POC site (cath lab), supply chain management, IT, research, and Mercy's "operational optimization" team.[25]

Interdisciplinary workgroups, which can be formal or ad hoc, also collaboratively assess other issues for UDI implementation, such as the capabilities of current IT systems and barcode scanning systems, interfaces, the "source of truth" database, billing and coding, needed project plans, documents and education materials, staff communication and dissemination, and future UDI uses.[28,37]

Relationships and collaborative work are the glue of UDI implementation. They are critical to understand the siloed systems surrounding medical device tracking and use within a health system and the impact of UDI implementation on processes across these siloes. Through collaborative work, knowledge is shared, different perspectives are discussed, siloes break down, broader buy-in is obtained, and the work of implementation so that UDIs can be electronically captured at the POC is accomplished.

Workflow Assessment & Redesign

Data flow and workflow re-engineering are critical aspects of UDI implementation at the POC. For success, these aspects need to be effective, efficient, and achieve satisfaction for staff and patients. How clinical workflows will change from the current state to the future state when UDI has been implemented must be assessed. The various stakeholders (in "Relationships and Collaborative Work") must be aware of how processes will change.[19] Data capture and flow will be a critical process change with UDI implementation. Business process modeling, which maps the process of medical device tracking within a health system, along with various metrics, is a formal assessment that can be performed for both the current (i.e., pre-UDI implementation) and anticipated future (i.e., post-UDI implementation) states.[37]

Education and Training

Available education on UDI implementation, uses, barriers, strategies, and opportunities for collaboration has grown significantly. Education and sharing of experiences has been occurring at conferences (e.g., hosted by FDA, industry groups such as Association for Healthcare Resource & Materials Management (AHRMM), Strategic Marketplace Initiative (SMI), Global Healthcare Exchange (GHX), and Global Standards 1 (GS1), as well as the UDI Conference and academic conferences), through interdisciplinary workgroups (e.g., AHRMM Learning UDI Community [LUC])[62], by visiting other health systems, and by reading publications and reports.[16-19,23-25,28] Other resources include the FDA UDI website,[3] NESTcc UDI Center,[22] BUILD webpage,[63] and the AHRMM LUC[62] workgroup reports and case studies. In addition to

serving as steps in self-education, this knowledge can be disseminated and used to educate peers as well as leadership and other organizational stakeholders.

For most individuals, education and training occurs at their health system through materials tailored to the health system's unique context. Education provided by a peer is more successful (e.g., physicians sharing with other physicians, supply chain staff sharing with other supply chain staff) or a dedicated education team.[16,28] Training should begin several weeks before implementation[19] through dedicated time. It must be convenient, high-quality, and succinct.[28]

In addition to directed education, materials should be made available (e.g., online, handouts at work sites, "tip sheets"). These materials should be appropriately tailored for the specific group that is targeted for learning, including hands-on training as appropriate. It is important to clearly define terms, minimize acronyms and avoid terms which can be confusing to the learner, which unfortunately is common in UDI discussions.[28]

- Supply chain staff: Inventory management personnel need training in light of changes in inventory management systems. One health system provided training through in-person classroom teaching, followed by e-learning sessions.[25]

- Charge capture/revenue personnel: The processes for posting charges, reconciliation, and workflow are changed with UDI implementation at the POC, necessitating education, hands-on training, and accessible support.[19,25]

- Clinical staff: Proper electronic capture of UDIs at the POC by clinical staff is critical. Education to facilitate this must include the purpose of UDI implementation, its benefit for clinical workflow and patient care, how user interfaces and workflow will change, what support will be available, and how to access support quickly.
    - Barcode scanning: Use of barcode scanning may be new and clinical resistance and confusion can result if faced with multiple barcodes, the need for duplicate scanning, or a requirement to only scan some devices.[33] Training must include guidance on barcode scanning itself and the negative impact of work arounds such as returning to manual data entry. Hands-on training is important,[19] including how to know that a product was successfully scanned and how to account for unexpected device application such as wastage or device failure. Clinical staff should be informed about what to do and steps to take when a medical device lacks a UDI or when the process does not work. Health systems have set up practice scanning sessions as well as simulation training with a requirement for a minimum practice time. Learning assessment to test readiness has also been included.[55]
    - Support: Guidance materials should be left at the POC for reference when needed and training should be offered frequently to refresh knowledge of established staff and train new staff. UDI-specific support should be very easy to access and should be available during pre-implementation training as well as for several weeks post-go live. One large health system developed its own app for clinical staff to report scanning problems they encountered at the POC.[17] Health systems also generally provide 24/7 IT systems support.

- Physicians: This is a key and influential stakeholder group within health systems who should receive targeted education on UDI and its benefits. This is most successful when the presentation is short, focused on clinical benefits (e.g., patient safety, clinical documentation improvements), and delivered in a department or medical staff meeting by a physician peer.[28]

UDI education should not be considered a one-time experience. Staff knowledge must be reinforced and refreshed, which some health systems have done effectively through online learning as well as presence of educators at POC sites.[25] Further, education must be available for new staff members and as implementation occurs at new sites.[16] Overall, the provision of helpful education/training and ongoing support through engagement, communication, a feedback loop, validation, and benefit is more likely to lead to greater acceptance and success in UDI implementation with clinical staff.

VI. Implementation

In anticipation of go live at the POC, the extent of UDI implementation for deployment should be determined and a specific date and time chosen.[19] Additionally, just prior to go live a complete, year-end inventory should be performed, which means that each device's label and associated data is reviewed within the item master list with updates that include stock locations. All items should be scanned to initialize products in the new system.

Although all staff need to be trained by the go live, there should be adequate on-site presence and support available from both super users as well as vendors, particularly at the POC.[16,19,28] A "command center" available both before go live and until processes are at a steady state (which may be several days) can be very helpful. Support hours may be needed for several weeks, with easily accessible support.[25]

Institutional lessons from prior go live efforts, such as with EHR changes or other point of use systems, are very important to inform go live of UDI implementation and contribute to its success. An example is that clinical volume may need to be decreased for a short period.[25]

VII. Sustainability and Advancement

Once UDI is implemented at the POC, the process is typically self-sustaining. At Duke University Health System, new staff that join clinical areas where UDI has been implemented are trained by existing staff.[37] At some health systems, there may be checks on process through site visits or monitoring UDI in a dashboard in order to identify unexpected deviations in data, which could indicate UDI capture issues within supply chain and/or by clinicians.[55]

Whereas cath labs and the OR have generally been the primary sites for UDI implementation, next steps in implementation have included additional sites such as IR, outpatient surgery, gastroenterology, endovascular, obstetrics, and otolaryngology.[28] A process similar to the initial implementation may be necessary, including performing a gap analysis, engaging leadership, reviewing technologies, approximating costs, calculating ROI, obtaining IT system clearance and

necessary approvals.[37] Identification of successes, learning from mistakes, and making changes as needed at primary implementation sites help guide successful advancement to additional POC sites and additional hospitals within a given health system.[28] Additionally, establishing policies, documenting process, maintaining availability of training and support as well as overall organizational support, relationships, engagement and communication all foster sustainability and advancement of UDI implementation. Last, but certainly not least, accrued operational and clinical benefit is highly supportive of sustainability and advancement of UDI implementation.[25] At the most advanced health systems, UDI adoption is the expectation for any new site.[55]

The vision for UDI availability and use has also broadened. This includes UDI inclusion in discharge summaries and patient portals, UDI transmission to clinical registries and claims (future), data analytics on clinical patterns, and collaborative work among manufacturers, health systems, and/or research teams using RWD to generate RWE evidence about medical devices.[12,15,16,18,20,48] The latter not only serves to further advance postmarket evaluations of the effectiveness and safety of devices to inform patient care, but advances the use of UDI-enriched RWD in RWE studies for regulatory purposes, such as label expansion and manufacturer postmarket studies.[64,65]

VIII. UDI Use

The benefits of UDI use for clinical care, supply chain management, finance and revenue, and beyond the health system have been well documented in Section III. Defining Steps, Awareness of UDI and its Benefits. The focus in this section is further delineation of UDI Use in RWE studies.

UDI has now been used to propel RWE generation about the safety and effectiveness of medical devices. Historically, studies of medical devices have been hampered by the lack of a device data standard that can facilitate identification, linking and aggregating device data, patient-level data, and clinical outcomes. With this lack of UDIs, only studies where one specific device is on the market and with a specific claims code have been possible.[20]

NESTcc Studies

UDI has been used in studies to inform label extension submissions to FDA using RWE. In the NESTcc ThermoCool Phase II project, data at two health systems (Mercy Health and Mayo Clinic) were leveraged to evaluate the safety and effectiveness of ablation catheters among patients with persistent atrial fibrillation. UDI availability facilitated identification of the ablation catheter device data in supply chain and POC inventory management systems. Patient cohorts treated with these devices were identified; device and EHR data were then linked via patient identification numbers. Once clinical data were linked, the EHR was used to identify specific patient cohorts (i.e., those undergoing a specific ablation procedure, for persistent atrial fibrillation), covariates, and clinical outcomes. A common data model approach was used to inform a label extension submission, through a federated model at both Mercy Health and Mayo Clinic. Results demonstrated that the study catheter met the prespecified noninferiority safety criterion (primary endpoint), with similar effectiveness.[15]

Building UDI into Longitudinal Data for Medical Device Evaluation (BUILD) Initiative

A UDI-enriched research (UDIR) database was previously created at Mercy, during the FDA-supported UDI Demonstration project.[12,47,66] The UDIR included data from the Mercy electronic health record, hemodynamic software (cath lab clinical data system), a POC inventory management system, the Global Unique Identification Database (GUDID), and a supplemental UDI database.[66] The UDIR was also linked to the Social Security Death Master File for mortality data. In a case study[54] utilizing the UDIR dataset, clinical outcomes were compared from use of various drug eluting stents to use of bare metal stents (comparisons between drug eluting stents were not possible due to limited numbers), using a propensity score matching approach. UDI was the key foundation for device identification. Limitations, however, were faced at the time of the UDI Demonstration project related to data extraction of unstructured data in clinical notes and determining timing of various events.

In the BUILD Initiative, the UDI demonstration project was extended to two additional sites, Geisinger and Intermountain Healthcare. UDIRs were created at the new sites and the Mercy UDIR underwent significant revision. The health system UDIRs were built using a distributed data network topology that combined device, registry, payor, and patient data in a common format (the BUILD Common Data Model). Patients who had received either of two types of drug-eluting stents (everolimus-eluting or zotaroliumus-eluting), with an encounter within the health system at least 12 months before implantation and with more than 90 days follow-up or death documented within 90 days, were identified. A comparative effectiveness study was performed across a single common query, using propensity matching of patients within each health system and focusing on six cardiovascular endpoints. Results found no significant difference in these six outcomes, which was consistent with prior randomized trials of these coronary stents.[12]

These are a few examples of UDI use in RWE studies about medical devices. Significant opportunity exists to build on the models and processes utilized in these early RWE studies using UDI-enriched RWD. The BUILD investigators anticipated future opportunities, including adding additional health systems to the distributed data network, studying other device types, and incorporating patient-reported data in the research databases, as well as continued work on EHR data quality and data missingness.[12] Other potential projects that have been discussed include integration of the UDI into registries of patients undergoing percutaneous coronary intervention to enable postmarket medical device surveillance and research across multiple health systems through partnership with manufacturers, FDA, registry leadership, and professional societies;[44] a pilot study focused on UDI data for cardiac rhythm management devices;[67] and an electronic health data quality maturity model supporting evaluations that inform clinical and regulatory decision-making.[43]

Manufacturers selectively partner with health systems that have implemented UDIs to obtain RWD for RWE studies.[20] Payers have expressed that RWE is particularly beneficial for coverage decisions when used for evaluation of the longevity of devices and the assessment of device performance in actual practice.[48] Availability of UDIs for NESTcc test cases has been deemed both reliable and critical for identification of devices.[18,20]

IX. Conclusion

The UDI Playbook was created to provide detailed information and guidance to NESTcc health system research network collaborators to advance UDI implementation at the POC and UDI availability in RWD sources in their respective health systems. However, the UDI Playbook is not limited to the NESTcc community as it can serve as a guide for all health systems. Findings from a valuable body of research and collaborative work conducted over the past several years about health system UDI implementation at the POC and UDI use have been evaluated, aggregated, and presented. Delineated for implementation are Defining Steps, Implementation Planning, Implementation Development, Implementation, and Sustainability and Advancement. Included are examples from specific health systems that not only augments the detail in the Playbook but highlights health systems advanced in UDI implementation and use. Salient examples include organizational ROI as well as the UDI champions that supported implementation within individual health system, details about building the necessary IT infrastructure, and descriptions of benefits of UDI through its use, with a focus on RWE studies about medical devices. A base of evidence and knowledge on health system UDI adoption has been growing. The time is opportune to capitalize and build on this work to realize the goals of the FDA UDI Rule, NESTcc, and use of RWD to generate RWE for medical device safety and effectiveness.

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