

# Advancing Patient Safety Surrounding Medical Devices: Barriers, Strategies, and Next Steps in Health System Implementation of Unique Device Identifiers

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**Background:** The requirement for medical device manufacturers to label their devices with a unique device identifier (UDI) was formalized by the 2013 US Food and Drug Administration Unique Device Identification System Rule. However, parallel regulatory requirement for US health systems to use UDIs, particularly the electronic documentation of UDIs during patient care is lacking. Despite the lack of regulation, some health systems have implemented and are using UDIs. To assess the current state, we studied representative health system UDI implementation experiences, including barriers and the strategies to overcome them, and identified next steps to advance UDI adoption.

**Methods:** Semi-structured interviews were performed with health system personnel involved in UDI implementation in their cardiac catheterization labs or operating rooms. Interviews were transcribed and analyzed using the framework methodology of Ritchie and Spencer. An expert panel evaluated findings and informed barriers, strategies, and next steps.

**Results:** Twenty-four interviews at ten health systems were performed. Identified barriers were internal (lack of organizational support, information technology gaps, clinical resistance) and external (information technology vendor resistance, limitations in manufacturer support, gaps in reference data, lack of an overall UDI system). Identified strategies included relationship building, education, engagement, and communication. Next steps to advance UDI adoption focus on education, research, support, and policy.

**Conclusions and Implications:** Delineation of UDI implementation barriers and strategies provides guidance and support for health systems to adopt the UDI standard and electronically document UDIs during clinical care. Next steps illuminate critical areas for attention to advance UDI adoption and achieve a comprehensive UDI system in health care to strengthen patient care and safety.

**Keywords:** unique device identifier, FDA, implementation barriers, implementation strategies, information technology systems, device manufacturer responsibilities

## Introduction

There is currently no requirement for US health systems to use the medical device unique device identifier (UDI) in the processes of patient care. In 2013, the US Food and Drug Administration's (FDA) Unique Device Identification System Rule regulated the critical first step towards UDI adoption, specifying requirements for manufacturer labeling of medical devices with a UDI.<sup>1</sup> A UDI includes a device identifier (DI) that identifies manufacturer and model of the device and a production identifier (PI) that identifies lot number, serial number, expiration data, and/or date of manufacture, as available for a device. UDIs must be on the label and packaging of a medical device in a format that can be electronically captured, such as a barcode, as well as human readable.<sup>1,2</sup> As a result of this rule, the vast majority of moderate- and high-risk devices and implantable devices are now labelled with a UDI. Lower risk devices increasingly are being labeled with UDIs.<sup>3</sup>

The FDA's UDI Rule delineated multiple public health objectives that a UDI system could serve: reduction of medical error, simplification of the integration of device information into health information technology (IT) systems, more rapid identification of devices with adverse events and development of solutions, more efficient recalls, better safety communication, strengthening of patient and provider information on devices implanted in patients, and support of more effective safety surveillance and postmarket studies.<sup>1</sup> However, the FDA does not have the authority to require health systems to electronically document UDIs in the patient care setting. Without this requirement UDIs are not available for broad use to identify, track, report on, study and comparatively evaluate medical devices, and fulfill these important public health objectives.

Despite the lack of requirement, some health systems have moved forward on their own to implement UDIs based on their internal projections of return on investment, clinical value, and safety benefits for their patients and health systems. Through internal UDI initiatives they have developed the necessary IT infrastructure and requisite dataflow and workflow processes.<sup>4-7</sup> These health systems have particularly discerned the value of having standardized medical device information in their IT systems to support safety and quality surrounding medical device use in patients, to accurately and efficiently manage recalls and device inventory, to augment data availability for device evaluations, and to prepare for future requirements to electronically transmit UDIs.<sup>4-8</sup>

The aim of this study was to understand the experiences of health systems that had implemented UDIs at the point of care (POC) in order to provide practical information and recommendations for other health systems, build on prior work,<sup>5,6,9-11</sup> and advance the field. This report adds to the literature the first collation of experiences across health systems regarding barriers to UDI implementation and use and strategies utilized to address these barriers. The intent of this innovation was to assess and report on commonalities across health system sites, rather than solely on a single health system experience, in order to inform UDI implementation and use. In a prior report, a roadmap for UDI implementation based on these health systems' leading practices was presented.<sup>4</sup> In support of further advancement, this report focuses on barriers, the strategies to overcome them, and next steps to advance UDI adoption in health systems.

## Methods

### Setting and Study Oversight

This project was overseen at Arizona State University and was part of a larger initiative, Building UDI into Longitudinal Data for Medical Device Evaluation (BUILD).<sup>12</sup> BUILD was overseen by Mercy and involved investigators from Mercy, Geisinger, Intermountain Healthcare, Duke University Health System, and Arizona State University.

### Data Collection

The methodology for data collection has been previously reported.<sup>4</sup> Briefly, semi-structured interviews of personnel in health systems that had implemented UDI for implantable devices in cardiac catheterization labs or operating rooms were conducted between June and November of 2018. Qualitative methodology was utilized in order to delve more deeply with interview participants into their experiences. Selection of the health systems was guided by the advisory group for the project, the BUILD Consortium.<sup>13</sup> A purposeful sampling approach was utilized so that participants were able to inform the research aim. A contact at each health system identified potential interviewees well-versed in UDI implementation from supply chain management, IT, and the POC. Prior to interviews each health system completed a pre-interview survey (Qualtrics, Provo, UT) to ascertain health system demographics and basic UDI information. Interviewees were orally consented prior to interviews conducted by telephone. Interview topics included reasons for UDI implementation, necessary support and infrastructure, barriers, uses of UDI, and current state in the health system. Interviews were recorded and transcribed. Data were stored on a secure server.

### Data Analysis

The methodology for data analysis has been previously reported.<sup>4</sup> Briefly, survey responses were aggregated using Microsoft Excel. Transcript analysis was guided by the framework methodology of Ritchie and Spencer: familiarization, identifying a thematic framework, indexing, charting, and mapping and interpretations.<sup>14-16</sup> Transcripts were reviewed, coded, and an analytic framework was applied to the transcripts. Ten percent of the transcripts were coded by two

members of the team and coding was compared to verify agreement. Coded data were reduced by charting into an Excel spreadsheet. Interpretation involved review of charted data to ascertain themes across health systems.

## Expert Panel

Project results, including barriers, were presented and discussed in detail at an expert panel meeting in April 2019, attended by BUILD Consortium<sup>13</sup> and research team members. The iterative work of the expert panel informed the previously published implementation roadmap<sup>4</sup> as well as the barriers and the strategies to overcome them. Next steps to advance UDI adoption in health systems were formulated. Further detail has been previously reported.<sup>4</sup>

The study protocol was approved by the Office of Research Integrity and Assurance at Arizona State University.

## Results

Twenty-four semi-structured interviews were conducted in ten health systems. Most participating health systems were non-governmental, not-for-profit, included an academic medical center, and incorporated a health care plan. Diversity of geographic location, health system size, and revenue was captured. All health systems were documenting UDIs in health IT systems, the majority by barcode scanning. Interviewees held executive level, director, manager, and clinical positions. Most had more than one focus area (clinical, supply chain management, IT, operational) along with UDI involvement. More extensive demographics of participating health systems have been previously reported.<sup>4</sup>

## Barriers

Barriers in UDI implementation are represented in Table 1.

Internal barriers refer to those within the health systems.

**Lack of Organizational Support:** Health system personnel engaged in UDI implementation work often felt a lack of organizational support. They discussed a lack of acknowledgement by supervisors and leadership of the time needed to do the necessary work and to address setbacks and make readjustments. As many interviewees stated, UDI work was generally being done in addition to one's "day job," as opposed to a carve out of designated time. In addition, they perceived a lack of prioritization for the necessary resources. An interviewee shared the "struggle of keeping the story alive."

**Information Technology Gaps:** Internal IT gaps fell into two main areas: interoperability and variability in IT systems. Health systems faced challenges with closed loop IT systems that were designed to accept but not transfer data. IT systems within health systems and within individual hospitals also had significant variability. Structures and formats of IT systems at the POC could be difficult for clinical staff to efficiently utilize within workflows. An interviewee shared, "No one really has an out-of-the-box [IT] solution ...".

**Clinical Resistance:** Clinical challenges were quite common. Staff resisted change and questioned the purpose of introducing a new process into their workflow. They also experienced confusion and frustration with barcode scanning which added to their resistance. Some medical device labels contained multiple barcodes making it unclear what to scan. Some barcode scans were unsuccessful. Some devices, such as sterilized implants (eg, orthopedic screws) could not be scanned. An interviewee shared that staff are facing "scan fatigue." UDI implementation tended to roll out in increments

**Table 1** Barriers in Implementation of Unique Device Identifiers

| Internal Barriers              | External Barriers                        |
|--------------------------------|--|
| Lack of organizational support | Information technology vendor resistance |
| Information technology gaps    | Limitations in manufacturer support      |
| Clinical resistance            | FDA GUDID gaps                           |
|                                | Lack of an overall UDI system            |

**Abbreviations:** FDA, US Food and Drug Administration; GUDID, Global Unique Device Identification Database; UDI, unique device identifier.

so barcode scanning of UDIs may only be in certain POC sites or for certain devices. The latter became a problem for staff that rotated between clinical sites and faced inconsistency in the need to scan. An interviewee shared, “When nurses were told [they] could not scan everything ..., [their response was], What good is this to me? and they just walked out of the room.”

External barriers refer to those generated by stakeholders outside of the health system.

**Information Technology Vendor Resistance:** This resistance fell into two main areas: resistance to providing needed IT changes to support UDI implementation and lack of ownership of the IT vendor role and responsibility to advance an overall UDI system. Significant time was required by health system personnel to discuss needed changes with their IT vendors, solutions were slow and often costly, and when solutions were made available, they focused on one health system’s individual needs rather than broad solutions that would benefit many health systems facing the same issues. An interviewee shared,

... we are working with three different [IT] systems ... they [vendors] should be doing changes ... because everyone in the marketplace needs it ... Whoever uses their system needs this.

**Limitations in Manufacturer Support:** These limitations fell into three main areas: labelling, collaboration, and lack of ownership of the manufacturer role and responsibility to advance an overall UDI system. A gap existed between the labelling by manufacturers and ease of UDI capture at the POC. Labels often contained multiple barcodes, in different formats, and in different locations. Multiple interviewees shared the problem of multiple barcodes. The perception of many interviewees was that manufacturers were “checking the box” to comply with regulation rather than considering the actual scanning done by staff and use of UDIs in health systems. Ascertaining who to talk to about these concerns was difficult and even when a health system was able to work with a manufacturer, approaches and solutions to problems were often individual rather than broad to benefit many health systems facing the same issues. An interviewee shared, “I don’t know that the suppliers understand or appreciate necessarily how the provider side is going to use this data going forward.”

**Gaps in the FDA Global Unique Device Identification Database (GUDID):** GUDID data were found to have errors and inconsistencies, limitations in depth/breadth of discrete data, and to lack full validation. An interviewee shared, “The GUDID database is not ... a good, effective working system ... for hospitals.” Another shared, “Do we see some limitations? Yes we do. I don’t think there is always a 100% clear match in the information, but we do find it useful.”

**Lack of an Overall UDI System:** Policy to drive a comprehensive UDI system was felt to be slow and fragmented. UDI implementation in health systems is not a requirement which impacted priority of UDI initiatives. Robust data to support return on investment for health systems, operationally and clinically, was felt to be lacking. Who is “in charge” of the broader UDI system across health care was perceived as unclear. An interviewee shared,

[The supply chain director] said there were going to be some policy drivers that were going to be placed on device manufacturing companies to standardize the barcodes ... but she didn’t say that there would be any implications or any sort of fine or penalty to a hospital who chose not to adopt barcode scanning for the UDI items.

## Strategies

Strategies utilized by health systems to address barriers in UDI implementation are presented in [Table 2](#).

**Lack of Organizational Support:** Strategies shared were developing relationships and providing information on UDI to build awareness, particularly with leadership and clinicians. Additional strategies included communication of the purposes underlying UDI implementation and of the needed resources. An interviewee shared the importance of “selling small wins to build bigger successes.”

**Information Technology Gaps:** Early engagement of IT vendors was shared as a needed strategy. Leader–leader relationships were touted as important as well as evaluation of third-party vendors who were generally felt to be more responsive, willing to be innovative, and work towards solutions. As an interviewee shared,

**Table 2** Strategies to Address Barriers in Implementation of Unique Device Identifiers

| Barrier                                  | Strategy  |
|--|---|
| <i>Internal Barrier</i>                  |   |
| Lack of organizational support           | <ul style="list-style-type: none"> <li>• Relationship building</li> <li>• Education</li> <li>• Communication</li> </ul>                                 |
| Information technology gaps              | <ul style="list-style-type: none"> <li>• Relationship building</li> <li>• Engagement</li> </ul>   |
| Clinical resistance                      | <ul style="list-style-type: none"> <li>• Relationship building</li> <li>• Engagement</li> <li>• Education</li> <li>• Communication</li> </ul>           |
| <i>External Barrier</i>                  |   |
| Information technology vendor resistance | <ul style="list-style-type: none"> <li>• Relationship building</li> <li>• Engagement</li> <li>• Contract provisions</li> </ul>                          |
| FDA GUDID gaps                           | <ul style="list-style-type: none"> <li>• Relationship building</li> <li>• Communication</li> <li>• Engagement</li> </ul>                                |
| Manufacturer support                     | <ul style="list-style-type: none"> <li>• Relationship building</li> <li>• Communication</li> <li>• Contract provisions</li> <li>• Engagement</li> </ul> |
| Lack of an overall UDI system            | <ul style="list-style-type: none"> <li>• Relationship building</li> <li>• Education</li> <li>• Policy advocacy</li> <li>• Engagement</li> </ul>         |

**Abbreviations:** FDA, US Food & Drug Administration; GUDID, Global Unique Device Identification Database; UDI, unique device identifier.

[We have] done a really good job at establishing leadership connections with the software vendors, and [this] has given us the ability to influence their development, future development ...

**Clinical Resistance:** Relationship building, engagement of clinicians in work teams, education, and communication were shared strategies. Clinical staff needed to know why UDI scanning was being done, what to scan so they needed training on barcodes, and who to contact for problems. The latter team members needed to be easily accessible and quickly responsive. A take-home message was that the process needed to work well with quick support. Without those elements, clinical staff members were reticent to change to a UDI-based workflow and may not do it. An interviewee shared, “We developed for ourselves a mobile app ... that allows them [clinical staff] to self-report a scanning issue.”

**Information Technology Vendor Resistance:** Early engagement and leader–leader relationships were shared strategies. Health systems evaluated third-party vendors who were felt to be more responsive and willing to innovate as well as creating or engaging an established internal IT team. In some cases, provisions were made that IT vendors would only receive data in their systems if they also transferred data. An interviewee shared, “We had to go into development with an [IT] company to deal with and deliver on our vision. There was not a company out there. I had to go on 20 site visits.”

GUDID Gaps: Strategies to address this issue were documentation of problems, good communication with the FDA on issues, and engagement internally and externally including in multi-stakeholder workgroups (eg, AHRMM Learning UDI Community) to work towards solutions. An interviewee shared,

... we're just trying to validate the information that's in the GUDID database. We've asked several of our different manufacturers and vendors that we deal with to get us the information for all the products that we purchase from them and – understand does the GUDID database have everything we're looking for ...

If it doesn't, where do we go? ... we reach back out to FDA and say, hey, this information is not what we're looking for. It doesn't have everything we need ...

Manufacturer Support: Relationship building, communication, and engagement in multi-stakeholder workgroups (eg, AHRMM Learning UDI Community) were shared as strategies to work towards solutions. In addition, some health systems included contract provisions requiring complete UDIs on purchased devices that could successfully be scanned at the POC and updates on any UDI transitions or changes. An interviewee shared,

There's nothing in the [UDI] regulation that says, gosh, you gotta implement this efficiently or effectively ... We've really tried to have a focused effort. Look, you [manufacturers] need to care about this. Your end user, the ones that you're representing, the clinicians care about this ... We've really tried to develop it as a partnership.

Another shared: “We now require [that] when the contracts are signed, the suppliers supply us with the barcodes.”

Lack of an Overall UDI System: Health system personnel developed cross-disciplinary relationships, educated themselves about UDI through conferences and articles, and engaged in multi-stakeholder workgroups. They became involved in policy efforts and in some cases in research projects focused on health system UDI implementation and use. An interviewee shared, “We've advocated for the DI on the claim.” Another shared, “When the [research] project came along, my team was involved in installing the barcode scanners in ... the ORs.”

## Next Steps

Needed next steps to address barriers to UDI implementation are represented in [Table 3](#).

Interviewees shared some important overriding insights:

When you think of retail ... they've redesigned an entire industry based on using data standards.

[UDI] is an enabler ... most people think of it more like a utility. It's electricity or it's water. It's the heating and air conditioning. It's something that should be there that enables everything else.

The goal was not UDI in isolation, but it was incorporating UDI into a bigger picture of something that was trying to make the care, in an innovative way, more efficient, safer, cost-saving.

By creating this national database with all of these items that are being used, we're creating and enhancing our existing relationships with FDA for post-market surveillance and patient safety and better recall management. The ROI seems obvious to me.

“Other institutions ... become leaders and champions for each other.”

## Discussion

A foundation of evidence and tools for UDI implementation in health systems is being built,<sup>4-9,17</sup> despite the gap in current policy requiring health systems to incorporate UDIs in processes of care. UDI implementation in health systems, similar to health IT implementations in general, can be complex due to the significant work required to build the IT infrastructure, the need for interoperability across multiple systems, clinical and administrative resistance to change, and the requisite resources including operational support and funding.<sup>4-7,10,18-20</sup> However, health systems that are “early adopters” of UDI implementation have paved the path with tools and information for others, including an implementation roadmap and individual health system cases studies.<sup>4-9,17</sup> By tapping into “early adopter” health systems and UDI



**Table 3** Needed Next Steps to Address Barriers in Implementation of Unique Device Identifiers

| Barrier                                  | Next Steps  |
|--|---|
| <i>Internal Barrier</i>                  |   |
| Lack of organizational support           | <ul style="list-style-type: none"> <li>• Create durable easily accessible UDI adoption presentation and education materials for organizational leaders, staff and clinicians.</li> <li>• Perform comprehensive workflow analysis of UDI implementation.</li> <li>• Create a job description for the UDI initiative leader.</li> <li>• Include barcode training as a requirement for new staff on-boarding.</li> </ul> |
| Information technology gaps              | <ul style="list-style-type: none"> <li>• Assess &amp; map the optimal IT infrastructure for UDI implementation.</li> <li>• Create a catalog of IT systems by vendor indicating functionality for UDI implementation including gaps.</li> </ul>  |
| Clinical resistance                      | <ul style="list-style-type: none"> <li>• Create standard education materials on UDI adoption for clinicians and clinical staff.</li> <li>• Map best practices for UDI integration into clinical workflows.</li> <li>• Include barcode training as a requirement for new staff on-boarding.</li> </ul>   |
| <i>External Barrier</i>                  |   |
| Information technology vendor resistance | <ul style="list-style-type: none"> <li>• Study health system-IT vendor relationships.</li> <li>• Engage IT vendors in multi-stakeholder workgroups.</li> </ul>  |
| FDA GUDID gaps                           | <ul style="list-style-type: none"> <li>• Study health system use, barriers, limitations</li> <li>• Collaboratively work with manufacturers.</li> </ul>  |
| Manufacturer support                     | <ul style="list-style-type: none"> <li>• Include UDI-focused requirements in contracting.</li> <li>• Collaboratively work on requirement of "UDI" on the device label next to the barcode.</li> </ul>   |
| Lack of an overall UDI system            | <ul style="list-style-type: none"> <li>• Collaboratively work on policy drivers.</li> <li>• Create durable easily accessible education materials for stakeholders.</li> <li>• Broaden dissemination avenues.</li> <li>• Study impact of UDI use on outcomes.</li> <li>• Develop metrics.</li> <li>• Delineate funding sources for UDI research and advancement.</li> </ul>  |

**Abbreviations:** UDI, unique device identifier; IT, information technology; FDA, US Food and Drug Administration; GUDID, Global Unique Device Identification Database.

leaders, this project was able to illuminate common barriers, strategies to overcome them, and needed next steps for advancement of UDI adoption in health systems.

The UDI has a critical role supporting patient safety and quality of care. A documented UDI supports clinician ability to identify a failed device prior to a revision procedure, thus supporting clinical decision-making and preparedness.<sup>21,22</sup> Patients' access to the UDIs of their implanted devices supports patient engagement in their care and safety, particularly in the case of devices that fail or are recalled.<sup>23</sup> UDI use by health systems in management of recalled devices supports accuracy and efficiency to remove these devices and find patients that are affected.<sup>5,24,25</sup> As a result of the COVID-19 pandemic and supply disruptions impacting patient care, UDI adoption has been recommended to strengthen the health care supply chain.<sup>26</sup>

The public health objectives of the FDA UDI Rule highlight the role of UDIs in improved adverse event reporting, recall management, safety communication, and more effective postmarket safety surveillance and evaluations.<sup>1</sup> The focus on generation of real-world evidence (RWE) for medical devices<sup>27–30</sup> and work utilizing UDIs in RWE studies highlights the centrality of UDI for device identification and linkage of real-world data.<sup>31–35</sup> The critical step to achieve these goals is UDI adoption in the processes of patient care.

Health systems in the project faced both internal and external barriers, yet commonalities existed in addressing them. Relationship building, relationships between the right level of leadership, and overall engagement of involved people,

internal or external, were critical in addressing challenges. Education to advance awareness of what UDI is, why it matters, and how it can be used enhanced responsiveness, support, and involvement. Engagement in multi-stakeholder workgroups<sup>17</sup> helped delineate the impact of challenges on different stakeholders and fostered collaboration to address problems. In addition, engagement in multi-stakeholder workgroups, research and/or policy advocacy helped deepen involvement in collective work for change and movement forward.

Building the IT infrastructure was an area that particularly faced challenges, with both internal and external barriers. As a starting point, the concept of using the UDI as the “single source of truth” across all IT systems and processes remains a difficult goal to coordinate and accomplish.<sup>7</sup> Issues of interoperability, diverse IT systems within and between health systems, and vendor resistance complicated work. The result was that in different health systems, different IT systems were interfaced, and different IT systems were accepting UDIs at the POC and transmitting them;<sup>4</sup> there was complexity in developing the necessary IT infrastructure; and there was a lack of generalizability from one health system to another. In some cases, to address challenges with IT vendors health systems defaulted to contract provisions or transitioned to third-party vendors to get what they needed to advance UDI implementation. Despite the challenges and differences in IT systems, the ultimate goal for health systems were interfaced IT systems that could store and transmit UDIs.<sup>4</sup> Dedicated effort to set interoperability and data standards for UDI-related data would likely help accelerate adoption at the individual health system level, so the mix and match of IT systems would become less problematic.

Salient next step recommendations were made for advancement of UDI adoption:

1. Education: Advance education through development of durable materials that can be easily accessed and utilized broadly in presentation to health system leaders, clinicians, clinical staff, and other stakeholders.
2. Research: Conduct further research including workflow analysis, assessment of IT infrastructure, health system use of the FDA GUDID, vendor relationships, and outcomes.
3. Support: Develop supporting measures for UDI implementation including staff barcode training, an IT system functionality catalog, standard contract provisions for external vendors, job description for a UDI initiative leader, and metrics.
4. Policy: Collaboratively work to address policy needs and drivers.

Study Limitations have been previously reported.<sup>4</sup> Our sample size was small which may limit generalizability. Not all recommended health systems participated in the project; however, a high percentage of those advanced enough in UDI implementation to study did participate. Some potential interviewees that met the desired criteria may not have been recommended, but 24 interviews in 10 health systems were conducted. UDI implementation in the inpatient arena and for cardiovascular procedures had greater representation although other areas and procedures were represented.

## Conclusion

Evidence generation has been advancing and contributing to the foundation for UDI adoption in health systems. The delineation of barriers and strategies to overcome them, along with the UDI implementation roadmap,<sup>4</sup> support health systems’ ability to develop and operationalize a UDI system to support patient safety and quality of care surrounding medical devices. Next steps lay out four critical areas for attention: education, further research, development of supporting measures, and policy. Effort in these critical arenas should pay high dividends in advancing UDI at scale to realize the public health objectives of the FDA UDI Rule of 2013 and goals for RWE generation for medical devices. Improved device safety and effectiveness for patients depend on it.

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