IMPLEMENTATION ROADMAP for POINT OF CARE CAPTURE OF UDI FOR IMPLANTABLE DEVICES

Excerpt from Wilson NA. BUILD Point of Care Capture of UDI for Implantable Devices Final Summary Report & Roadmap. June 2019. http://mdepinet.org/wp-content/uploads/BUILD-Update.pdf

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.

I. 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

II. 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.[i] Join interdisciplinary workgroups through the Learning UDI Community (LUC).[ii] Follow ongoing research projects on UDI, such as *BUILD*[iii] and *UDI2Claims,* a PCORI-funded initiative focused on UDI-DI in claims.[iv,v] Access websites, such as the FDA UDI website[vi] and the BUILD website[iii], 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

III. 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**

IV. 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.

---

[i] Healthcare Transformation Group. https://www.healthcaretransformationgroup.com/ Accessed June 18, 2019

[ii] AHRMM. Learning UDI Community. http://www.ahrmm.org/resources/learning-udi-community/index.shtml Accessed June 18, 2019

[iii] Medical Device Epidemiology Network. BUILD. http://mdepinet.org/build/. Accessed June 18, 2019

[iv] Brigham Health. Brigham and Women's Center for Surgery and Public Health. Improving Patient Safety with Medical Device Identifiers. http://csph.brighamandwomens.org/udi2claims/ Accessed June 18, 2019

[v] Zerhouni YA, Krupka DC, Graham J, et al. UDI2Claims: Planning a Pilot Project to Transmit Identifiers for Implanted Devices to the Insurance Claim. *J Patient Saf. 2018* Nov 21. doi: 10.1097/PTS.0000000000000543. [Epub ahead of print]

[vi] U.S. Food and Drug Administration. Unique Device Identification (UDI) System. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system. Updated June 5, 2019. Accessed June 18, 2019