GAPS, CHALLENGES AND STRATEGIES in POINT OF CARE CAPTURE OF UDI FOR IMPLANTABLE DEVICES

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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.[i,ii,iii] 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[iv] and its public facing portal AccessGUDID[v] 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

[i] Drozda Jr J, Helmering P, Moore V, Smith T. Advancement of Innovative Methodologies and Medical Device Specific Infrastructure for Evidence-Based Regulatory Science and Public Health Surveillance. Implementation of Unique Device Identification Demonstration Projects. Final report. Contract DHHS/FDA-22320172C from the Center for Devices and Radiological Health, US Food and Drug Administration. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/BenefitsofaUDIsystem/UCM416128.pdf. Accessed June 18, 2019

[ii] Drozda JP Jr, Dudley C, Helmering P, Roach J, Hutchison L. The Mercy unique device identifier demonstration project: Implementing point of use product identification in the cardiac

catheterization laboratories of a regional health system. *Healthc (Amst)* 2016;4:116-119. doi:10.1016/j.hjdsi.2015.07.002

[iii] Drozda Jr JP, Roach J, Forsyth T, Helmering P, Dummitt B, Tcheng JE. Constructing the informatics and information technology foundations of a medical device evaluation system: a report from the FDA unique device identifier demonstration. *J Am Med Inform Assoc.* 2018;*25*(2):111-120. doi: 10.1093/jamia/ocx041

[iv] U.S. Food and Drug Administration. Global Unique Device Identification Database (GUDID). https://www.fda.gov/medical-devices/unique-device-identification-system-udi-system/global-unique-device-identification-database-gudid. Updated May 14, 2019. Accessed June 18, 2019

[v] U.S. National Library of Medicine. ACCESS GUDID Identify Your Medical Device. https://accessgudid.nlm.nih.gov/. Accessed June 18, 2019