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

Point of Care Capture of UDI for Implantable Devices
Final Summary Report & Roadmap

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EXECUTIVE SUMMARY

This report is designed to serve as a practical and usable guidance on implementation of unique device identification (UDI) for implantable devices at the point of clinical care. Included is an Implementation Roadmap as well as gaps and challenges commonly faced in UDI implementation with strategies currently being used by hospital systems in response. Also included are detailed recommendations on needed next steps to improve adoption of UDI, consisting of pilot projects, topics for workgroup initiatives, further stakeholder engagement, and areas of policy focus.

This project was undertaken to address a gap in development of a comprehensive UDI system in U.S. health care. This gap occurs at the point of care where electronic capture and documentation of UDI for implantable devices in patient electronic health records is not routinely being done throughout the U.S. health care system. Information presented in this report is based on interviews of UDI leaders from hospital systems that have implemented a UDI system for implantable devices at the point of care; a survey of these participating hospital systems; evaluation and discussion of project findings by the BUILD Consortium leadership group; and input by the BUILD research team.

The report is divided into several sections allowing readers to focus on the area(s) most germane to their needs and purpose.

The **Project History** provides an introduction to the *BUILD* Initiative, an ongoing research project since 2015 focused on implementation of UDIs for implantable devices at the point of care, movement of UDI-related device data through multiple electronic information systems, and merging of data with electronic clinical data to support improved patient care, improved population health, and lower costs. *BUILD* includes two components, Extension of the UDI Demonstration Project and Medical Device Data Capture and Exchange: Leading Practice and Future Directions.[1]

The **Introduction** provides an overview of the current landscape for development of a comprehensive UDI system in U.S. health care and the gap we face in electronic documentation of UDI at the point of care. Also discussed is the importance of a realized UDI System to achieve Triple Aim goals.

The **Methodology and Analysis** section introduces the reader to details of methodology and data analysis for this project. The **Data on Interviewees and Represented Hospital Systems** section presents survey data in a series of tables and figures that indicate demographics of the interviewees and hospital systems, UDI-focused data, information technology systems used, and procedural sites where UDI for implantable devices is being captured in the participating hospital systems.

The **Implementation Roadmap** is designed to serve as a stand-alone section and be pulled out of this document for use. The Roadmap, which was informed by the leadership interviews, delineates four key areas in UDI implementation for implantable devices at the point of care: Foundational Themes, Key Components, Key Steps, and

UDI Use. It is designed to serve as a guidance for hospital systems to develop their own organization-specific roadmaps.

Gaps & Challenges presents six reported gap and challenge areas: Clinical, Information Technology, the Global Unique Device Identification Database (GUDID), Manufacturers, Support, and the Overall UDI System. Included is a table of Challenge Areas & Strategies Utilized by Hospital Systems (Table 6).

Next Steps to Address Gaps/Challenges and Improve Adoption of UDI includes specific recommendations for needed next steps such as pilot projects, topics for workgroup initiatives, expanded stakeholder engagement, and areas for policy focus (summarized in Table 7) This section was informed by the leadership interviews and significant input by the BUILD Consortium and BUILD research team.

Developing a comprehensive UDI system in U.S. health care is a public health priority of national importance. As discussed in this report, activities enabled by UDI use have broad benefit for clinical, population health, operational, safety surveillance, research, and regulatory purposes. This report provides guidance and support to advance point of care capture of UDI for implantable devices.

PROJECT HISTORY

Building UDI Into Longitudinal Data for Medical Device Evaluation (*BUILD)* has been an ongoing U.S. Food and Drug Administration (FDA) and industry funded initiative since September 2015. The *BUILD* Initiative stemmed from the Medical Device Epidemiology Network (MDEpiNet) SMART Informatics Think Tank Meeting held earlier that year.[2] The primary emphasis of *BUILD* has been implementation of unique device identifiers (UDIs) for implantable devices at the point of care (POC), movement of UDI-related device data through multiple electronic information systems, and merging of this data with electronic clinical data to support improved patient care, improved population health, and lower costs. The two projects within *BUILD* are Extension of the UDI Implementation Project (Demonstration Project) and Medical Device Data Capture and Exchange: Leading Practices and Future Directions (Leading Practices). Whereas individual project work has provided significant building blocks, it has been the integrative work of its parts that has continued to support cutting-edge and innovative deliverables from *BUILD.*[1]

BUILD: Extension of the UDI Demonstration Project. The Extension Project stemmed directly from the *Implementation of Unique Device Identification Demonstration Project* that was performed at Mercy Health under a subcontract with the MDEpiNet Methodology Center. Prototype coronary stent UDIs were incorporated into Mercy's electronic information systems, including supply chain, inventory management, cardiac catheterization laboratory (Cath Lab) clinical documentation, and billing systems. A key intervention was the implementation of barcode scanning of all consumable Cath Lab devices including stents. This enabled the capture of UDI at the POC and its inclusion in the clinical record allowing for integration of device and clinical data at the patient level

in a database termed the UDI Research database (UDIR). The device data were drawn from the FDA's Global Unique Device Identification Database (GUDID) and a database containing clinically significant coronary stent attributes (Supplemental UDI Database or SUDID). The demonstration provided proof of concept that UDI of an implantable medical device can be captured and exchanged across multiple information systems of a single large integrated delivery system, and that devices can be linked to patients at the POC, enabling creation of a surveillance system with both device and clinical data. Subsequent publications have laid out the process, IT infrastructure, challenges faced, strategies used, and benefit for Mercy from implementation of a UDI system.[3,4,5,6]

In the Extension Project, Geisinger and Intermountain Healthcare, have followed the Mercy template and created coronary stent UDIRs. Additionally, a common data model (CDM) has been created based on the Sentinel CDM and the CathPCI Registry and implemented in the health systems' UDIRs, enabling the linkage of the databases in a distributed data network (DDN). Finally, the health system UDIRs have been linked to AccessGUDID using its new API functionality and to the SUDID, which is now termed the Augmented UDI database (AUDI) and is currently housed at Mercy.

Analyses of coronary stent effectiveness and safety are currently being carried out through use of the BUILD DDN. Additionally, plans are underway to expand the network to other health systems and to extend work to other implantable device types.

BUILD: Leading Practices had four main tasks: Establishment of the BUILD Consortium; Creation of the BUILD website; Performance of interviews in hospitals that had implemented UDI for implantable devices at the POC; and Construction of *Point of Care Capture of UDI for Implantable Devices Implementation Roadmap* (Roadmap).

- The BUILD Consortium is a multi-stakeholder consortium of UDI leaders focused on POC capture of UDI for implantable devices and UDI use. Members include UDI leaders from hospital systems, manufacturers, the federal government, patient and industry advocacy groups.[1] During the *BUILD* project period, the Consortium met regularly, discussed the current UDI environment and hot topic issues, developed a Roadmap framework, assessed project data on leading practices and gaps in UDI capture and documentation of implantable devices at the POC, and conceptualized needed next steps to address gaps and challenges.
- The BUILD website is a resource for information sharing on broad aspects of UDI, including work and deliverables from *BUILD* and cross-cutting projects, education on UDI, the GUDID and benefits of a UDI system, national initiatives and policy, relevant publications, and links to other sources of information.[1] Goals were to create a publicly available, user-friendly website that provided on one site current and reputable information on broad aspects of UDI, and for this website to attract groups that are often not as well-versed in UDI knowledge, such as clinicians, clinical researchers, others in academia, patient advocates and patients. This resource was regularly updated throughout the *BUILD* project period.
- A series of semi-structured interviews of UDI leaders representing the clinical POC, clinical and operational information technology (IT), and supply chain management (SCM) at hospital systems capturing UDI for implantable devices at

the POC was performed. The primary goal was to assess commonalities in leading practices and gaps in UDI implementation and to use this information as the critical building blocks of the Roadmap.

- The ultimate goals of *BUILD*: Leading Practices were to create a roadmap to be used as a reference by hospital systems wishing to implement UDI for implantable devices at the POC; and to identify needed next steps to address identified gaps and challenges in implementation and advancement of UDI use.

INTRODUCTION

BUILD: Leading Practices was undertaken to address a gap in development of a comprehensive UDI system in U.S. health care. This gap occurs at the clinical POC where electronic capture and documentation of UDI for implantable devices in patient electronic health records (EHRs) is not routinely being done throughout the U.S. health care system. It is well-accepted that electronic documentation of UDI is a critical linchpin for broad availability of UDI and use in downstream activities surrounding medical devices.[7,8] Without broad development of seamless, accurate, efficient systems to electronically capture and document UDI at the POC in hospital systems, advancement of a realized UDI system faces a significant barrier.

A realized UDI system provides significant opportunity to support Triple Aim goals of improved patient care, improved population health, and lower costs. When a hospital system facilitates capture of UDI for implantable devices at the POC, electronic documentation of UDI, link of UDI-related device data with clinical data, and capability to transfer this data, UDI is established as an important enabler of a myriad of downstream activities surrounding implantable devices that can be accomplished in a more comprehensive, efficient, and error-free way. These activities benefit clinical, population health, operational, safety surveillance, research, and regulatory purposes.

Many hospitals are seeking comprehensive, practical information on UDI implementation and use. However, they are not sure how to start and proceed. They want to know how to engage their organizational leadership, the “nuts and bolts” needed to implement a UDI system for implantable devices at the POC, how to address challenges as they arise, how to most effectively use UDI and for what purposes. This project attempted to fill this need and support closure of the larger gap in advancing a realized UDI system by studying and sharing experiences of hospital systems advanced in UDI implementation and use for implantable devices.

BUILD: Leading Practices objectives were to: 1) Assess and document approaches to UDI implementation, current practices for electronic capture and documentation of UDIs for implantable devices at the POC, and use of UDIs in hospital systems, 2) Delineate gaps & challenges faced in UDI implementation and use, 3) Create a Point of Care Capture of UDI for Implantable Devices Implementation Roadmap for generalizable use by hospital systems; and 4) Delineate strategies and needed next step areas to address challenge areas, such as further research, stakeholder

engagement, and policy. This document shares the results of *BUILD: Leading Practices* project work in achieving these goals.

METHODOLOGY AND ANALYSIS

Twenty-four semi-structured leadership interviews in ten different hospital systems that were currently capturing UDI for implantable devices in their Cath Lab or surgical services were conducted. These interviews were conducted to assess and document approaches to UDI implementation, current practices for capture and documentation of UDI for implantable devices at the POC and uses of UDIs.

Hospital systems were identified in preliminary work through *BUILD* with input from key UDI experts at FDA, in industry, and investigators in ongoing UDI projects who had current knowledge of hospital system UDI implementation and use. Communication with each hospital system was undertaken to assess stage of UDI implementation for implantable devices and obtain commitment for project participation. Participating hospital systems were asked to identify potential interviewees who were leaders in UDI implementation for implantable devices in three areas, SCM, the clinical POC, and IT.

Potential interviewees received an email invitation and were orally consented prior to the interview. One-hour phone interviews were conducted by the same researcher using a standard interview protocol. Interviews were recorded. Topics included reasons for UDI implementation, changes made, facilitators, barriers, UDI use, current state, and future plans. (Appendix A: Interview Recruitment Email Invitation; Appendix B: Interview guide; Appendix C: Oral Consent form)

Demographics of participating hospital systems such as size, revenue, IT systems, and UDI-specific information were obtained via a survey administered through Qualtrics. (Appendix D: Hospital Demographic Survey Questions)

An IRB application was submitted to the Arizona State University Office of Research Integrity and Assurance and was approved prior to commencement of the interviews and survey.

The semi-structured leadership interviews were transcribed verbatim by a professional transcription service previously used by the research team. All interview transcripts were read, salient themes and notable quotations were identified, and a list of thematic codes was drafted. To verify agreement and establish inter-rater reliability (IRR), ten percent of transcripts were analyzed by two members of the research team. Results were organized by themes that emerged from the interview data. These results were used to create the Implementation Roadmap and the Gaps and Challenges section in this report. Survey data was aggregated and organized using Microsoft Excel. These results are presented in the Data on Interviewees and Represented Hospital Systems section of this report.

The *BUILD* Consortium was engaged in an extended meeting on April 3, 2019 as an expert panel to react to project findings, guide development of the Roadmap, and identify needed next step areas including further research, stakeholder engagement, and policy. (Appendix E: Summary Report from April 3, 2019 BUILD Consortium Meeting) Results of this work by the BUILD Consortium is presented in the Next Steps to Address Gaps/Challenges and Improve Adoption of UDI section of this report.

Results of the semi-structured leadership interviews, hospital survey, and the April 3, 2019 BUILD Consortium meeting were used to create this document and meet outcomes of *BUILD*: Leading Practices of: 1) a Roadmap for UDI implementation for implantable devices at the POC and UDI use and 2) Needed next-step areas to address gaps and challenges to further adoption of UDI.

DATA ON INTERVIEWEES AND REPRESENTED HOSPITAL SYSTEMS

Interviewees represented a variety of position types including executive level, director, manager, and clinical. Six of the twenty-four interviewees had a direct clinical background. Approximately one-third had been involved for a relatively short time in UDI work in their hospital system; others had significant longevity in their involvement with UDI. Most interviewees had two or three focus areas (clinical, supply chain management, IT, and/or operational) in their jobs as well as their involvement in UDI. (Table 1)

Table 1: Interviewee Demographics (n=24)

	Response
Type of Position	
Executive	**4**
Director	**9**
Manager	**5**
Clinical	**4**
Other	**2**
Years Involved with UDI	
Up to 2	**9**
>2-5	**7**
>5-10	**6**
>10	**2**
Primary Focus Area	
Clinical	**4**
SCM	**6**
IT	**8**
Operational	**6**

# Focus Areas (Clinical, SCM, IT, Operational)	
One	**7**
Two	**15**
Three	**2**
Clinical Background	
Yes	**6**
No	**18**

For most organizations studied, UDI implementation was an initiative at the hospital system level. Most organizations were nongovernment, not-for-profit, contained an academic medical center, and a health care plan. (Table 2) Interviewed hospital systems represented a range of location in the U.S., size, and revenue (Table 2 & Table 3). The majority of studied hospital systems were capturing UDIs at the point of care via barcode scanning and all were documenting UDI in electronic systems. (Table 4)

Table 2: Hospital Demographic Data I (n=10)

	Response
Organizational Level for UDI Implementation	
Hospital System	**8**
Individual Hospital in a Hospital System	**1**
Both	**1**
Type of Organizational Structure	
Nongovernment, not-for-profit	**9**
Government	**1**
Academic Medical Center in System	
Yes	**8**
No	**2**
Health Care Plan in System	
Yes	**8**
No	**2**
Primary Region in US	
South	**1**
Northeast	**3**
Midwest	**2**
West	**3**
All	**1**

Table 3: Hospital Demographic Data II (n=10)

	Response
Number of Hospitals in System	
<5	**3**
5- <10	**1**
10-25	**3**
25-60	**2**
>100	**1**
Revenue in 2017 (billions $)	
1-<5	**3**
5-15	**5**
>50	**1**
N/A	**1**

Table 4: Hospital UDI Focused Data

	Response
Primary UDI Capture at POC	
Barcode	**8**
Mixed	**2**
Capture Method Same Between Sites	
Yes	**10**
No	**0**
Type of Capture at POC	
UDI	**9**
UDI Prototype	**1**
UDI Documented in Electronic Systems at POC	
Yes	**10**
No	**0**

The majority of hospital systems studied were utilizing Epic as their EHR. (Figure 1) Many had significant longevity in use of their current EHR and were at a mature stage of the Healthcare Information and Management Systems Society (H*i*MSS) Analytics EMR Adoption Model.[9] Additionally, the same EHR was used in all clinical areas for each of the interviewed hospital systems. (Table 5) Whereas more variability in use of enterprise resource planning (ERP) systems was exhibited in the hospital systems studied, the majority were using Infor Lawson or Peoplesoft. (Figure 2)

Figure 1: EHR Vendors at Studied Hospital Systems (n=10)

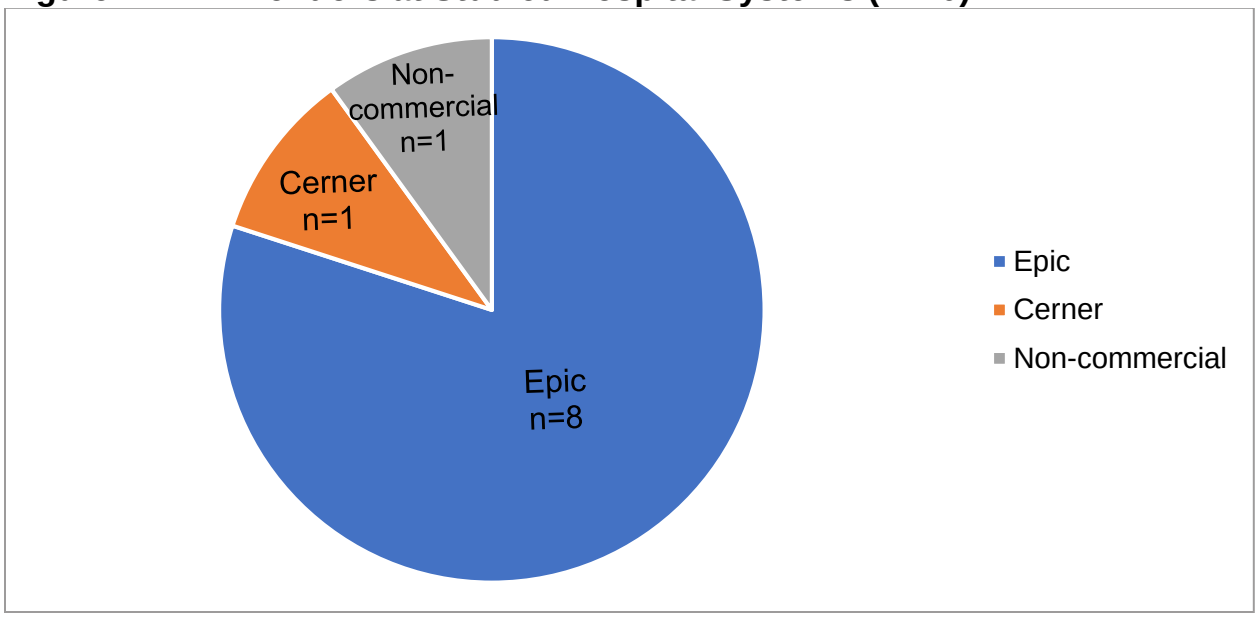
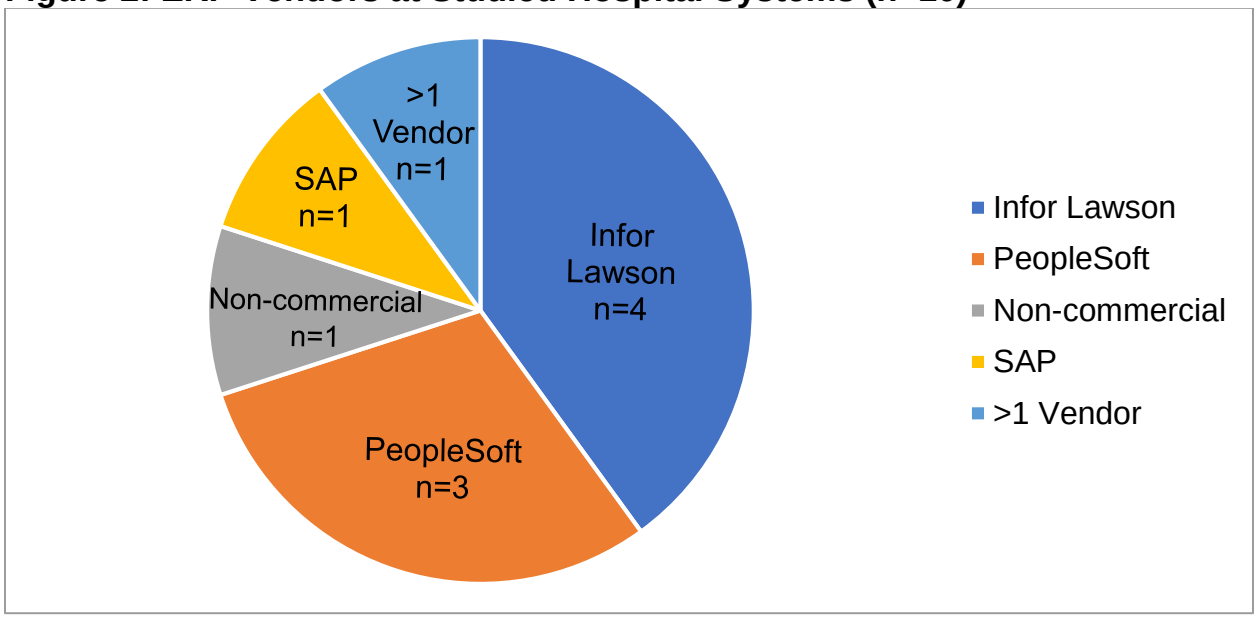


Table 5: Hospital EHR Focused Information (n=10)

	Response
Year current EHR was implemented	
Pre-2000	**1**
2000-2005	**2**
2006-2010	**2**
2011-2015	**3**
After 2015	**2**
Same EHR in All Clinical Areas	
Yes	**10**
No	**0**
Stage of HiMSS EMR Adoption Model	
Stage 6	**3**
Stage 7	**6**
Unavailable	**1**

Figure 2: ERP Vendors at Studied Hospital Systems (n=10)



Procedural sites where UDI was being captured in the studied hospital systems were led by the Cath Lab, followed by the OR, and Interventional Radiology (IR). (Figure 3 and Figure 4)

Figure 3: Procedural Sites Where Capturing UDI for Implantable Device Individual

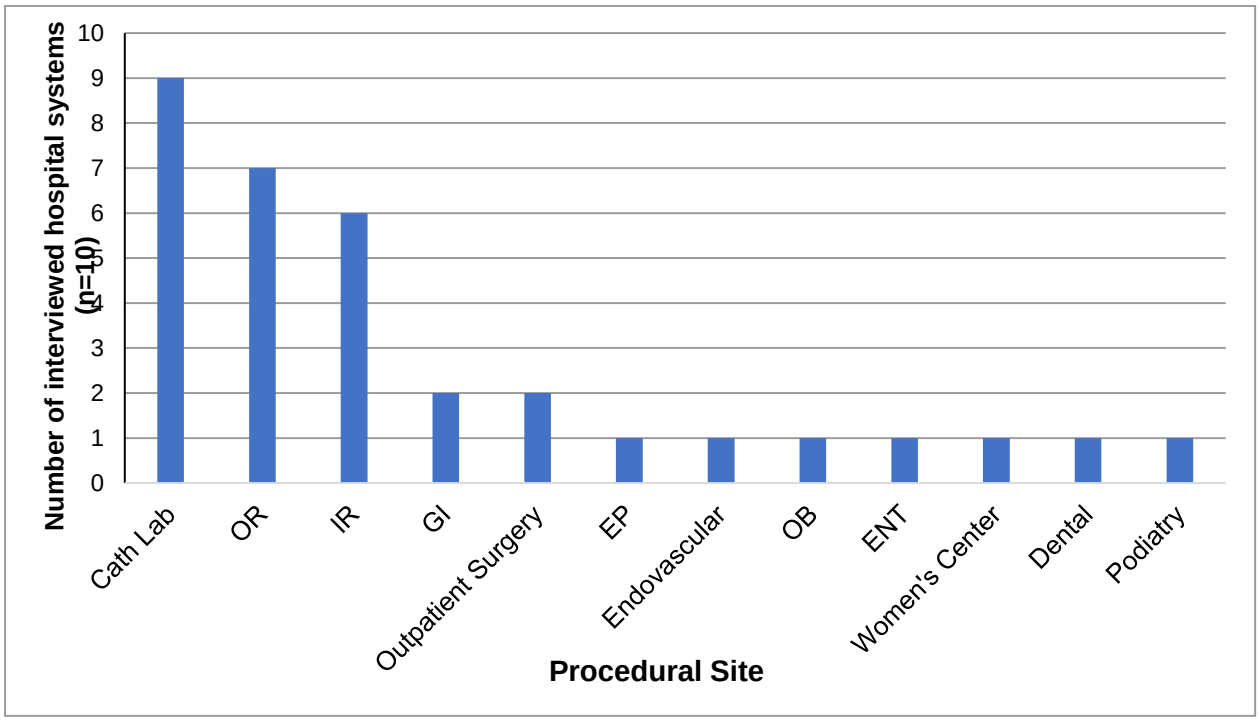
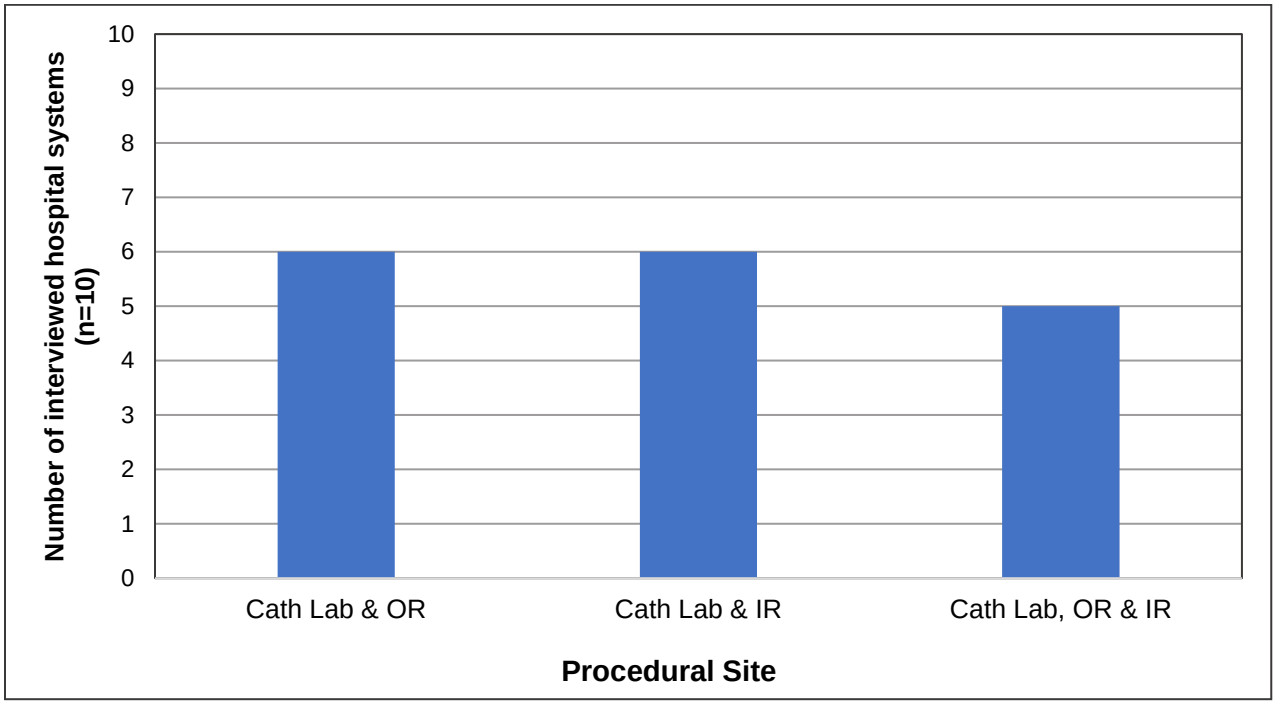


Figure 4: Procedural Sites Where Capturing UDI for Implantable Devices Combination



POC systems vendors used for documenting UDI were quite diverse in both the Cath lab and OR, although more diversity was exhibited in the Cath lab. (Figure 5 & Figure 6)

Figure 5: Cath Lab Point of Care System Vendor Where Documenting UDI (n=9)

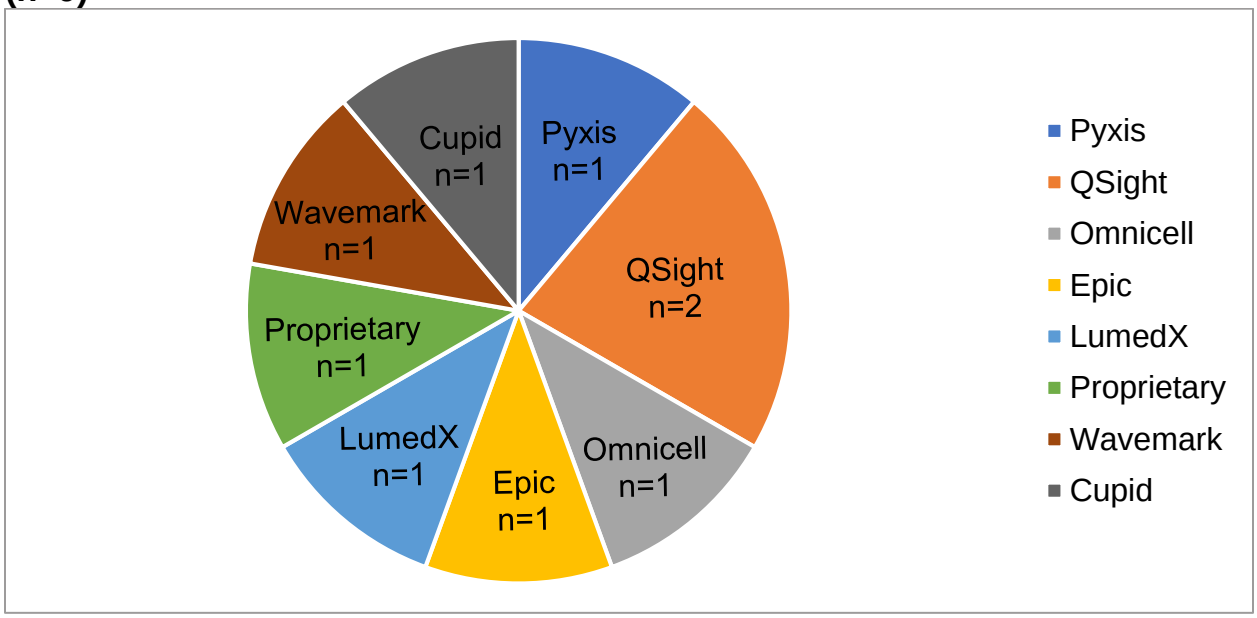
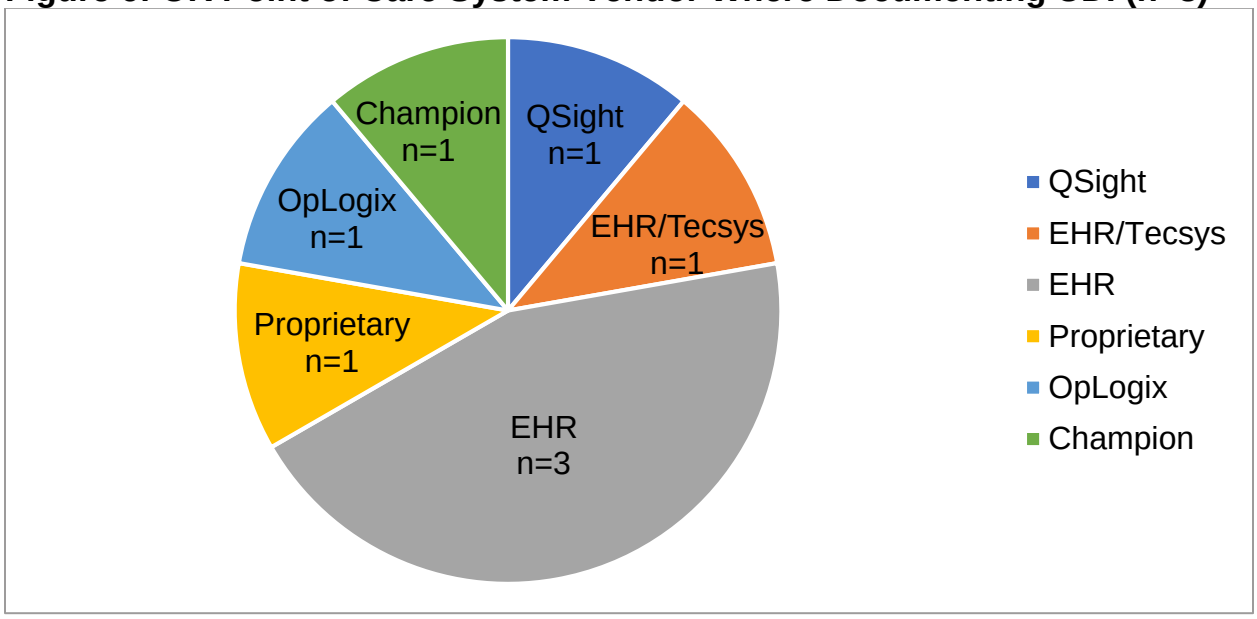


Figure 6: OR Point of Care System Vendor Where Documenting UDI (n=8)



IMPLEMENTATION ROADMAP

This Roadmap is designed to serve as a guidance for hospital systems to develop their own organization-specific roadmaps for UDI implementation for implantable devices at the POC. Acknowledged is that hospital systems have differences in size, resources, IT systems and maturity, and competing initiatives that will impact their approach to UDI implementation for implantable devices and use. Because of these well-known differences, this Roadmap is not meant to be prescriptive, rather meant to guide hospitals in key areas for implementation that can be tailored to the individual environment. Presented in this section are four key areas in implementation and use: Foundational Themes, Key Components, Key Steps, and UDI Use.

Foundational Themes

A set of foundational themes underpin UDI implementation for implantable devices in hospital systems and establish a necessary culture for success. Leadership and relationships are grounded in these foundational themes:

1. *Holistic Vision*: A vision that transcends individual siloes or units within a health care organization
2. *Interprofessionalism*: Involvement of personnel from different professions or disciplines to share different perspectives, integrate knowledge, and work together
3. *Collaboration*: Work together towards a common goal
4. *Communication*: Creating and sharing meaning
5. *Integrity*: Focus on development of process that ensures accurate and valid data
6. *Innovation*: Designing new process or models to create a high-value outcome

7. *Resilience*: Ability to persist and maintain the vision despite barriers, setbacks or the time requirement
8. *Sustainability*: Development of a plan for maintenance and long-term viability

Key Components

As a hospital organization plans UDI implementation for implantable devices at the POC, six components are critical to identify and develop: *Purpose, Leaders and Champions, Expertise and Support, Relationships, Education,* and *Governance.*

Purpose

Purpose is the reason(s) for pursuing UDI implementation for implantable devices at the POC. Four focus areas were identified: *Clinical, Research, Regulatory,* and *Operational*. An organization may identify Purpose stemming from more than one area.

From a *clinical* perspective, achieving high quality, safe, patient-centered care and enabling analytics to assess success in these areas are top Purposes. Desired for implantable devices is a seamless process for use, documentation, and recall management; easy access to accurate information; support of patient well-being and ability to access information on their implants.

Desired from a *clinical analytics* perspective is robust, high quality, and accessible data for assessment of current state and to support achieving Triple Aim goals, reductions in readmissions, device failures and revisions.

From a *research* perspective, availability of standard device data that can be collected easily and transferred into a data warehouse, registries, or research databases is a top Purpose. This data can be used in clinical comparative effectiveness research and performance assessment.

From a *regulatory* perspective, organizations want to achieve readiness to meet "meaningful use" requirements as well as be prepared for the future need for UDI-DI of implantable devices to be transferred in insurance claims.

Desired from an *operational* perspective is accuracy and efficiency surrounding device data so it can be effectively used to achieve value for the organization.

Leaders and Champions

Identifying and engaging leaders and champions is central for success. Although a leader may function in more than one area, four competency areas were identified: *clinical, administrative, SCM,* and *a UDI Initiative Leader*.

Clinical champions are most generally physicians but may also be a nurse at the POC in a clinical and/or operational role. Physicians may be department chairs (e.g. cardiology or orthopedic surgery) or a clinical researcher leading a UDI project. They generally have operational, IT or committee involvements in addition to their clinical duties. Their abilities are fueled by relationships that predate the UDI initiative.

Administrative champions may be in hospital leadership (COO, CFO), be a POC director, or perioperative leader.

SCM champions are often a vice president or executive leader. They may have brought a vision of a UDI system from another institution or experience outside of health care. This leadership is often the genesis of a UDI implementation initiative.

A UDI Initiative Leader, formal or informal, is a critical leader and relationship builder who provides the glue for UDI implementation at the POC. They will need to identify leaders and champions, meet with people in affected areas, visit and observe process at the POC, bring people together across siloes through regular meetings, build structure, communicate, motivate, anticipate, plan, and advance foundational themes. Very importantly they need to lead and maintain the focus on holistic value.

Expertise & Support

Four key areas were identified for the needed expertise to support UDI implementation for implantable devices: *SCM, clinical POC, IT,* and *Other*. SCM, clinical POC, and IT will be impacted by UDI implementation. Leaders and staff in these areas are needed as members of interprofessional work teams.

SCM is generally the starting point where significant effort and resourcing is required. Important teams for involvement are the item master team to create and maintain the source of truth database, the sourcing and contracting team that liaisons and establishes standards and rules with those that provide implantable devices, category management, and the master data management team.

The *IT* team assesses current IT system capabilities including capability to accept and transfer data, the need for updates and interfaces, and must develop, test, and implement changes in the IT infrastructure. Relevant IT systems are the EHR, the ERP, and third party POC systems. IT Teams may be internal to an organization, which is an optimal state, or an organization may work with external vendor support.

The *clinical POC* is an area that requires a concerted effort to engage. Key to success is availability of a physician champion, a POC nursing leader and/or clinical staff member that can provide information about workflow and clinical priorities to the implementation team as well as lead change management. Nurse educators, as available, are important to train and educate the clinical staff on the new process.

Other includes those who may be engaged to broaden value and use of UDI. These include leaders and staff in recall management, quality management, performance improvement, risk management and for the EHR “Meaningful Use” incentive program.

Relationships

Relationships are the bread and butter of UDI implementation initiatives. Relationships must be grounded in the Foundational Themes as well as a team-based approach, respect for others, receptivity to varying perspectives and input, trust, and a

focus on value for all over value for one. Key relationships include *SCM-clinical; clinical-clinical; SCM-IT; SCM-manufacturers;* and *Other*.

The *SCM-clinical* partnership is critical for a UDI implementation initiative to progress. SCM has most generally provided the framework and significant legwork for the initiative. Clinical leaders and teams at the POC must be engaged. Approaches to foster success include a SCM-clinical leader partnership; POC leader sponsorship so managers and staff get involved; development of grassroots interdisciplinary teams, involving SCM and clinical staff, to work together to solve and take ownership of problems that need to be addressed; and SCM integration at POC sites.

In UDI implementation initiatives, clinicians must lead communication, education, and engagement of other clinicians. *Clinical-clinical* relationships involving both physicians and nurses are needed for successful advancement at the POC. **Supply chain management will not be successful advancing the initiative alone.**

Significant work will be required between SCM and IT to create the infrastructure for POC capture and documentation of UDI for implantable devices. The correct vendor partners are necessary to assure that scanning processes integrate well, and clinical workflow does not become burdensome. The *SCM-IT* relationship is key to not only foster responsiveness of IT partners but their willingness "to work outside the box" as needed. If available, internal IT teams (especially EHR teams) allow greater efficiency in addressing IT needs for a seamless UDI system.

SCM-manufacturers will need to address barriers and work together. Manufacturers have the opportunity to leverage the data they submitted to GUDID to support the hospital systems use of AccessGUDID as a source of truth for core UDI data, work to resolve labelling issues that cause confusion at the POC and provide merger/acquisition updates as relevant to UDI capture downstream.

Other may include specialty groups or consultants, often with a clinical background, that work to bridge siloes and address barriers, especially with IT at the clinical POC.

Education

Education is a large and important component of implementing UDI in an organization. Education falls into two important areas: *How to become educated as a leader* and *How to educate others*

How to become educated as a leader: Attend conferences to learn current information, the bigger picture of UDI, and what other hospital systems are doing. Examples include the UDI Conference and GHX Conferences. Learn from leading systems, for example HTG.[10] Join interdisciplinary workgroups through the Learning UDI Community (LUC).[11] Follow ongoing research projects on UDI, such as *BUILD*[1] and *UDI2Claims,* a PCORI-funded initiative focused on UDI-DI in claims.[12,13] Access websites, such as the FDA UDI website[14] and the BUILD website[1], articles, case studies, and other materials to become a local expert on UDI and its implementation.

How to educate others: In person meetings are critical. Education must be convenient so both online and classroom are important. Easy access for questions must be provided. Peer to peer education is most effective, especially for POC clinical staff. Understanding purpose and why an individual's contribution matters is incredibly important to increase staff engagement in the initiative, and their accountability for ensuring data quality and overall success.

Physician education is best done by physicians at peer meetings. Presentations need to be short, to the point, and focus on clinical benefits as the primary purpose. These include patient safety, identification of expired devices, and better process.

Nurse education is best done by a POC nurse leader or nurse educator that can train and teach staff. Important elements of this education are the why, the vision, process specifics, a tips sheet, and contact for 24/7 support.

Governance

A formal governance structure for UDI implementation initiatives was generally lacking for hospital systems more mature in UDI implementation and efforts not operationalized at the system level. When used, examples included a tri-chair model with leaders from the clinical POC, SCM, and IT; an IT governance process; and a collaborative effort between SCM leadership and a POC Director.

A detailed example of a formal governance structure involves

- Leadership by a UDI Governance Committee
- A designated UDI Initiative Leader
- Creation of a charter & timeline
- Involvement of analysts
- Workgroups
    1. Communication & Dissemination
    2. Barcode Scanners
    3. Source of Truth
    4. Interfaces
    5. EHR-Billing
    6. Use of Information
    7. Ancillary data

Key Steps

Seven key steps have been put forth for UDI implementation for implantable devices at the POC: *Planning and Preparation, Gaining Support, Source of Truth Database, IT Systems Assessment, Engagement, Pre-Implementation,* and *Go Live*.

PLANNING and PREPARATION

1. Start early (at least six months)
2. Identify the **Purpose**: the problem and/or advancement want to address
3. Consider the life cycle of implantable device use: all processes and touch points in your hospital system need to be understood
4. Delineate the value for patient care, safety, quality, health outcomes
5. Identify key drivers: cost, quality, health outcomes, requirements
6. Aggregate supporting data
7. Identify **Leaders/Champions**
8. Identify units & stakeholders that will be impacted by the change
9. Delineate needed **Expertise & Support**
10. Consider if UDI implementation can be rolled into another initiative: e.g., EHR implementation, Supply Chain modernization
11. Decide who will lead the initiative
12. Garner local support

GAINING SUPPORT

1. Determine who approves the work that needs to be done and who provides resources
2. Consider if this can be included in another initiative, in a research project or a small self-run pilot project can be started
3. Consider if funds can come from more than one unit or source
4. Present the **Purpose,** Data, Vision, Plan to those who provide resources

SOURCE OF TRUTH DATABASE

1. Determine the desired primary location of your "source of truth" database
   i. ERP Item Master – desired state
   ii. POC 3rd party system database – alternative state
   iii. EHR – alternative state
2. Assess current state and process to develop your source of truth
   i. How advanced is your current item master
   ii. Time, human resources, and other resources needed for development
   iii. Consider a targeted group of implants first (used in a pilot site)
3. Assess the process to rely on external data to support your source of truth and meet the goals of the UDI system
   i. AccessGUDID – desired state
   ii. Vendor data – additional resource
   iii. 3rd party data – additional resource
4. Consider future state/next steps
   i. What next after a pilot site
   ii. How to achieve the desired state for the source of truth database
   iii. How to achieve the desired state for external data support

IT SYSTEMS ASSESSMENT

1. Assess the current state of IT systems including barcode scanners, ERP, EHR, POC systems
2. Determine needed new system(s), upgrades, interfaces
    i. Desire interfaced systems so
        - The source of truth database supports and regularly updates the POC system where UDI is scanned
        - UDI can be scanned and captured at the POC
        - UDI can be documented in the POC system and then transferred to other IT systems for further documentation and use
    ii. Need barcode scanners that can scan different types of barcodes and communicate with the receiving IT system
    iii. Need an IT environment that can accept, parse, and transfer UDI
    iv. Want the ability to store UDI in a designated retrievable field in IT systems including the EHR
3. Delineate IT **Expertise & Support**
4. Consider future state/next steps
    i. What is the full IT infrastructure desired for UDI capture, documentation, and use
    ii. Identify gaps
    iii. Identify IT vendors and systems to work with to achieve the desired infrastructure and to close gaps

ENGAGEMENT

1. Meet with stakeholders to discuss the “why”, the benefit add and how this will be done - Build **Relationships**
    i. Meet face-to-face, listen, observe, lead with the carrot not the stick, lead with clinical benefits
    ii. Address workflow and site priorities
    iii. Discuss education and support the staff will receive
    iv. Elicit buy in, build trust, engage staff in interprofessional workgroups
2. **Education**
    i. Needs to be short, to the point, peer-to-peer is the best
    ii. Be aware of the multitude of acronyms and terms that are confusing when discussing UDI
    iii. Make user friendly
3. Ongoing communication
    i. A champion at the POC can move mountains

PRE-IMPLEMENTATION

1. Establish your **Governance** and team structure
2. Pick a pilot site
   i. Characteristics: a smaller, contained POC site; more limited procedures and implants used; dedicated staff; clinical champion; easy to define the benefit add (e.g., Cath lab)
3. Develop a working document with the plan, deliverables, timeline
4. Anticipate and address potential barriers – make sure clinical staff know what to scan and who to contact if problems arise
5. Assure you have a comprehensive source of truth database with daily updates to the POC system
6. Plan for lots of testing before go live
7. Continue to observe, learn, engage, further **Relationships**

GO LIVE

1. Plan for a lot of on-site presence the day go live and for days thereafter
2. Assure that long-term support is clear and easy to access for clinical staff doing barcode scanning
3. Communicate, Listen, React, Make changes as needed
4. Be positive
5. Continue to foster **Relationships**

UDI Use

Work towards UDI implementation for implantable devices at the POC has been much more robust than actual UDI use. Areas indicated for UDI are for *clinical, research*, and *operational purposes*.

Clinical purposes include documentation in procedure reports and the EHR implant log; reports to manufacturers; reports to FDA; and prior to revision surgery to ascertain the failed device and be prepared for the surgery. Also indicated was that through a health information exchange, participating hospitals have access to UDI and other device information for use in clinical care for patients that may present to their hospital.

An important *research* purpose is for clinical comparative analysis.

Operational use of UDI is much more robust in hospital systems. Uses are in contracting, purchasing and reordering, inventory management, charge capture, implant tracking systems, recall management, expiration date management, contract compliance, and analyses for cost, outcomes, and variation in utilization by physician, procedure, hospital, and within the overall hospital system.

Significant opportunities and goals for future use exist. These include UDI availability in discharge summaries and patient portals, UDI use in predictive analytics and cost-

outcomes analysis, transfer of UDI to clinical registries, transfer of UDI-DI to claims, and partnership with manufacturers to collect data, assess implant quality, and work collaboratively with hospital systems for device iteration and improvement.

GAPS AND CHALLENGES

Through *BUILD*: Leading Practices commonalities in gaps and challenges and approaches taken by hospital systems to address them were identified. Six gap and challenge areas were identified and discussed below: *Clinical, Information Technology, the GUDID, Manufacturers, Support,* and *the Overall UDI System*. Table 6 portrays strategies utilized by hospitals in addressing these challenges. An outcome of the April 3, 2019 BUILD Consortium meeting was delineation of needed next step areas, elaborated upon in the next section, for work towards long-term solutions.

Clinical

Clinical challenges are quite common in UDI implementation and use. These include *resistance, confusion and frustration of clinical staff; limited UDI use for clinical purposes;* and *underdeveloped education and information dissemination on UDI to clinicians*.

Resistance, confusion, frustration of clinical staff at the POC is common. Staff may resist change in general, perceive that the new process will negatively impact workflow, question the value and purpose of changing to a new method for documenting device use, and resist instruction or training from non-clinical staff. If the initiative is not an organizational mandate, they may not engage.

Significant confusion and frustration surrounds scanning itself. Staff may not be able to scan all implants at the POC. This occurs if a device is considered an implant clinically but not required to be scanned from an operational perspective; if scanning is only being done for a select group of devices; if scanning is only being done in one clinical area (such as in the orthopedic surgery operating rooms), but clinical staff also work in other areas (such as the general surgery operating rooms); and for sterilized implants (e.g., sterilized screws). Some IT systems may require clinical staff to choose an implant or supply screen prior to scanning. Device labels may contain multiple barcodes. A scan may be unsuccessful because the device UDI is not available in the source of truth database, the barcode label is degraded or operator issues.

In response to clinical staff confusion with scanning at the POC, hospitals have developed different methods to provide assistance. However, these tend to be time-consuming and/or expensive work-arounds that do not address root cause issues.

UDI use is limited. Limitation in number of hospital systems electronically capturing and documenting UDI at the POC, availability of UDI data, and broad knowledge of UDI benefits have contributed to the underdevelopment of UDI use. Clinical providers and patients do not know enough about UDI to demand availability. Many involved in UDI

implementation initiatives are not well-versed in its broad use. Metrics and data are also lacking to robustly support the benefit of UDI use.

Underdeveloped education and dissemination of information on UDI. The result is an overall lack of clinical knowledge on the value and benefit of UDI use.

Information Technology

IT challenges exist in four main areas: *interoperability; resistance by IT vendors to easily provide needed change for addressing fundamental gaps; lack of ownership by IT vendors of their role in creating a realized UDI system in U.S. health care;* and *variability in IT systems used within different hospital systems*.

Hospital systems face significant *interoperability* challenges due to proprietary/closed loop IT systems that can accept but not transfer data.[3,5,6] In addition, IT systems may have structures or formats that are difficult for clinical staff. Hospital systems found themselves engaging in significant discussion with individual vendors to achieve needed changes. However, they faced *resistance* to providing a quick solution; wait times were typically long to get needed updates and changes and cost was involved.

Noted was that third party POC IT vendors were generally more willing to think outside of the box, be nimble, and be responsive in a timely fashion compared to large vendors. In many cases, hospital systems adopted a third party POC IT system and worked with these smaller vendors to fill their gaps.

Overall there is the perception that IT vendors have a *lack for ownership* for their important role in supporting an optimal UDI system. Hospitals work with IT vendors individually, but a broad approach to the problem is lacking.

There is significant *variability in IT systems (EHR, ERP, POC systems) used in hospital systems* and in individual hospitals within a system. Additionally, there is variability in many other aspects of developing the IT infrastructure for a UDI system: location of the source of truth database, which systems are interfaced, the POC system that receives the scanned UDI, and the IT systems that receive UDI information from the POC. An outcome of this is that the IT infrastructure for a UDI system is not easy to develop or easy to generalize beyond the hospital system in which it was created.

GUDID

Significant work has been undertaken to develop, maintain, and address challenges with the GUDID[15] and its public facing portal AccessGUDID.[16] However, limitations and process issues remain. Hospitals feel that data in the GUDID still has inaccuracy and errors, is not fully validated, has substantial gaps, and has limitations in terms of attributes submitted and the depth/breadth of the data. How manufacturers interpret the required data elements and enforcement of the required process, are limitations. Overall, the process is not felt to be optimal and it is not clear who owns the data.

The outcome is that the GUDID is not viewed as the “go to” source of truth. Hospitals supplement their UDI database with data obtained directly from the manufacturer which is felt to have greater accuracy but is labor intensive to obtain.

Manufacturers

Manufacturer challenges exist in three main areas: *labelling inconsistency; lack of collaboration with providers;* and *lack of ownership of their role in creating a realized UDI system in U.S. health care*.

Hospital systems face significant *inconsistency in labelling*. There are multiple barcodes on labels, different barcode formats, different labelling agencies, and different locations for the barcodes on the box. This makes it difficult for clinical staff at the POC to know what to scan. Transitions that occur at manufacturers such as version changes, mergers or acquisitions, or labelling agency conversion are not communicated well to providers leading to more confusion and problems with scanning at the POC.

There is felt to be a *lack of broad collaboration* between manufacturers and providers surrounding the downstream impacts of manufacturer labelling decisions. Providers expressed a perception that manufacturers are “checking the box” with the UDI regulation rather than thinking more broadly about clinical end-user needs and broader use of UDI. Hospitals find it difficult to determine the best partner within a manufacturer to address these issues as there are multiple siloes within these organizations - sales representatives, POC support, regulatory, supply chain management, etc.

Overall, there was the perception that manufacturers had a *lack of ownership* for their important role in supporting an optimal UDI system. Some hospitals do work with manufacturers individually, but lacking is a broad approach to the problem.

Support

Hospital staff felt a lack of overall support to accomplish their goals in UDI implementation initiatives. Particular frustrations included the time required to do the requisite high level of work, the necessary incremental steps with setbacks and readjustments, and working on UDI implementation in addition to one’s day job. Often faced were challenges in getting resources prioritized for the work.

Overall UDI System

The overall development and implementation of a UDI system faces particular challenges with *policy drivers, innovation, hospital system implementation,* and *a supporting structure*.

Policy drivers have been slow, fragmented, and not comprehensive. UDI as an *innovation* lacks robust data on its effect on performance, quality of care, health outcomes, and cost. *Hospital system implementation* is not mandated and has been slow. Manufacturers and IT vendors lack incentives to invest in developing a comprehensive UDI system. Who is in charge of a *robust supporting structure* for an overall UDI system is unclear.

Table 6: Challenge Areas and Strategies Utilized by Hospital Systems

CHALLENGE AREA	STRATEGIES UTILIZED BY HOSPITAL SYSTEMS
Clinical	Resistance, Confusion, Frustration of clinical staff • Engage physicians, nurses, clinical staff on teams • Educate & communicate **why** doing this • Maintain ongoing communication & collaboration • Teach clinical staff about barcodes • Provide a scanning cheat sheet for clinical staff • Put a sticker or dot where staff need to scan – alternative state • Use a UDI prototype – alternative state • Develop system(s) in SCM to compensate for clinical barriers, e.g., knowing implant vs. supply • Determine clearly what is an implant vs. a supply as an organization and communicate this to clinical teams • Provide an easily accessible system for scan challenges: 24/7 contact by phone, email, or app, place a designated bin at the POC for device boxes that present scanning challenges UDI Use is limited • Educate self – attend conferences, join interdisciplinary workgroups (e.g.,LUC), follow research, become a local expert • Educate within your organization Dissemination and Education on UDI is underdeveloped • Develop education materials for physicians, nurses, clinical staff • Engage clinical champions • Submit clinically-focused journal manuscripts • Write articles on UDI for internal dissemination in a hospital system
Information Technology	Interoperability and Resistance to change • Engage IT vendors early • Identify capabilities want, assess capabilities of current systems, request changes of your vendor and/or incorporate a new system • Evaluate capabilities of third-party vendors and their willingness to partner • Establish leadership relationships with IT vendors so leaders can influence requested change • Build an internal IT team • Develop an arrangement that IT vendors will only receive data if there is capability for data to also transfer out

GUDID	Limitations and process issues • Document issues • Communicate with FDA • Engage in workgroups (e.g., LUC)
Manufacturers	Lack of consistency, collaboration, ownership • Communicate to manufacturers POC challenges • Require in contracts a complete UDI and ability to scan the UDI at the POC • Require update on UDI transitions for contract compliance • Engage in multi-stakeholder workgroups (e.g., LUC)
Support	Needed time, human resources, prioritization • Engage leadership • Engage clinicians • Clearly delineate problem(s) trying to solve • Clearly delineate needed resources • Determine if this can be part of a larger organizational initiative, e.g., EHR implementation or supply chain modernization
Overall UDI System	Be involved in • Policy efforts • Multi-stakeholder workgroups • Research • Dissemination of outcomes from analytics or research utilizing UDI data Educate yourself and others • Engage with FDA • Engage with leading hospital systems • Attend conferences • Read publications • Access other sources: websites, case studies

NEXT STEPS TO ADDRESS GAPS/CHALLENGES AND IMPROVE ADOPTION OF UDI

As detailed above, six gap and challenge areas in UDI implementation for implantable devices at the POC were identified: *Clinical, Information Technology, GUDID, Manufacturers, Support,* and *the Overall UDI System*. The BUILD Consortium members and *BUILD* project team worked together to develop recommended next steps and strategies to address these areas. These recommendations are summarized in Table 7. It should be noted that the AHRMM Learning UDI Community through workgroup initiatives is addressing some of these areas.[11]

Clinical

Several next steps are recommended to address clinical challenges with UDI implementation for implantable devices at the POC. Expansion of awareness and broad education on the value of standard, automated capture of data on devices at the POC, *inclusive of UDI but not exclusive to UDI*, is needed to generate knowledge for patient care and population health. Methods to do this include engagement of a marketing expert to develop strategy for framing and advancing dissemination of information; broadening methods for dissemination of information, particularly through use of social media (e.g., Twitter); continued presentation at clinical conferences, submission of manuscripts to clinical journals and engagement with clinical specialty societies. A premium is placed on releasing clear, concise, freely available, and easy to find information on UDI quickly into the public domain.

Three next step projects are recommended.

- Creation of durable, publicly accessible education materials/content for clinicians, including education modules and case studies for continuing education (CME, CEU).
- An interdisciplinary project where clinical end-users are engaged in the research team along with manufacturers to inform medical device labelling based on their experience at the POC.
- Documentation and mapping of best practices for integrating UDI capture into clinical workflows.

Recommended next steps to support POC staff with challenges they face include working towards a manufacturer requirement for “UDI” on the label next to what needs to be scanned and requirement for barcode scanning training as a part of on-boarding for new clinical staff in hospital systems. In terms of the former area, an ISO standard is currently open for vote for “UDI” to be placed next to what needs to be scanned. The U.S. FDA, EU, and most users are in favor of this option, but it will be voluntary.[17] This is an area of work that should be pursued and potentially expanded with a U.S. focus.

Information Technology

Challenges in the IT area are difficult to address due to the business model of IT vendors where data is viewed as an asset with revenue opportunity implications. Lacking is an industry standard or regulation that requires sharing of data or prevents information blocking, although ONC’s Notice of Proposed Rulemaking to Improve the Interoperability of Health Information was recently under public comment.[18] IT vendors play a critical role in supporting creation of a seamless UDI system for implantable devices in U.S. hospital systems. Current solutions to address challenges such as work-arounds, implementation of third-party IT systems to compensate for deficiencies, and individual work between hospitals and IT vendors are not consistent with development of a long-term, seamless, efficient, and generalizable UDI system.

Next steps recommended to address IT challenges include detailed delineation of the IT functionality needed for implementation of an end-to-end UDI system for implantable devices; creation of a catalog of IT systems that fulfill this functionality and/or compensate for deficiencies in other IT systems; identification of gaps by specific

IT vendors and IT systems; and broader study of hospital system-IT vendor relationships and strategies to address challenges. A recommended next step project is study and mapping of an optimal hospital system IT architecture for UDI implementation for implantable devices at the POC. The other identified areas would also be well-suited as the focus of small contained projects.

There is desire to create a UDI-focused IT vendor group to inform optimal development of UDI systems within hospital systems, address challenges, and identify potential solutions. There is significant opportunity to close existing gaps between the IT vendor and hospital system/clinical POC staff through interdisciplinary collaboration. This not only includes opportunity to address challenges with interoperability and functionality, but also opportunity to eliminate through an IT solution confusion faced by clinical staff at the POC for easily entering information into the receiving IT system.

GUDID

Due to ongoing limitations and process issues, the GUDID faces barriers in becoming the source of truth for a comprehensive UDI system. In order to understand the problems and develop an informed solution, a project to survey hospital systems on their use of AccessGUDID data, barriers faced, and perceived limitations is needed. Additionally, a recommendation is work with manufacturers to close the gap of accuracy between GUDID data and other public data sources supported by the manufacturer.

Manufacturers

Three important needed next step areas are recommended to address manufacturer challenges. One is a national scorecard inclusive of measures of manufacturer UDI compliance and functionality. HTG had previously created a vendor scorecard on UDI adoption for use with their top twenty vendors. Further development of this work or standard questions on UDI compliance and functionality to include in other tools use by hospital systems would be an important first step. A second is broad inclusion of UDI-focused requirements in contracting such as capability for easy scanning at the POC and updates on UDI transitions. Lastly, needed is education and work with manufacturers to develop a collaborative approach to POC challenges including advancing the standard of “UDI” on the label next to what needs to be scanned.

Support

Addressing challenges surrounding support for UDI implementation and use in hospital systems necessitates a change in the vision and messaging about the value in capturing and managing device information. Addressing this is consistent with previous recommendations for expanded dissemination of information and education through marketing, social media and a focus on release of quick, easy and publicly accessible information along with more traditional routes. Important to add to this next step area is presentation of information that is clearly linked to priority outcomes for hospital organizations and that minimizes use of the many acronyms and abbreviations typical in UDI discussions and presentations that leads to confusion.

Comprehensive workflow analysis of UDI implementation for implantable devices at the POC is a necessary project to document the time, steps, human resources, barriers and setbacks, etc. required as well as to illuminate potential solutions to challenges.

A UDI Initiative Leader in a hospital system with designated FTE is required to orchestrate implementation, influence the hospital culture, and create a sustainability plan. A next step is a job description for this role. Once UDI is implemented and the process is on-going, ownership is needed to maintain the quality and value. Preferable is development of a self-sustaining process that becomes part of the culture of the organization where staff teach and support one another. Barcode scanning should be part of the onboarding of new clinical staff. Next step areas include development of organizational policy changes and guidelines to foster these areas.

Further support will accrue from expansion of knowledge not only to clinicians but to those in leadership, finance, and other operational roles. Development of durable, publicly accessible education materials/content is a needed next step for these groups as well as for clinicians as discussed earlier. From a policy perspective, requirement of UDI-DI in claims for implantable devices will necessitate that hospital systems develop a UDI system for implantable devices at the POC.

Overall UDI System

The overall UDI system needs better framing that focuses on a much broader picture, *inclusive of UDI but not exclusive to UDI*. UDI is a tool that enables a myriad of downstream activities that uses medical device data to benefit patient care, population health, and cost containment. Needed next steps include engagement of broader stakeholders; focus on effectiveness; focus on availability of the right tools, such as UDI, to enable knowledge generation on medical devices for patients, populations, and operations; more outcomes data from UDI use from patient, population, and cost perspectives; development of metrics; and further policy drivers. Opportunity exists to further explore Joint Commission mandated nursing documentation.

Additional needed next step areas include Education, Funding, and Sustainability. A project to focus on education and marketing of UDI is recommended. Needed are durable publicly accessible education materials/content for the various stakeholders and broad methods to disseminate information including short videos, such as YouTube videos, that are catchy, short and to the point; TED talks; generalizable slide decks; and use of gamification which can take tedious information and make it fun so people will remember it.

A workstream to undertake a rigorous review of funding opportunities is critical to continue UDI work. Researchers from other disciplines should be engaged in UDI work, such as health economists to expand focus to events/outcomes and cost effectiveness analysis. Focus areas for grant funding should be expanded to include innovation, implementation and dissemination, translational research, nursing, and population health. Grant opportunities from government, industry, and foundations, along with targeted funding agencies such as FDA, PCORI, PCOR trust fund, and NESTcc need to

be reviewed and a usable list of opportunities created. It will be critical to advance involvement in cross-cutting projects as has been done in the *BUILD* Initiative to develop a collaborative approach to further research and funding. Marrying work with that of other projects, such as RAPID which is focused on evaluation of devices used in peripheral artery disease[19] and UDI2Claims which is focused on UDI-DI in claims[12,13] as well as with other successfully funded principal investigators is recommended.

Lastly and very importantly, development of a sustainability plan with a constant revenue stream is needed to continue future work.

Table 7: Challenge Areas and Recommended Next Steps

CHALLENGE AREA	PILOT PROJECTS	OTHER
Clinical	• Creation of durable, publicly accessible education materials/content for clinicians, including education modules and case studies for continuing education (CME, CEU) • An interdisciplinary project involving clinical end-users and manufacturers to inform medical device labelling based on experience at the POC • Documentation and mapping of best practices for integrating UDI capture into clinical workflows.	• Engagement of marketing expert(s) to assess best dissemination methods • Use of social media • Work towards a manufacturer requirement for “UDI” to be placed on the device label next to what needs to be scanned • Barcode training as a requirement for new staff on-boarding
IT	• Study and mapping of an optimal hospital system IT architecture for UDI implementation for implantable devices at the POC • Study of hospital system-IT vendor relationships and strategies to address challenges	• Creation of a catalog on IT vendors and systems indicating functionality for a UDI system; gaps; and ability to compensate for common gaps • Creation of a UDI-focused IT vendor group
GUDID	• Survey of hospital systems’ use of AccessGUDID data, barriers faced, and perceived limitations	• Direct work with manufacturers
Manufacturers	• Assessment of hospital system use of a national scorecard or standard questions on manufacturer UDI compliance and functionality	• Standard inclusion of UDI-focused requirements in contracting

		• Direct work with manufacturers including towards a manufacturer requirement for “UDI” to be placed on the device label next to what needs to be scanned
Support	• Comprehensive workflow analysis of UDI implementation • Creation of durable, publicly accessible education materials/content for clinicians, those in leadership, financial and other operational roles, including education modules and case studies for continuing education (CME, CEU)	• Job description for the UDI Initiative Leader • Barcode training as a requirement for new staff on-boarding • Organizational policy change and guidelines
Overall UDI System	• Assess best methods for education & marketing • Creation of durable, publicly accessible education materials/content for broad stakeholders inclusive of generalizable slide decks, short videos, TED talks, gamification • Studies linking UDI use to outcomes • Assessment/creation of metrics	• Focus on policy drivers including Joint Commission mandated nursing documentation; inclusion of UDI in required quality metrics • Comprehensive delineation of funding opportunities/resources • Collaboration of UDI-focused researchers for further research and funding • Expansion of involved disciplines in research, e.g. health economists • Development of a sustainability plan

CONCLUSION

Developing a comprehensive UDI system in U.S. health care is a public health priority of national importance. A realized UDI system provides significant opportunity to support the Triple Aim goals of improved patient care, improved population health, and lower costs. UDI is a tool or enabler of a myriad of downstream activities surrounding implantable devices which benefit clinical, population health, operational, safety

surveillance, research, and regulatory purposes. UDI implementation augments ongoing work and priority in the U.S. for a comprehensive electronic system for health data documentation, use, and exchange.

A large gap in development of a comprehensive UDI system in U.S. health care exists because electronic documentation of UDI at the POC is not standard practice. This Summary document and Roadmap addresses this area.

The Implementation Roadmap includes detail on Foundational Themes, Key Components, Key Steps and UDI Use, and serves as a guideline for development of organization-specific roadmaps for implementation of UDI for implantable devices at the POC and UDI use. Gaps and Challenges are identified as well as strategies being utilized by hospitals to address these areas. Included in this document are next steps to address these areas such as pilot projects, topics for workgroup initiatives, policy needs, expansion of involved stakeholders and collaborative opportunities.

This project had significant strengths: 1) Studying an area with significant benefit for patient care, patient safety, and population health; 2) Studying a health IT process where there is a knowledge gap and impactful health policy changes; 3) Engagement of leaders from ten hospital systems advanced in UDI implementation at the POC for implantable devices and UDI use for project interviews; 4) Active engagement of a multi-stakeholder group of UDI leaders (BUILD Consortium) to react to project findings, provide input on the Roadmap and work collaboratively to conceptualize next steps; 5) Actionable outcomes – a roadmap and delineation of next-step areas including pilot projects; 6) Investigator experience in UDI-focused work; 7) A project team experienced in qualitative and quantitative methodologies.

Limitations include: 1) Semi-structured interviews contain a measure of subjectivity. However, well-defined methodological approaches coupled with best practices in data analysis were used. IRR was established; 2) The team was unable to engage an additional two hospital systems advanced in UDI implementation at the POC for implantable devices and UDI use in the project. However, a high percentage of those advanced enough to study participated in the project. A total of twenty-four interviews were completed with leaders from the ten participating hospital systems; 3) Funding challenges impacted project progress which caused a one-year delay, necessitated elimination of the workflow analysis, as well as support for additional members of the research team with expertise in human-computer interactions, clinical decision support, and data standardization. Despite these challenges significant work was accomplished by the project team as evidenced by this report.

This is an exciting time to be engaged in health care. Growth, change, shared learning, and advancement to benefit our patients and populations is occurring all around us. As a health care system we are transitioning to new models, using advanced technologies and responding to change in policy. This document is an important step forward in this wave of health care change and the on-going collaborative work towards

development of a comprehensive UDI system in U.S. health care to garner the safety and well-being of patients and populations surrounding implantable device use.

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APPENDIX

Appendix A: Interview Recruitment Email Invitation

Subject: BUILD Project – Request for Interview

Dear XXX,

I am a professor in the School for the Science of Health Care Delivery at Arizona State University and co-investigator in the *Building UDI Into Longitudinal Data for Medical Device Evaluation (BUILD) Initiative*, a project focused on UDI implementation and use for implantable devices. I plan to conduct interviews to understand the UDI implementation process in hospital systems. You have been identified as a leader in UDI implementation in your organization.

Phone interviews will last approximately one hour. Your participation in this study is voluntary. You have the right not to answer any question, and to stop participation at any time. If you choose not to participate or to withdraw from the study at any time, there will be no penalty or impact on your employment.

Although there is no expected direct benefit to you for your participation, your responses are expected to inform leading practices and barriers to UDI implementation and use in U.S. health care. There are no foreseeable risks or discomforts to your participation.

Your responses will be confidential. Interview results will be analyzed in aggregate. Results may be used in reports, presentations, or publications but your name will not be used.

I would like to audio record the interview. The interview will not be recorded without your permission. Please let me know if you do not want the interview to be recorded; you also can change your mind after the interview starts, just let me know.

If you have any questions concerning the research study, please contact Natalia Wilson at Natalia.wilson@asu.edu. If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.

Lara Salvo, MS, from the project team will be in touch to schedule an interview. Lara can be reached at lara.salvo@asu.edu.

Thank you in advance,

Appendix B: Interview Guide

1. What has been your role including area(s) of focus & contributions in UDI implementation for implantable devices at the POC in your hospital (system)
   Probes
   - Area(s) of focus – SCM, IT, clinical, combination, other
   - Length of time involved
2. Why was UDI for implantable devices implemented at the POC in your hospital (system)
   Probes
   - Problem attempting to solve
   - Externally influential factors – MU 3 requirements? Future UDI in claims? Payment?
   - Characteristics of hospital system – leader in innovation, IT, data?
   - Data or evidence that supported
   - Have the reasons evolved over time? - Expanded value proposition? Clinical?
3. How was support & consensus developed for UDI implementation for implantable devices at the POC in your hospital (system)
   Probes
   - Who led & approved this?
   - Were there key materials presented – internal data, published evidence, projections
   - Who were key stakeholders involved?
   - Who composed the leadership team
   - How was it funded
   - What was the role of clinicians – engaged?
   - Rate difficulty of gaining support & consensus (1-5: 1 very easy, 2 easy, 3 neither easy or difficult, 4 difficult, 5 very difficult)
   - Please explain your rating
   - Has support evolved over time? – Clinical? Researchers? Quality team?
4. Please indicate the key components/steps necessary for UDI implementation for implantable devices at the POC. Please elaborate on the key steps you were involved in
   Probes
   - Infrastructure
     i. What were key areas: SCM, HR, IT, clinical, other

     Prompts for IT interview
     1. In which IT system(s) is UDI being documented? – How, what type of field?
     2. Were updates needed
     3. What interconnectivity issues were faced
     4. Process for documentation in multiple IT systems
     5. Scanning –can scanners capture 2-D forms of AIDC
     6. GUDID – using GUDID data as “single source of truth” & linking

7. Link of UDI to other data – clinical data, research database, what else
8. Role of IT vendor(s)
9. Future plans

- Project development
  i. What were critical work teams
- Interdisciplinary involvement/collaboration
  i. Who were the key stakeholders?
  ii. How addressed communication, “everybody being on same page”
  iii. How addressed clinical engagement (MDs, RNs & other end users) – what done?
  iv. How addressed holistic vision/value of UDI implementation & use
- Training & support
  i. How did this
  ii. How assessed if appropriate, well received
- Workflow
  i. How elicited end user input
  ii. Is there any manual capture or all electronic?
- Finances
  i. What is needed
  ii. How obtained
- External stakeholders & environment
  i. Who & what?
- Evaluation
- Maintenance
- What changes were made to facilitate implementation?
- Rate difficulty of the key steps for implementation (1-5: 1 very easy, 2 easy, 3 neither easy or difficult, 4 difficult, 5 very difficult)

5. What were successes
   Probe
   - Facilitators
6. What were barriers & gaps
   Probes
   - Variations in way manufacturers implemented UDI
   - Culture of organization
   - Workflow, IT, communication
   - Strategies to address
   - Workarounds
   - What innovation needed/future plans
7. What was the length of time for implementation – initially & subsequent sites
   Probes
   - Initial site(s) of implementation
   - Subsequent sites
8. How & by whom is UDI for implantable devices being used in your hospital (system) once it is captured at the POC

Probes

- By whom: SCM, hospital other, clinicians, researchers, patients, external
- How:
    i. Is UDI being linked with clinical data? Other device data included?
    ii. Is UDI part of implantable device data transferred to external stakeholders - clinical registries, FDA, payers, etc.
    iii. Is UDI part of implantable device data included in research databases
    iv. Is UDI being used for recalls
    v. Is UDI available for use by clinicians & patients for clinical care
- What challenges are being faced for use – knowledge of UDI availability?
- Has use expanded over time – if so, in which areas?
- Is GUDID data being downloaded & linked to UDI & used as "single source of truth"
- Future plans

9. How & in what areas is your hospital (system) assessing the value of UDI implementation & use for implantable devices at POC
   Probes
   - Who assessing?
   - What areas - Quality, safety, efficiency? Clinically focused areas?
   - What metrics are being used?
   - Is there internal data available?
   - Barriers for assessment
10. Please rate the current state of 1) UDI implementation for implantable devices at the POC & 2) UDI use for implantable devices in your hospital (system). Base on extent UDI implemented or used across hospital (system) & level of implementation or use at sites (1-5: 1 very basic, 2 basic, 3 neither basic or comprehensive, 4 comprehensive, 5 very comprehensive/ideal state)
    Probes
    - Why gave these ratings?
    - Indicate lessons learned about implementation & use
    - Future plans
11. Comments & advice to hospital systems planning to implement & use UDI for implantable devices at the POC
12. Comments & advice on creating a usable & generalizable UDI Roadmap for hospital systems

Appendix C: Oral Consent Form

Study Title: Building UDI Into Longitudinal Data for Medical Device Evaluation (BUILD) - Medical Device Data Capture and Exchange: Leading Practices and Future Directions

I am a professor in the School for the Science of Health Care Delivery at Arizona State University. I am conducting a research study to assess leading practices and barriers to UDI implementation for implantable devices.

I am inviting your participation, which will involve an interview anticipated to last one hour to assess the implementation process at your hospital organization. You have the right not to answer any question, and to stop participation at any time. Your participation in this study is voluntary. If you choose not to participate or to withdraw from the study at any time, there will be no penalty or impact on your employment.
Although there is no expected direct benefit to you for your participation, your responses are expected to inform leading practices and barriers to UDI implementation and use in U.S. health care. There are no foreseeable risks or discomforts to your participation. Your responses will be confidential. Interview results will be analyzed in aggregate. Results may be used in reports, presentations, or publications but your name will not be used.

I would like to audio record the interview. The interview will not be recorded without your permission. Please let me know if you do not want the interview to be recorded; you also can change your mind after the interview starts, just let me know.

If you have any questions concerning the research study, please contact Natalia Wilson at Natalia.wilson@asu.edu. If you have any questions about your rights as a subject/participant in this research, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.
Please let me know if you wish to be part of the study.

Appendix D: Hospital Demographic Survey Questions

Introduction
Thank you for completing this demographic questionnaire. The information provided will be very important to know prior to starting interviews.

Is implementation of UDI for implantable devices at the point of care in your organization currently an initiative at the hospital system level for many hospitals or occurring at individual hospital(s) as pilot sites or independent initiatives?

○ Hospital System (1)

○ Individual Hospital(s) (2)

End of Block: System I

Start of Block: A: General

A1 Name of hospital system
_____

A2 Organizational structure

○ Government, federal (1)

○ Government, non-federal (2)

○ Non-government, not-for-profit (3)

○ Investor-owner, for-profit (4)

A3 Academic medical center in system

○ Yes (1)

○ No (2)

A4 Health care plan in system

○ Yes (1)

○ No (2)

A5 Primary Region of country

○ Northeast (1)

○ South (2)

○ Midwest (3)

○ West (4)

End of Block: A: General

Start of Block: A: Numbers

A6 Number of hospitals in system

_____

A7 Number of hospitals with cardiac catheterization lab(s)

_____

A8 Number of out-patient facilities (ASC, clinics, free-standing EDs, extended care) in system

_____

A9 Number of licensed beds in system

_____

A10 Number of patients cared for in 2017 in system

_____

A11 Revenue in 2017

_____

End of Block: A: Numbers

Start of Block: A: UDI Details

A12 Primary method of capture of UDI for implantable devices at the point of care?

- ○ Barcode Scanning (1)
- ○ RFID (2)
- ○ Manual (3)
- ○ Other (indicate): (4) _____

A13 Primary method of capture of UDI for implantable devices is the same between hospitals and/or procedural sites?

- ○ Yes (1)
- ○ No (2)

A14 Capture of UDI or UDI prototype for implantable devices at the point of care:

- ○ UDI (1)
- ○ UDI Prototype (e.g. overlaid sticker with barcode created by hospital) (2)

A15 Procedural sites where capturing UDI for implantable devices (Indicate all that apply):

- ☐ Cath Lab (1)
- ☐ Operating Room (2)

☐ Interventional Radiology (3)

☐ Other (indicate) (4) _____

A16 Percentage of hospitals in system capturing UDI for implantable devices in any procedural site:

0 10 20 30 40 50 60 70 80 90 100

% Hospitals Capturing UDI ()

A17 Year of first UDI capture for implantable devices at the point of care in system?
▼ 2010 (1) ... 2018 (9)

A18 UDI for implantable devices is documented in electronic systems at the point of care?

○ Yes (1)

○ No (2)

A19 Clinical sites where capture UDI for NON-implantable devices:
_____

End of Block: A: UDI Details

Start of Block: A: Information Technology

A20 EHR vendor

○ Epic (1)

○ Cerner (2)

○ Other (indicate) (3) _____

A21 Year EHR was implemented:
▼ 2000 (1) ... 2018 (19)

A22 Same EHR is in all clinical areas?

○ Yes (1)

○ No (2)

A23 Stage of the HiMSS Electronic Medical Record Adoption Model:
▼ 0 (1) ... 7 (8)

A24 Stage of Meaningful Use achieved:

○ Stage 1 (1)

○ Stage 2 (2)

A25 Supply Chain Enterprise Resource Planning (ERP) vendor

_____

A26 Point of care system vendor where documenting UDI:

○ Cath Lab (indicate) (1) _____

○ Operating Room (indicate) (2)
_____

○ Other (3) _____

A27 Other relevant IT systems in UDI implementation:
_____

A28 Further Comments

_____
_____
_____
_____
_____

End of Block: A: Information Technology

Start of Block: B: System II

B1 Is your hospital part of a system?

○ Yes (1)

○ No (2)

End of Block: B: System II

Start of Block: C: General

C1 Name of hospital system

_____

C2 Organizational structure

- Government, federal (1)
- Government, non-federal (2)
- Non-Government, not-for-profit (3)
- Investor-owned, for-profit (4)

C3 Number of hospitals in system

_____

C4 Percentage of hospitals in system capturing UDI for implantable devices in any procedural site

0 10 20 30 40 50 60 70 80 90 100

% hospitals capturing UDI ()

C5 Name of hospital most advanced in UDI implementation for implantable devices at the point of care

_____

C6 Is this hospital an academic medical center

- Yes (1)
- No (2)

C7 Primary Region of country for this hospital

- Northeast (1)
- South (2)
- Midwest (3)
- West (4)

End of Block: C: General

Start of Block: C: Most Advanced
C8 When answering the remaining questions please answer for the Hospital Most Advanced in UDI Implementation for implantable devices that you indicated

End of Block: C: Most Advanced

Start of Block: C: Numbers

C9 Number of licensed beds
_____

C10 Number of patients cared for in 2017
_____

C11 Revenue for 2017
_____

End of Block: C: Numbers

Start of Block: C: UDI Details

C12

Primary method of capture of UDI for implantable devices at the point of care

- ○ Barcode Scanning (1)
- ○ RFID (2)
- ○ Manual (3)
- ○ Other (4) _____

C13
Primary method of capture of UDI for implantable devices at the point of care is the same between procedural sites

- ○ Yes (1)
- ○ No (2)

C14
Capture of UDI or UDI prototype at the point of care

○ UDI (1)

○ UDI Prototype (e.g. overlaid sticker with barcode created by hospital) (2)

C15
Procedural sites where capturing UDI for implantable devices (indicate all that apply)

☐ Cath Lab (1)

☐ Operating Room (2)

☐ Interventional Radiology (3)

☐ Other (indicate): (4) _____

C16
Year of first UDI capture for implantable devices at the point of care in hospital:
▼ 2010 (1) ... 2018 (9)

C17
UDI for implantable devices is documented in electronic systems at the point of care

○ Yes (1)

○ No (2)

C18
Clinical sites where capture UDI for NON-implantable devices
_____

End of Block: C: UDI Details

Start of Block: C: Information Technology

C19 EHR Vendor

○ Epic (1)

○ Cerner (2)

○ Other (indicate) (3) _____

C20 Year EHR was implemented
▼ 2000 (1) ... 2018 (19)
C21 Same EHR in all clinical areas?

○ Yes (1)

○ No (2)

C22 Stage of the HiMSS Electronic Medical Record Adoption Model
▼ 0 (1) ... 7 (8)

C23 Stage of Meaningful Use achieved

○ Stage 1 (1)

○ Stage 2 (2)

C24 Supply Chain Enterprise Resource Planning (ERP) vendor
_____

C25
Point of care system vendor where documenting UDI

○ Cath lab: (1) _____

○ Operating Room: (2) _____

○ Other (indicate) (3) _____

C26 Other relevant IT systems in UDI implementation
_____

C27 Further Comments
_____
_____
_____
_____
_____

End of Block: C: Information Technology

Start of Block: D: General

D1 Name of Hospital

_____

D2 Organizational structure

- Government, federal (1)
- Government, non-federal (2)
- Non-government, not-for-profit (3)
- Investor-owner, for-profit (4)

D3 Academic medical center

- Yes (1)
- No (2)

D4 Primary Region of country

- Northeast (1)
- South (2)
- Midwest (3)
- West (4)

End of Block: D: General

Start of Block: D: Numbers

D5 Number of licensed beds

_____

D6 Number of patients cared for in 2017

_____

D7 Revenue for 2017

_____

End of Block: D: Numbers

Start of Block: D: UDI Details

D8
Primary method of capture of UDI for implantable devices at the point of care:

- ○ Barcode Scanning (1)
- ○ RFID (2)
- ○ Manual (3)
- ○ Other (indicate): (4) _____

D9
Primary method of capture of UDI for implantable devices at the point of care is the same between procedural sites:

- ○ Yes (1)
- ○ No (2)

D10 Capture of UDI or UDI prototype at the point of care:

- ○ UDI (1)
- ○ UDI Prototype (e.g. overlaid sticker with barcode created by hospital) (2)

D11 Procedural sites where capturing UDI for implantable devices (indicate all that apply):

- ☐ Cath lab (1)
- ☐ Operating Room (2)
- ☐ Interventional Radiology (3)
- ☐ Other (indicate) (4) _____

D12 Percentage of procedural sites where UDI for implantable devices captured:

0 10 20 30 40 50 60 70 80 90 100

% sites where UDI is captured: ()

D13 Year of first UDI capture for implantable devices at the point of care:
▼ 2010 (1) ... 2018 (9)

D14 UDI for implantable devices is documented in electronic systems at the point of care?

- Yes (1)
- No (2)

D15 Clinical sites where capture UDI for NON-implantable devices
_____

End of Block: D: UDI Details

Start of Block: D: Information Technology

D16 EHR Vendor

- Epic (1)
- Cerner (2)
- Other (indicate) (3) _____

D17 Year EHR was implemented
▼ 2000 (1) ... 2018 (19)

D18 Same EHR is in all clinical areas

- Yes (1)
- No (2)

D19 Stage of the HiMSS Electronic Medical Record Adoption Model
▼ 0 (1) ... 7 (8)

D20 Stage of Meaningful Use achieved

○ Stage 1 (1)

○ Stage 2 (2)

D21 Supply Chain Enterprise Resource Planning (ERP) vendor

_____

D22 Point of care system vendor where documenting UDI

○ Cath lab (1) _____

○ Operating Room (2) _____

○ Other (indicate) (3) _____

D23 Other relevant IT systems in UDI implementation

_____

D24 Further Comments

_____
_____
_____
_____
_____

End of Block: D: Information Technology

Appendix E: Summary Report from April 3, 2019 BUILD Consortium Meeting

BUILD Consortium Meeting 8	
Facilitator	Natalia Wilson
Date and Time	April 3, 2019 8:30AM – 2:30PM CT
Location	Mercy Virtual, Chesterfield MO
Notetaker	Lara Salvo
Attendees (In-Person)	Kim Collison-Farr, Mercy, Joe Drozda, Mercy, Curtis Dudley, Mercy, Terrie Reed, FDA, Jimmy Tcheng, Duke, Natalia Wilson, ASU
Attendees (WebEx Conference Line)	Kevin Capatch, Geisinger, Melina Cox-Ferreras, ASU, Jove Graham, Geisinger, Ted Heise, Cook Medical/Med Institute, Tom Maughan, JNJ, Lara Salvo, ASU,

	Cynthia Shumway, Intermountain Health, Paul Varosy, VA

OPENING REMARKS

- The overall BUILD Initiative – Joe Drozda
    - Current BUILD projects to wrap up by 6/30
    - Extension of UDI Demonstration Project
        - Establishing distributed data network; each hospital system had to develop an identical system
        - Moving into hypothesis driven query
        - Seminal work in AUDI database using First Database to provide needed information
    - Opportunity working w/ industry partners now & into future/next steps
- BUILD-Leading Practices – Natalia Wilson

Leading up to today

- BUILD Consortium
- BUILD Website
- Framework for UDI Roadmap
- Interviews assessing implementation of UDI for implantable devices at point of care
    - Identify commonalities
    - Ascertain leading practices, gaps/challenges

Today

- React to research data
- Ask questions
- Provide input on leading practices & gaps
- Delineate next steps: Pilot projects, partnerships development, new workgroups or consortia, new topics to address in ongoing groups, etc.

Goals for the roadmap

- Strengthen advancement of POC capture of UDI for implantable devices
- Provide a common view of best path forward
- Serve as guideline for development of hospital-specific implementation roadmap
- Support improved patient care, health outcomes, lower costs through use of implantable device UDIs

Overall impressions after Interviews

- Continuum of maturity
- Areas of Difficulty
    - Identifying the right people and engagement in project
    - Broader picture is not fully understood
    - Clinical use
- Heavy focus on implementation over use
- Pivoting to clinical focus – not fully there
- Many lessons learned

SESSION 1: Presentation of Leading Practices Data I & Discussion

- Methodology

    - Mixed Methods
    - Protocol approved by ASU IRB
    - Hospital systems identified through recommendation of FDA, industry, researchers
    - Interviewees recommended by hospital system
    - 24 semi-structured interviews conducted by phone
        - Recorded and transcribed
        - Thematic analysis
    - Survey done by each hospital system, provided information on demographics, IT, UDI (n=10)
- Hospital system demographic data – highlighted points
    - Majority implementing UDI at hospital system level
    - Majority had a health care plan in system
    - Range of hospital represented by virtue of US location, size, revenue
    - Majority scanning barcodes & using UDI not prototype
- Hospital System IT Systems Data
    - Majority using Epic for EHR
    - Significant longevity in use of current EHRs
    - Robust, mature use of EHR (Stage 6 or 7 HiMSS EMR Adoption Model)
        - CURTIS: Maturity was an important part of this at Mercy
    - Important point: Other hospital systems will look at maturity in EHR systems as potential difference from their own system
    - Majority using Infor Lawson, Peoplesoft for ERP
        - Enterprise content management, supply chain infrastructure is key
        - Content behind the barcodes must be robust
        - Content links across manufacturer – supply chain – clinical care – regulatory needs
    - Many different POC IT vendors used AND cath lab (or OR) systems may not communicate well with EHR (e.g. Epic's Cupid module for cath lab does not communicate well with Epic EHR)
        - More variation in Cath lab than OR
        - More use of EHR in OR for receiving UDI scan
- Primary sites of UDI capture: Cath lab, OR, IR, then several other service areas in low volume
- Interviewees Demographic Data – highlighted points
    - Some with significant longevity in involvement
    - # people that had moved on still maintained connection with the UDI initiative
    - Majority had more than one focus area (Clinical, SCM, IT, Operational), were able to float between siloed areas
- Noted Gaps
    - Support at hospital
    - Overall UDI system – policy, mandate, etc.
- COMMENTS & DISCUSSION

Did you get a feel as to whether or not degree of maturity is required to build UDI implementation?

- NATALIA: Systems not quite as mature will have to approach in pieces, piece together and then reach a higher level. Won't accomplish goal in a day, but can build capability in a small pilot site
  - Long journey of building
- CURTIS: Most people go beyond implant record. If they're not scanning, face problems w/ manually entering into record, workflow issues. Build tech around point of capture to address these issues. Mercy is finding continued improvement and refinement captures more accurate patient charges, inventory management & replenishment; manual capture a challenge. **Iterative**
  - Why do hospitals pursue this? UDI itself is means to an end. Only way to add value is have barcode on product to create a seamless capture. Charge capture, inventory management, auto-replenishment, other value components can't be done without seamless capture
- NATALIA: How do we build data and thought process to drive that? The why. What about clinical side? How linked to quality metrics, readmissions, outcomes
- TERRIE: Let's think about standards and role of regulation to make this easier, drive this
- NATALIA: Struggles faced in clinical space; nurses need IT solution so they don't have to think about barcodes
- CURTIS: EHRs have functionality, although differences in being able to do, but larger issue is a content issue. Health care enterprise content manager, originator of information (manufacturer) makes it effortless for information to flow into health system through a number of parties, but **content is the challenge**
- TERRIE: Policy important, Movement of UDI through all IT systems is a 2-way street; could benefit from policy implementation
- JIMMY: Need all of the components in place to meet a regulation. Someone should write a regulation, then use that & resources to address
- JOE: Regulation can help us out of chicken vs egg situation. Content from manufacturers is one example. Manufacturers say not big ask of them. Once hospitals know how to do it, know value, have systems ready to go, will be demanding information/data
- JIMMY: Duke did own single **source of truth. Better to do universally. But lacking are resources**
- CURTIS: Mercy had to do this with own content management team

Point of Care Systems: # POC vendors engaged – in some cases they're being used to compensate for lack in EHRs

- JOE: But create islands of communication that make moving data difficult – clinical goes in X, UDI goes into Y, etc.
- CURTIS: procedural level, supply chain management level, physician level doc. Every system that tracks info on patient is part of EHRs. Other systems part of whole picture, brought together in data warehouse

- CURTIS: Some will scan barcode of patient ID, then supply documentation. Apart from clinical, some are bridging gap to EHR w/ flavor of procedure and surgeon documentation
- NATALIA: **Could this group map out the functionality of these disparate systems, as well as the needs of the users for UDI implementation**
- TERRIE R: Only EHRs getting certification
- CURTIS: On manufacturer side, if not in Epic, understand that other systems are part of it & brought together in data warehouse. Confusing & need clarification
- NATALIA: Interfacing w/ EHR becomes confusing
- JIMMY: UDI has to talk to 5 systems – Epic, ERP/item master, clinical documentation system, replenishment system, inventory management system
  - If tried to do it in Epic, like a black hole with data, need to manage UDI on front end and distribute, 2-way street. Becomes very complex very fast & EHR is not designed to do that
  - Movement of UDI & all uses is what needs to be described & added into regulation
- NATALIA: Ability to not just accept data but be able to pass data on becomes black hole w/ proprietary systems, how they send data to another systems is a huge problem

BUILD FRAMEWORK FOR THE ROADMAP

- Original Framework draft will be updated
  - A. Foundational Themes, B. Key Components, C. Key Steps (new), D. Facilitators (new), E. UDI Use, F. Outcomes/Triple Aim Goals
- A. Foundational themes
  - Holistic vision
  - Interprofessional
  - Collaboration
  - Communication
  - Innovation
  - Resilience
  - Sustainability (new)
- B. Key components
  - 1. Purpose, 2. Leaders & Champions, 3. Expertise & Support, 4. Relationships, 5. Governance, 6. Education
- 1. Purpose – 4 main areas
  - Clinical
    - High quality, safe, patient-centered care: Seamless, Accurate, Accountability for patient well being
    - Analytics to assess: Address gaps, inform clinical decision making
  - Research
    - Availability of standard device data
    - Capabilities – augment research mission
  - Regulatory
    - Only about ½ of interviewees brought this up

        - Thinking about meaningful use
        - Teeing up for when DI in claims is required
    - Operational, SCM
        - Automated system
        - Master data management
        - Having data available and optimize what you're doing in hospital system efficiently
            - JOE: Supply chain modernization
            - JIMMY: **Saving money not included & should be**
            - JOE: Everyone is looking for hardcore cost-savings. Margins are shrinking
            - NATALIA: No one had hard data on cost savings, tends to be internal, need more data showing what was done and saved
- 2. Leaders & Champions – 4 main areas although may be same person fulling role in different areas
    - Characteristics: have trust, cross silos, information providers, people listen to them
    - Clinical
        - Physicians – department heads, on committees, people know them, have influence
        - POC Champion: Nurse in clinical and operations role, influence managers/staff for buy in
            - JOE: Nurse cath lab leader helped make it happen
    - Administrative
        - POC directors, perioperative leaders
        - Clinical background very important to understand environment
    - SCM
        - Leader with vision
        - Focus on broad implementation and use
    - UDI Initiative Leader
        - The glue, unsung hero, critical leader & relationship builder, catalyst for resources, right people, brings people together, visit POC sites
        - Role/job description of this person is not full blown in organizations
            - JIMMY: Who is this at Mercy?
            - JOE: Vance gave Curtis and I our marching orders, Curtis' area includes performance optimization group who did a lot of this work including training
            - CURTIS: Highest quality at best cost journey initiated by Vance Moore
            - KEVIN: Group is good, Deb Templeton would be person who got me involved, have a physician lead now & in past, Jove Graham has been key partner in use of data collected from QSight, single person initiator, but involves IT, data people, SCM, administrators
            - PAUL: Add that they have admin support from Washington and great support at number of levels with rolling UDI data into single

nationwide tracking system demanding what they're doing in Cath lab. Large group working together
    - NATALIA: UDI initiative leader(s) is often in addition to their day job. What's difficult is not having someone who can oversee everything and has designated time
    - JIMMY: This person sounds like a catalyst for this work. Recommend not static. Coordinator
    - **Would a "job description" from this group be helpful?**
- 3. Expertise & Support – 3 main areas
    - SCM – generally starting point, significant legwork
        - Item master team, sourcing, contracting, MDM team
    - IT – legwork, testing
        - EHR, ERP, 3rd party POC vendors
        - Support necessary from vendors, also internal teams
    - Clinical – need to engage
        - Physicians, nurses, nurse educators
    - Other – engage to broaden value & use
        - Recall management, quality, risk, MU
        - Defining value and use for organization
        - **Opportunity areas for these other groups in UDI initiative to define value & use**
- 4. Relationships – 4 main areas
    - Communicating the "why" and value is critical; can only thrive in a collaborative culture
    - Characteristic: Focus on value for all over value for one
    - Good model for team-based work
    - SCM – Clinical
        - At POC sites clinical can foster further involvement
        - Key for leaders to identify problems and engage cross disciplinary team
        - SCM integration at POC
            - PAUL: One thing that came out of work is getting clinicians & logisticians to work together; convergent thinking that working together is creating ways to fix old problems; clinician driven strategic sourcing, much to be gained by building bridges
            - CURTIS: Clinically integrated supply chain – championed whole thing so understood charge capture to reduce cost and variation. UDI key enabler to make this all happen. Closed gap between clinicians and supply chain so saw each other as collaborative partner. Other facilities were asking when they would be next & weren't resistant for once to changes being made
            - JOE: Non-clinical folks start to see impact this will have on patient care, motivates them
    - Clinical – Clinical
        - Clinicians best to communicate to other clinicians
        - Validating the work clinical staff is doing important and necessary

        - Educating and communicating the why, the value, and their importance
            - JIMMY: Key is to provide alternative workflow that replaces something that already exists, but makes overall system more efficient; change that isn't detrimental to workflow
    - SCM – IT
        - Correct vendor partner critical
    - SCM – Manufacturers
        - Source of truth support
        - Issues w/ labels
        - Mergers and acquisition updates
        - Right now ,one hospital system: one manufacturer rather than broader
    - Other
        - Bridge silos
    - TERRIE: Recent presentation went very well because made real to people
    - TED: Wondering why these relationships never happened w/ drugs, maybe effect of this being a component of physician use of med devices in their application
- 5. Governance
    - Formal governance structure for initial UDI implementation generally lacking
    - Bring together silos
    - Example: Formal UDI governance committee, designated UDI initiative leader, workgroups
    - **How do you develop proper structure for this? Not a lot came from interviews**
        - JOE: Governance around data, ideal of an org vs value of org, not formal
        - CURTIS: Ideal but not supported, people get pulled for other things, centralized idea that engage people that know data the best but cannot keep them in that role
- 6. Education – 2 important aspects
    - How to become educated as a leader – many interviewees pursued on own
        - Attend conferences (GS1, UDI, GHX), lacking were clinical conferences
        - Learn from other systems (HTG)
        - Join workgroups (LUC, Brookings-UDI WG)
        - Follow ongoing research (BUILD, RAPID)
    - How to educate others
        - Need to meet people in person; Peer to peer; make it convenient
        - Physician education – by clinical leaders
        - Nurse education – POC clinical leader teach/train
        - Things often fall down on the why
            - JIMMY T: With rolling out in OR, he was key to present how it should be done, teamed up w/ Ortho head
- FURTHER DISCUSSION & COMMENTS
    - TERRIE: Education piece – How do we get to a higher-level w/ dissemination of information

        - Want to reach more people
        - Include in clinical education
    - NATALIA: Physicians and nurses have CME/CEU courses, getting new curriculum introduced in med schools is VERY difficult, tough environment
    - JIMMY: As we try to come up w/ innovative ways for students to think about other things, delivery of content is difficult – are we thinking about this the right way w/ CME? How do you create awareness today? Get people excited about it and raise awareness. **Use social media. Twitter feed** from Terrie at FDA? Short leap for clinicians about possibilities of UDI, but need a community that is actually behind them
        - Get patients engaged to want their UDI
    - NATALIA: Need to think out of the box, all need to come together to make plan as next step
    - CURTIS: Why aren't folks grabbing onto this and running with it? Outcomes analyses w/ UDI are key, to make interesting discoveries – X device performing better than Y device. UDI is necessary for practicality of other things. Need to get others want to do similar & realize need UDI to do
    - NATALIA: Not enough data right now. **Next step with discovery is then what do with it: how changes clinical decision making, protocols, how impacts outcomes, etc.**
    - CURTIS: With distributed data network (DDN), should have something to inform publications and hopefully motivate people about what can be enabled by UDI
    - NATALIA: Need to discuss what coming, next steps, capabilities
    - CURTIS: UDI should not be the title. Should be a background thing now – reason why want it to do XXX leading to impact on outcomes, care

SESSION 2: Presentation of Leading Practices Data II & Discussion
CONTINUATION OF BUILD FRAMEWORK FOR THE ROADMAP

- C. Key steps
    - 1. Initial Planning, 2. Gaining Support, 3. Source of Truth Database, 4. IT Assessment, 5. Engagement, 6. Pre- Implementation Planning, 7. Shared Advice & Successes
- 1. Initial planning
    - Start early
    - Identify **Purpose** to drive vision and work
    - Pull together data to support this
    - Identify **leaders and champions**
    - Delineate needed **expertise & support**
    - **Can UDI implementation be part of something bigger? Some systems have done this, need to frame it within bigger picture and hasn't been fully delineated yet**
        - Roll into other initiatives (EHR implementation, SC modernization), should help identify and amplify value
        - UDI provides means for SCM automation
        - UDI provides means for preference card accuracy

- Value in initiating UDI implementation within a controlled environment, such as the cath lab
- COMMENTS & DISCUSSION
  - JOE: Hard to answer ROI for UDI but SC modernization, EHR implementation have ROI
  - JIMMY: RM is playbook. UDI should be thought of as critical for supply chain modernization, documentation is very think-tank & should make this recommendation
  - CURTIS: All about modernization, but business case comes back to inventory where automated means allows selection, data, etc. UDI is enabler for recognizing key steps in making automation possible, so directly tied to making these changes. Preference card accuracy has been discussion forever. Tied to automation & UDI is enabler
  - JOE: Define ROI for clinical, what patients have in them, track them over time for safety
  - NATALIA: Not everyone started w/ supply chain modernization, so what should people be trying to achieve
  - JIMMY: Define "preferred" approach. In pilot in cath lab, did not do **SC modernization.** But now in OR much broader & tackling SC. Parts are easier. **Use as example in Purpose** & building out slide decks for presentation
  - JOE: For RM – Give recommendations with options if cannot do X
  - CURTIS: Different schools of thought. Saw this with recent visiting system. One school of thought is that bundled payments driving thinking with POC capture, knowing all items used doesn't matter b/c payments are bundled anyway. Everyone must do devices – implant log. But can't leverage value of implants without POC capture. Other school of thought is this can be done w/ charge codes. These are alternative to what is being discussed here and should be addressed in the Purpose. These are alternative thoughts to what we are proposing. POC vs. bundled or charge code approach vs. true cost approach. If these aren't addressed, people won't understand why they're different. DI in claims is huge to drive. If DI & PI required, then charge code will not work.
  - NATALIA: Policy drivers so important
  - **Discussion of Leading Practices output**
    - Roadmap that allows flexibility
    - Includes a core mechanism
    - Includes steps for appropriate modification to support specific site needs
    - How should bundled care vs actual items used approaches be addressed?
      - DI use policy will be a defining element for this question
- 2. Gaining support
  - Present **Purpose,** data, vision, plan to those who approve work/provide resources

- 3. Source of Truth Database
  - Many still have database in POC system rather than ERP Item Master
  - Need to think more long term about preferred approach
  - Need to consider how mature item master is & resources will take to achieve goal
  - Supporting source of truth with data from GUDID, vendors, &/or 3rd parties
  - Assess process to use GUDID data, vendor data
    - Need to supplement this space (similar to AUDI)
    - Use of 3rd parties to gather this type of info
  - Health care is unique as devices are assigned multiple identifiers
    - Why this occurred is not as important as recognizing this is where we are and asking how we adapt
  - COMMENTS & DISCUSSION
    - JOE*:* Next step happening already - *SCANHealth & HTG just announced a challenge to address multiple identifiers and identification accuracy concerns*
      - *Submission due Aug 2019*
      - *Will discuss opportunities at their annual meeting in Oct 2019*
    - KEVIN: Retail built with barcode around it; we started the opposite
      - We need to clean up that data
      - GDSN does not do all because need to support HIBCC also
    - NATALIA: Tough area for definite recommendation because murky
    - CURTIS: Manufacturers are source of truth of their product. Problem = getting that info to provider system. Walmart requires vendors to follow GS1 standards, attributes must be submitted to GDSN to do business with them. Driving compliance for single source of truth. We don't do this in health care where we have collection of stuff. **We can replicate a lot from retail and apply it**
    - NATALIA: Maybe include in contracting have to put data into GUDID & have to be usable (?)
- 4. IT assessment
  - Define functionality requirements and then build IT infrastructure around needs
    - Clinical workflow must be defined, burdensome steps will not be adopted
  - Assess scanners, determine new system requirements, upgrades, interfaces
  - Very important to delineate IT **expertise & support**
  - Important to consider future needs
  - There is very important work left to do
  - **May want to do a basic figure for the Roadmap of preferred or ideal IT**
  - COMMENTS & DISCUSSION:
    - CURTIS: Decide on functionality want 1st – then look at IT systems – can reach functionality for what want to do/purpose/use
    - CYNTHIA: Biggest challenge is clinical workflow that may prohibit adoption of system; need to emphasize its importance. Quite a bit very IT driven

        - CURTIS: Lots of **process engineering** to drive better workflow to provide path that works clinically & supports operations. More likely to be adopted. Most effective is engineering background, use of process engineering in clinical workflow & engineering from ground up
- 5. Engagement
    - **Education**
    - Building **relationships**: Meet with stakeholders, discuss why, benefit add & how
    - Ongoing communication
- 6. Pre-Implementation Planning
    - Pick small contained POC site (pilot site) – typically Cath lab or area in OR
    - Establish **governance** and team structure
    - Develop working doc w/ plan, deliverables, timeline
    - Anticipate & address barriers
    - Assure comprehensive source of truth database w/ daily updates to POC system
    - Plan for testing before going live
    - Continue learning and furthering relationships
    - JIMMY: Need to minimize "cognitive burden" – automation, ease, not too many similar (thus confusing) steps
- 7. Shared Advice & Successes
    - It takes a long time
    - When it's working clinicians love it, don't want a partial system
    - People don't want to be a "checkout person", they want to care for patients
- D. Facilitators
    - Key Components, organizational endorsement, strong SCM leadership, clinical buy-in, IT support, Pilot 1st, ongoing/easy access for support
- E. UDI Value/Use

Clinical Value

- **This would be a good area for a figure in the RM**
- Documentation – easer, less error-prone
    - JOE: Fits very well with structured reporting
- Recall management – more efficient, accurate
- Device tracking – enhanced
- Data, analytics, predictive analytics – availability for patient care, to assess value
    - NATALIA: haven't thought previously about using data for predictive analytics – seeing patterns w/ devices being used
- Enabler of large networks/data sets to – analyze patterns & outcomes, use for patient care, assess population health
- Outcomes – longitudinal value for patient care, patient safety, population health

Use – 4 main areas

- Clinical
    - Documentation, reports, clinical care
- Research

        - CER
    - Other
        - In HIE so available to other hospitals
    - Operational
        - Most robust area for use
        - Contracting, purchasing, inventory management, charge capture, tracking systems, recall management, expiration data management, compliance, analysis
    - Future – Lots of future plans for use in patient portal, claims. How can we get there?
        - There has been much more focus on implementation over use
        - Plans but not fully developed
            - Greater use clinically and in research
            - Discharge summaries
            - Predictive analytics
            - Cost-outcomes data
            - Registries
            - Partner w/ manufacturers to assess implant quality
                - Total product lifecycle
        - Device surveillance and regulatory responsibility
        - **How can clinical use be advanced within health care delivery sites? This is an important next step**
            - JIMMY: Device surveillance; TPLC key; regulatory decision-making – extension of indications; clinical trials enabler; analytics for signal detection
            - JOE: Create IT infrastructure to aggregate data on devices, not just individual patient. How do we identify that population of patients if not aggregating data to answer those clinical questions?
                - Example: Using newly determined information to guide clinical actions; use of paclitaxel balloons in PAD space and subsequent mortality. How do we identify this population of patients?
        - Not a lot of emphasis on future, due to focus on now
- F. Outcomes/Triple Aim Goals
    - **Area in need of development/delineation**

SESSION 3: Presentation of Gaps/Challenges & Next Steps Discussion

- Potential Next Step Areas
    - Pilot projects
    - Partnership development
    - New workgroups or consortia
    - New topics to address in ongoing groups
    - Needed technologic advancement
    - Policy
- Gaps/Challenges – 6 primary areas
    - 1. Clinical, 2. IT, 3. GUDID, 4. Manufacturers, 5. Support, 6. Overall UDI System

- 1. Clinical
    - End-user issues at POC - resistance to change, confusion on what to scan, inconsistency because cannot scan all
    - UDI use cases – underdeveloped and difficult to achieve full value
    - Dissemination & education – not a common topic at conferences, in journals; lack of ready to go education materials, limited data on benefits
    - COMMENTS & DISCUSSION:

Where could we go practically? Next Steps? What could we foster?

- JIMMY: A few ideas – lack of content, presentations and education materials can be turned around by **making a project to create durable content**. Content is often in the form of documents and Powerpoints that can be quickly adopted. Everything needs to be tuned to the particular audience
- JOE: **Moving vocabulary away from UDI to generating knowledge for clinical use, safety for individual patients plus populations**. POC information is what is captured at time of care, so education should center on medical devices rather than just UDI

Are there places where we should be writing about this so we are framing information in a different way?

- JIMMY: A lot has changed w/ Google searches to find content. Focus on academic publications could be minimized. Get information out there, make it freely available, create content that can be found. **Use social media, twitter**? Need to standup a website that is more accessible, has tags, social media presence, etc. Need **marketing** around the subject/engagement of someone with competency. Move beyond a UDI platform, frame within overall care of patient
- JIMMY: How can we leverage the need to capture that information? Roadmap should say that when info is captured it must go into billing form, device management database, etc. for multiple uses
- TED: Regulatory action for implementation of processes could be a very effective way to disseminate this information
    - JOE: Need to ask why is it in the claim form? In order for it to mean anything, insurance companies have to start using it. Important for outcomes reporting. Hospitals need to not perceive the action of DI on claim as the single end point, rather one of many uses. May drive hospitals to do but may end there, rather than getting claims data back. Must be action between willing trading partners. So, at some point, we need to advocate for use of it.

Any next steps we need to recommend?

- JIMMY: This speaks to need for industrial/process engineering and processing and limited number of **best practice approaches for clinical workflow** to maximize value. Need to map out, manage, and come up with diagrams to guide minimizing work, maximizing value
- NATALIA: Support for end-users by **putting UDI next to what needs to be scanned**

- TERRIE: ISO standard up for vote for Ref next to what need to scan – what EU wants to adopt. Voluntary

- 2. IT
  - Resistance – Interoperability, EHRs, Prioritization, Broad change – 3rd party POC vendors are more receptive than large vendors
  - Variability – lots of differences in UDI system, no one off the shelf system available, siloed external & internal IT efforts
  - Lack of ownership
  - Outcome = IT infrastructure for the UDI system not easy to develop, not easy to generalize
  - COMMENTS & DISCUSSION

What do we need to address for the gaps/challenges in IT?

- JOE: Two important areas of focus – one external (relationships w/ vendors) and internal (IT priories). Need to start internally to get buy-in before engaging vendors and make it a priority. Be respectful of IT prioritization process too. Need buy-in at senior level to get this on IT priority list for it to be fully implemented.
- JIMMY: IT is 3 things – people, processes, and tech itself. Process stuff is what are you trying to accomplish and what processes will allow you to accomplish those things supported by tech. For this, need data interoperability to capture UDI once and use it for many different purposes. Take a step back, with people & the organization. What are IT solutions to reach goals? Compartmentalize into different pieces of IT. Most EHR's don't want to be in inventory management, and EHR has said this, but organization still need inventory management. Zero variability is what you're trying to accomplish. With that framework, you can plug into it components and integration. Components in system: Data, item master, health record, clinical documentation, order management, inventory management. Variability is how they're put together. **One project should be LAY OF THE LAND – ARCHITECTURE**.
  - What is the framework – if use this vendor to do X, will get this but not Y
  - Duke uses BD – integration function.
  - Can put components together differently
- Framework should address systems with lower maturity EHR levels

What are next steps, where should we go with this? How engage group of IT vendors?

- JOE: Recognize reality that vendors' business model recognizes data as an asset, a revenue opportunity. They're not interested in sharing that with anyone. Information blocking is a reality we have to deal with. Need to talk about what kind of leverage we have on vendors. Step up and become part of the system. Not sure how the roadmap really helps individual hospitals with this area?
  - Mercy had to pay a data extraction fee to one of its 3rd party vendors

- JIMMY: Vendors are happy to sell data to you. Nothing in public domain to accomplish this.
- JOE: Regulatory solution likely exists, although not sure what basis of regulation would be. Can see Congress requiring regulatory authority exerted over those in the business of collecting PHI

- 3. GUDID
  - Limitations – gaps, data inaccuracy
  - Process – optimal process not set
  - Outcome – GUDID one source but not only source
  - COMMENTS & DISCUSSION

Other areas/next steps for it to be the source of truth?

- JIMMY: Leverage Audi Workgroup into something sustainable so what needs to be done is a demo. No specific project from BUILD to come out of it since they're already working on it – planning to extend to other classes of devices
- JOE: In RAPID, working on quality of GUIDID data. Make data more accurate. GUIDID is a repository. Working on getting manufacturers involved. More to do with how they repot data than true accuracy. **A lot of leeway in how they report, so may need to tighten standards.** GUIDID needs to be improved so it becomes good source of data.

Next step - Why are we seeing this?

Survey/evaluation of GUDID data for practical use

- JOE: We need to understand the issues of this, specificity of this
- JIMMY: **Need to truly understand the problem, not just present a solution**
- GUDID data from manufacturer should match and be as accurate as other public data sources supported by the manufacturer. **Work with manufacturers regarding their concerns about using GUDID**

- 4. Manufacturers
  - Inconsistency – device labels, transitions
  - Collaboration – gap between manufacturers doing labeling & provider/end user perspective and needs
  - Lack of ownership
  - COMMENTS & DISCUSSION

Next step areas to really address?

- JOE: HTG Group rating top 20 vendors on compliance with GS1 standards
- TERRIE: **Quality measures with a national scorecard**
- Put in contracting
- **Ask HTG colleagues about work in this area**

- 5. Support
  - Time, HR, Resources
  - Implementation vs ongoing operational process/maintenance and required resources. New processes need to be embedded in workflow
  - COMMENTS & DISCUSSION

Thoughts on what would be helpful

- JOE: Create something self-sustaining with a broader approach for inventory management, training, and overall processes. Becomes part of culture. See one, do one, teach one so self-sustaining
- NATALIA: Could **barcode scanning be part of onboarding**?
  - JOE: Yes, it should be
- KIM: Not short-term initiative, change in how managing information, lifecycle is implementation but ongoing. Lack of understanding that ongoing, so take ownership of ongoing process
- JIMMY: Capital investment initially, then operational/ongoing. 1000 person hours for bringing UDI on, across # people
- NATALIA: Focused on implementation rather than ongoing piece to impact patient care, pop health, operations, cost
- JOE: Separate out costs – initial, then operational
- TERRIE: Tracking of implants project rather than UDI? SCAN Health is track & trace initiative. Met someone from USPS in charge of tracking packages. Hearing about UDI at FDA, he said he had 400 people to do the tracking project at USPS – investment in track & trace of letters; investment in benefit; postmaster general said would be done & it was; excellent support. UDI needs this top-level support at all levels – hospital, manufacturer
- NATALIA: **Develop something catchier, more understandable**, visibility into tracking

- 6. Overall UDI System
  - Policy drivers – slow & fragmented
  - Market – lack of incentive to do it
  - UDI as innovation – don't have robust data, metrics are underdeveloped
  - Supporting structures – who owns the UDI system as a whole?

Thinking about bigger drivers, providing incentives, moving forward, provide data

- JOE: who owns the international ATM system?
- JIMMY: Organization internationally that owns data standards/interoperability for ATM. UDI could have been viewed as a business and treated as such from the beginning with well-defined pieces that can be integrated. So now we're doing it backwards
- NATALIA: These are all ideas for the future that need funding support

SESSION 4: Wrap-Up/Creating the UDI Roadmap

- Draft outline of Roadmap
  - Basic areas plan to include: Exec Summary, Project History, Intro, Methodology, Results, Next Steps, Broader Picture of UDI Use & Health Care Outcomes, Conclusion
  - Results section may not be put out as results
  - Likely to be tweaked
- Plan for Roadmap
  - Today's meeting Presentation & Discussion important to inform
  - Post-Meeting
    - Writing and updating figure
    - Review

        - Finalization
- Figures for RM
    - Overall Figure needs to be updated
        - This is necessary before delving into details, needs to be simple enough
        - Joe: Need a central figure. Want RM with specificity but not too granular – balance; want simple enough
        - Define outcomes into Triple Aim components
    - Other potential figures:
        - Challenges
        - Basic IT flow map – "preferred method"
            - What happens with the data? What happens with the people?
            - Audiences – high level and IT system architects
            - Connects back to components Jimmy T mentioned earlier
                - **JIMMY: Need 2 flow maps – what happens to data and process map for what happens with people. Complexity is putting them together to see where they intersect. People needs to understand how this impacts them, what they need to do, so they get it**
                - **JOE: Process map needs to go to implementors (clinicians that will have to do). System map to orient IT people in terms of what needs to be integrated and done to lay out foundation of system**
                - **NW input later: I will need help with this; also get Mayo barcode project figure used for OR with nurses**
        - UDI value w/in components of Triple Aim
            - Previous Mercy presentation in which connection was represented well-resource
            - JIMMY: Good start but not going to accomplish visceral enough beyond cheerleading. How does it affect me? Only partially reflects value. How do you convince C-suite folks this is something they should do? **UDI value to health care itself & health care org**
        - Use of UDI
            - Previous graphics created by Natalia and Terrie
            - JOE: Good to develop the "why"
            - NATALIA: Beyond POC figure helps illustrate the WHY for implementation
- Next Steps
    - Many identified in Session 3
- Other Next Steps

Funding & Revenue Stream

- Investigate Funding Streams
    - Review broad grant opportunities (government, industry, foundations)
    - FDA, PCORI, PCOR trust fund
    - NESTcc

        - Feasibility projects first
        - Budget should support projects with demonstrable value, especially regulatory support mechanisms
        - Reviewing a business case for the creation of a distributed data network platform
    - Collaborate
        - Marry the work with other funded projects
        - Work with other successfully funded project leaders
        - Frame the work within translational research so create collaborative opportunity
    - Broaden areas: IT, supply chain, population health, nursing, medical device innovation, implementation & dissemination
    - Create something to share with potential funders (e.g. Amy Abernathy, FDA CIO)
    - Need sustainability model/revenue stream
        - JOE: test case w/ J&J looking at a specific device. Look at observational data on success to see if labeling application can be presented to FDA. This is typical of the types of studies being done where industry partner has a question they want answered and very focused and have regulatory impact. Not basic research in terms of UDI implementation. Focus on outcome, not the foundation.
        - CURTIS: Need to figure out business model with revenue stream to continue work

Education

- Create short videos that help to educate and spill over into the marketing side
- YouTubes, short, to point, supports how do this
- Generalizable slide decks
- Gamification of tedious information – create inanimate processes into characters, make a story, set up storyboard, fun & people remember

Broaden Engagement

- Frame work in terms of effectiveness & efficiency should increase interest & involvement
    - Right tools used with right patient population in a standardized, efficient manner

SUMMARY GAPS/CHALLENGES & NEXT STEPS (FROM FLIP CHARTS)

- Clinical
    - Awareness/Education
    - Public Access Materials – For physicians & nurses
    - Generate Knowledge about standard, automated capture of data on devices for patient care, Population Health. Not just UDI
    - Think beyond peer review journals for dissemination of information
        - Social media
        - Marketing
    - Best practice Approach to Labeling Project – End-users inform
- IT

    - Delineate functionality need for end-end UDI solution; who offers what IT solutions to meet; what IT solutions compensating for others
    - Project – IT architecture internal
    - IT vendor group
    - Policy solution?
- GUDID
    - AUDI (work in progress)
    - RAPID looking at this area
    - Evaluation of GUDID data through survey or other means
- Manufacturer
    - Quality Measures/Scorecards
- Support
    - UDI Initiative Leader with designated FTE
    - Teach barcode scanning as part of onboarding staff
    - 2 parts to delineate: Implementation + Maintenance
        - Value, use, bigger picture
- Overall UDI System
    - Better framing not focus on UDI alone
    - Opportunities with Joint Commission requirements
    - Need more Outcomes Data from use
    - Policy
    - Videos/gamification as an option
    - Funding – Rigorous review to delineate areas
        - Innovation
        - Implementation & Dissemination
        - Nursing
        - PCORI
        - Translational
        - Tap into Joel W, Jove G, Mitch
        - Combine w/ other work