ENGELBERG CENTER for Health Care Reform at BROOKINGS

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Meeting Summary

Unique Device Identification (UDI) Implementation Expert Workshop: Identifying Steps for Implementation and Integration of UDI within Electronic Data Infrastructure of Care Delivery Sites

Introduction

Medical devices have played a critical role in revolutionizing the ability to provide care in hospitals, patients' homes, and other settings. As medical device use continues to expand and care delivery becomes less centralized, the need to conduct longitudinal tracking of specific device use and associated patient outcomes becomes even more imperative. However, without a standardized medical device identification system, it remains challenging, if not impossible, to conduct a range of important tracking activities that rely on specific device information, including quickly identifying potential safety concerns associated with a particular medical device, efficiently notifying providers and patients who may be affected by a device recall, and establishing the value of specific medical devices for patients. In contrast, these capabilities are much more readily conducted for drugs due in large part to the availability and widespread use of the National Drug Code (NDC), which acts as a common language for the identification of specific drugs. Recognizing the need for an analogous identification system for medical devices, Congress included provisions in the Food and Drug Administration Amendments Act of 2007 (FDAAA) directing the U.S. Food and Drug Administration (FDA) to create a unique device identification (UDI) system that would enable tracking and identification of medical devices. FDA, in developing a plan for an effective system, actively worked to gather and incorporate stakeholder input through public meetings, pilots, and other efforts. These efforts culminated on July 10, 2012, in the release of the Proposed Rule for a Unique Device Identification System in the *Federal Register*.[1]

The Proposed Rule, which was available for public comment through November 7, 2012, includes in its provisions that UDIs will be developed and included by manufacturers on labels for relevant medical devices and that accompanying device information will be made available to the public through the Global UDI Database (GUDID).[2] With certain exceptions, roll-out of these requirements will occur based on device class over a period of five years from the release of the Final Rule. For devices affected by the Final Rule, the GUDID, which is currently under development by FDA, will contain a set of standardized attributes submitted by manufacturers, such as brand, model, and clinically relevant size. Once the GUDID is operational, any interested party will be able to use the UDI to look up or download important information about a medical device. In addition to significantly enhancing the detail and quality of device information available to the public, the GUDID is intended to serve as an important data source to health systems, researchers and other stakeholders invested in using UDI to improve the supply chain, better understand device effectiveness, and conduct a range of other activities.

Currently, manufacturers are at various stages in their readiness for the upcoming UDI labeling and device information submission requirements, with only some manufacturers fully incorporating UDIs

[1] U.S. Food and Drug Administration, Unique Device Identification; Proposed Rule. *Federal Register.* Retrieved August 22, 2012, from http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0090-0001.

[2] An amendment to the Proposed Rule was issued on November 19, 2012, as a result of amendments made by the Food and Drug Administration Safety and Innovation Act (FDASIA) to the Federal Food, Drug, and Cosmetic Act. More information can be found here: https://www.federalregister.gov/articles/2012/11/19/2012-28015/unique-device-identification-system.

into their labeling and tracking mechanisms. This current lack of uniformity in device labeling has made it challenging, if not impossible, for other stakeholders to derive significant value from available UDIs. The Proposed Rule provides an important step toward ensuring that medical devices are consistently labeled. With this foundation, the true value of a UDI system clearly lies in its broad adoption and use by manufacturers, distributors, payers, providers, patients, and other stakeholders with important roles throughout the medical device lifecycle.

To this end, the Engelberg Center for Health Care Reform at Brookings is collaborating with FDA and Chickasaw Nation Industries, Inc., to explore the potential promise of broad, stakeholder-driven UDI implementation and the challenges it may face. To accomplish this, Brookings assembled a work group of expert stakeholders with interests that span the medical device lifecycle to advise on issues related to the implementation of UDI, explore potential strategies for resolving them, and identify topics in need of further exploration. On July 16, 2012, the UDI Implementation Work Group met for an initial, in-person kick-off meeting to outline major priorities for successful UDI implementation; materials and a summary can be accessed on the Brookings website.

To unlock the full potential of successful UDI implementation, stakeholders at this initial meeting emphasized the importance of incorporating UDI into electronic data sources. To begin exploring this issue, Brookings held an expert workshop on October 15, 2012, which focused on the opportunities and challenges associated with incorporating UDI into claims; materials from this meeting can be accessed on the Brookings website. Work Group members also emphasized the value of enriching the electronic data infrastructure of care delivery sites, specifically administrative and clinical data systems, with device-specific information captured as part of the routine delivery of care. Incorporating UDI into these data systems could enable an array of enhanced capabilities such as ensuring recalled and expired products are removed from the inventory and providing access to device information to inform patient and provider point of care decisions. Moreover, Work Group members emphasized that by including UDI in these data sources, the resulting data could be leveraged by researchers for a number of activities, including active safety surveillance, effectiveness research, and evaluation of patterns of care. However, Work Group members also recognized that the task of achieving this goal is not trivial and will require broad stakeholder input.

To further explore these issues, on December 13, 2012, Brookings convened an expert workshop on the topic of "Identifying Steps for Implementation and Integration of UDI within Electronic Data Infrastructure of Care Delivery Sites." This workshop brought together a diverse set of stakeholders to discuss the potential barriers and paths forward for capturing UDIs in the electronic data infrastructure of health care delivery sites. Over the course of the day, participants discussed potential challenges and strategies associated with capturing and integrating UDI into and across administrative and clinical data systems. Key themes from the discussion are summarized below.

Incorporating UDIs into Administrative Systems

Health care delivery sites employ administrative systems to help facilitate internal supply chain management, appropriate and accurate billing, and a host of other functions. Efficient communication across the internal supply chain is crucial to enable health care systems and providers to understand their inventory, ensure the quality of their stock (e.g., so that expired products are not dispensed to patients), and effectively manage recalls. However, current medical device inventory and recall management can be challenging due to the lack of specific identifiers or use of non-unique device identifiers that may simultaneously identify two or more disparate devices used by a particular health system. This, coupled with error-prone manual processes for entering device identifiers, can make it

very challenging to specifically and accurately identify medical devices. Participants indicated that with greater access to more specific device information through the use of UDI, health care delivery sites can augment their ability to track medical devices and efficiently deliver care to patients. However, participants also emphasized that incorporating UDI into administrative systems will be associated with a host of challenges, which will necessitate the development of workable solutions and appropriate incentives for UDI adoption. Prominent themes from the discussion are summarized below.

Challenges

Participants put forth a series of technical and motivational challenges that are likely to be encountered as part of integrating UDI into administrative systems of care delivery sites. One challenge that participants noted was the disparity in information technology capabilities across care delivery sites, with some sites having extremely sophisticated capabilities and others still using manual processes to keep track of their internal supply chain. Participants pointed out that even among care delivery sites that have adopted electronic administrative systems, which are generally dominated by a few leading enterprise resource planning (ERP) system vendors, care delivery sites still operate a variety of software versions and there is uncertainty surrounding the timing of future updates. Participants added that there are significant hurdles with regard to inconsistent and/or incomplete data in these systems. Without a single, universal source of truth with regards to device information, each care delivery site may populate a local item master (a comprehensive list of items used throughout the supply chain) without reference to a globally unique set of device identifiers and associated standard meta-data. Without globally unique identifiers, participants noted that one identification code may be linked to more than one device. This may complicate essential supply chain processes as well as other health system processes that rely on data automatically being populated from the supply chain systems.

In addition to issues regarding ERP systems and their data, participants highlighted some challenges that could raise the cost of UDI adoption for care delivery sites. Specifically, participants underscored that the incremental, class-based roll-out of UDI outlined in the Proposed Rule could cause certain problems with regard to supply chain management. Specifically, participants indicated that early adopters of UDI would potentially have to build redundant systems to accommodate both UDI and non-UDI labeled devices. Alternatively, care delivery sites could choose to wait to adapt systems to accept UDI until the end of the phased-in roll-out period. Additionally, participants raised the issue of the Proposed Rule's neutrality regarding manufacturer selection of automatic identification and data capture (AIDC) technology (e.g., barcodes, RFID). In particular, participants observed that this neutrality could increase the burden on care delivery sites as multiple AIDC readers may be needed to enable consistent recording of UDIs. Another barrier discussed was that the current provisions of the Proposed Rule allow for the potential use of more than one standard for UDI (e.g., GS1, HIBCC). Under the Proposed Rule, manufacturers would be able to obtain UDIs for their devices by engaging with one or more accrediting bodies, which may use slightly different formatting of the UDIs. Participants expressed concern that this could cause difficulties when providers capture UDI at the point of care if UDIs are not labeled consistently from one device to another.

Participants also discussed a series of motivational hurdles for supply chain adoption of UDI within a care delivery site, including the variety of stakeholders with different needs within and across care delivery sites, an already challenging fiscal environment, and attention being diverted to other requirements and implementation efforts.

Strategies

With these challenges in mind, participants suggested potential strategies that transcend health information technology vendors to facilitate successful UDI integration into administrative systems. Participants noted that a short-term strategy for ensuring that existing item master data is useful could be for care delivery sites to establish rules for initial and ongoing detection and correction of inaccurate records as part of a process known as data cleansing. In the long-term, participants supported the notion of a cloud-based, universal item master populated by key device information, which would enable administrative systems to download standardized data on medical devices. Having a single source of truth for populating this device information would help to avoid inaccuracies or redundancies in supply chain systems and other systems that are populated using data in supply chain systems. This could also help to ensure that devices scanned at the point of care are recognized and accurately logged in the care delivery site's electronic data systems.

Participants also presented a number of strategies that FDA and manufacturers could consider to help support and reduce the cost of adopting UDI within administrative systems. For example, participants discussed that the strongest incentives for adoption of UDI within the supply chain will lie in final category (i.e., Class I) as these generally represent high volume low unit cost items. As such, participants suggested that FDA could begin the roll-out of UDI labeling requirements with this category or require that all three device classes are labeled with UDI at once. This could help generate broad supply chain adoption among care delivery sites by eliminating the need for redundant systems and facilitating quicker adoption. Another idea proposed was the creation of a manufacturer consortium to set an industry-wide standard for AIDC technology adoption. If manufacturers could agree to use one or a limited number of AIDC technologies as part of representing the UDI on a device label, this could help prevent some burden on care delivery sites by focusing the number of types of AIDC reading systems they must purchase.

Additionally, participants identified a set of strategies to overcome some of the motivational hurdles UDI implementation may face. In particular, participants underscored the importance of engaging stakeholders in a variety of roles within a care delivery site, highlighting the need to articulate specific value propositions to each stakeholder group to gain support for UDI implementation efforts. Participants noted that although the attention of stakeholders within care delivery sites may be focused on implementing other requirements at this time (e.g., meaningful use), long-term incentives may exist for care delivery site adoption of UDI. One such incentive is the long-term cost savings UDI may facilitate in an already challenging fiscal environment, particularly through optimizing the supply chain and improving billing and claims process. In addition to highlighting the importance of engaging stakeholders within a care delivery site, participants also called special attention to the need to engage patients and consumers to create awareness about UDI and generate demand for UDI implementation. This could act as a strong incentive for care delivery sites to meet the demands of their patients and distinguish themselves from other care delivery sites.

Participants also discussed that the supply chain may not be the best vehicle to drive UDI implementation. This is due to the difficulty in addressing a number of challenges, including the delay in the strongest incentive for supply chain adoption: the availability of UDIs on Class I devices. However, participants emphasized that because the supply chain systems can feed into clinical systems, tying the supply chain implementation of UDI with the need for UDI to support clinical activities within a care delivery site, particularly with regard to safety, must be considered. Participants suggested that this strategy might create the greatest urgency with regard to UDI adoption within a health care delivery site.

Capturing UDIs in Clinical Data Systems

Electronic health records (EHRs), laboratory management systems, and other clinical data systems allow providers to quickly record and access information on many aspects of a patient's current health status and background. However, clinical data systems often lack device-specific information, which, if accessible, could enrich the existing data and facilitate a number of benefits for providers, patients, and the public. For example, providers could enjoy a more complete patient record that provides information regarding device use and associated patient outcomes. This, in turn, could allow for rapid identification of risks and benefits associated with a device within specific subpopulations. By linking clinical detail and information regarding device use, more effective device safety surveillance and evaluation studies could be conducted, contributing to a more complete safety and effectiveness profile for devices and enabling more appropriate and timely remedies when potential safety concerns are identified. As described below, participants emphasized that despite the clear benefits of incorporating UDI into clinical data systems, there remains a host of challenges that must be addressed in deriving a path forward.

Challenges

In discussing key barriers to successfully incorporating UDIs into clinical systems, participants indicated that a number of the administrative system barriers (e.g., regarding UDI format and multiple AIDC technologies) are also relevant for clinical systems. In addition, participants expressed concern over multiple barcodes and identification numbers that are currently present on some device labels, adding that another number or barcode on the label for UDI may further confuse providers and create added steps in their workflow as they try to determine which barcode to scan or number to record. Moreover, participants pointed out that a UDI is expected to have two components (i.e., device identifier and production identifier), creating an added layer of complexity in provider point of care scanning.

Participants also underscored that determining which UDIs will be most important to capture will be particularly challenging. Often, a series of devices are used in a single visit or intervention, some of which may be more important than others to record in relevant clinical data systems. Furthermore, implants and other devices may have multiple components that may each be important to record as different combinations may have variable impacts on patient outcomes. Participants indicated that this issue, along with the proposed set of exceptions (e.g., over-the-counter devices) to the UDI labeling requirements, could impede safety and evaluation studies of device combinations as not all of the UDIs of devices are likely to be recorded as part of the delivery of care.

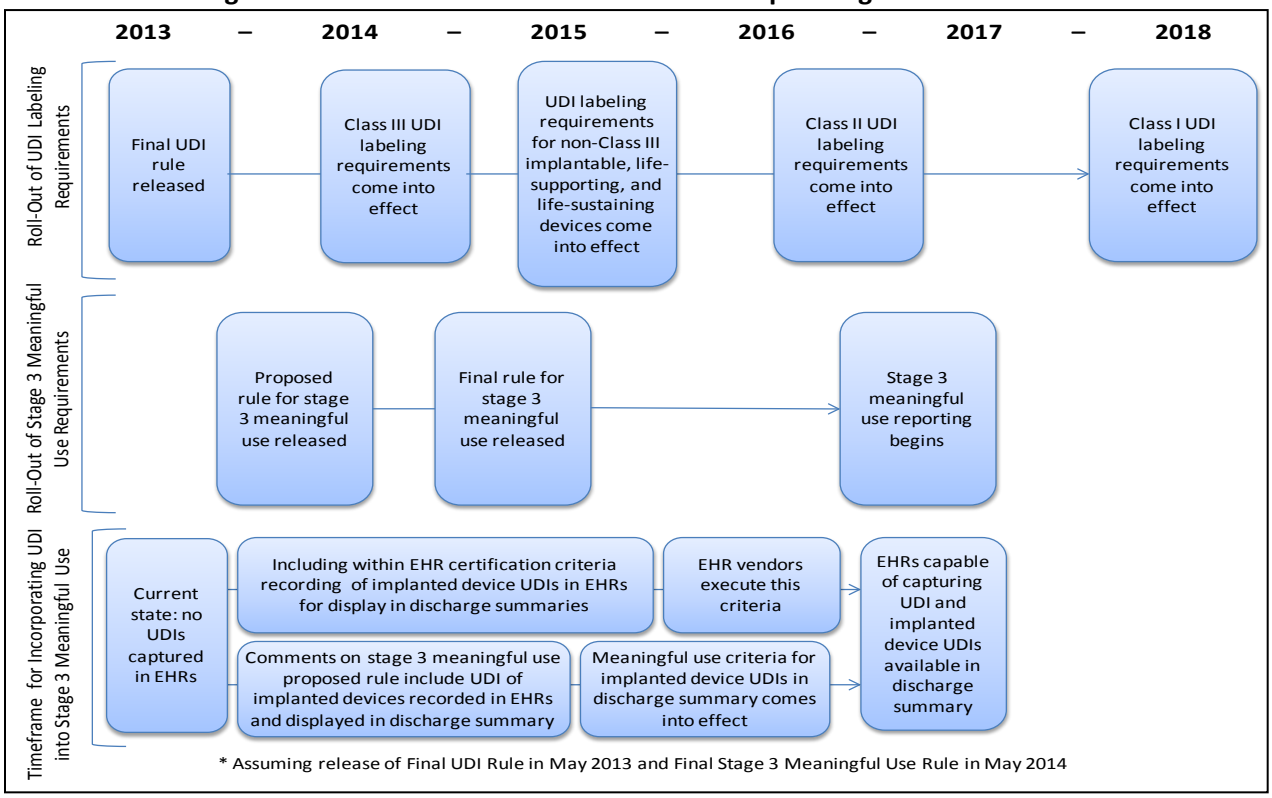
Additionally, participants discussed that there may be a difference in priorities between administrative and clinical systems with regard to UDI implementation, with the supply chain benefiting most from the availability of UDIs for Class I devices and clinical processes benefiting most from the availability of UDIs for Class III devices. This misalignment of needs and the associated timelines for the UDI roll-out may create additional obstacles in implementing UDI and discourage adoption by care delivery sites

Strategies

To work toward successful UDI implementation, participants made clear that a series of strategies and incentives to drive adoption will be needed. One strategy participants put forth was to incorporate UDI recording capabilities into the EHR certification technology standards being developed by the Office of the National Coordinator for Health Information Technology. This, participants offered, would help accelerate UDI adoption by first ensuring that EHRs are able to support capturing UDIs appropriately, efficiently, and in a reportable way, eventually allowing them to be leveraged for additional uses. Once UDIs can be captured in EHRs, participants added that incorporating UDI into stage 3 meaningful use

requirements may further drive care delivery site adoption of UDI. One proposed initial requirement for EHR certification and subsequently for meaningful use was that UDIs for implanted devices be included in patient discharge summaries. This would help start UDI recording, and help make implanted device UDIs available to primary care physicians, follow-up providers, and patients through the widely-read discharge summary. Figure 1 shows an approximate timeline for incorporating UDI into EHR certification standards and stage 3 meaningful use requirements efforts based on the workshop's discussion, alongside timing of the anticipated roll-out of the UDI labeling requirements.

Figure 1. Potential Timeline of Efforts for Incorporating UDI into EHRs



As with administrative systems, participants highlighted the need to engage stakeholders regarding UDI implementation within clinical systems. In particular, generating support for UDI relies on the engagement of clinicians, nurses, chief information officers, and chief medical officers. As these stakeholders are especially likely to be concerned with workflow, participants emphasized that it will not be sufficient to avoid worsening workflow through UDI implementation, but instead that incorporating UDI must actually improve workflow. Participants suggested that UDI could potentially help improve workflow and also minimize error through the adoption of appropriate AIDC technology. Participants added that the UDI could be accompanied by a human readable text next to the code (e.g., "UDI: A12345") to distinguish it from non-UDI barcodes that may appear on the label. This would help ensure that the correct identifiers are being efficiently captured by appropriate stakeholders. Participants noted that workflow considerations will be especially important to consider in particularly fast-paced specialties (e.g., emergency medicine) where there might not be sufficient time to record UDIs. In addition to engaging the above stakeholders, participants again underscored the power of patients and

consumers as active participants in their care and emphasized the need to engage them in creating demand for UDI implementation within health care delivery sites.

Additionally, participants discussed issues related to capturing UDIs for further uses (e.g., billing) and indicated that a number of existing frameworks for device categorization (e.g., HCPCS, LOINC, SNOMED, ECRI) already exist. There was discussion as to whether cross-maps could be created between these categorization systems to enable care delivery sites to more easily access, translate, and use the UDI to augment these existing frameworks. Also, regarding the use of multiple devices in a procedure, some participants put forth the possibility of capturing and storing as many UDIs as possible for now, and then determining how to leverage that data at a later date, once the use cases for UDI become clearer. However, participants also recognized that while it may be useful to capture UDIs and other device-related data with a high level of granularity, it will be important to carefully consider the cost-benefit tradeoffs, taking into account the potential burden on providers tasked with capturing UDIs and the most important use cases for the data.

Integrating Across the Electronic Data Infrastructure

Over the course of the day, participants emphasized that incorporating UDI into disparate systems will not be enough to achieve the full value of UDI implementation; meaningful integration across electronic data systems within a care delivery site will be needed. One important element of this integration is the seamless ability to flow the UDI, along with other important data, from one system to another, thereby enabling the UDI to be entered once and then leveraged for a number of purposes (e.g., supply chain optimization, efficient identification of patients affected by a recall, enhanced billing capabilities) For example, a provider could theoretically scan a device at the point of care, triggering the local item master to pull device information from the GUDID, which could then be used by the clinical systems. However, participants recognized that most systems are currently limited in their ability to flow information, and, therefore, there may be a need for new and disruptive technology to drive this forward. Participants also discussed that any efforts to achieve meaningful integration must be done in a way that that will maximize the value of UDI, while making sure to minimize the cost, in order to incentivize care delivery site adoption. One strategy offered to accomplish this was the use of a stronger, overarching theme to accelerate adoption (e.g., requiring UDI in claims or EHRs). In looking toward integration, participants also suggested prioritizing a few use cases to explore first by launching pilots, then extracting useful information and lessons from these pilots. Although each use case for UDI will require a different level of data granularity, an initial focus identified by the group was implants because of their importance to care delivery sites in terms of cost and clinical significance.

Mercy Health's UDI Pilot

As mentioned above, pilots could offer an important means for care delivery sites begin to understand potential early wins, challenges, and strategies for incorporating UDI into administrative and clinical systems. Details regarding one such pilot currently being conducted at Mercy Health were presented at the workshop. This pilot is examining the potential for capturing and leveraging the UDIs of coronary stents throughout the health system's electronic data infrastructure. A key factor in Mercy's ability to initiate this pilot was the wide range of stakeholder engagement and support that existed for the project. From health system administrators to cardiac catheterization lab personnel and throughout the provider network, stakeholders saw the value of an integrated approach to UDI implementation and subsequently led efforts to push it forward. Although the pilot is still in its initial stages, a number of early wins have already been accomplished. Among those early wins was that the supply chain is now able to electronically manage the expiration dates of Mercy's medical devices, shifting from a system in which boxes were marked with color-coded sticky notes to a sophisticated ability to produce reports of

the inventory closest to expiration for immediate use. This, Mercy indicated, provided huge cost savings to the health system, and helped further support for an integrated approach to UDI adoption.

A number of challenges have also been encountered so far in this pilot. One challenge encountered was the inability for the disparate administrative and clinical systems to communicate information to one another. For example, UDIs captured in Mercy's ERP systems could not be transferred to the clinical systems because these two systems could not interface effectively. To work around this issue, Mercy moved the data in the administrative system to a data warehouse. Then, Mercy was able to transfer that data into the EHRs with some manual processes that they hope to improve in future iterations of the pilot. Mercy indicated that having UDIs in the EHRs then provided them with the ability to link a device to a patient and query their systems for all patients with a particular device. However, while EHRs had some UDI recording capabilities, Mercy found that the cardiac catheterization software was limited in its ability to handle UDIs and software developers were not planning to incorporate this ability in the near future. Another issue encountered by Mercy was that clinical personnel were frequently scanning the incorrect barcodes found on device labels. Mercy found that this was largely due to confusion around the presence of the UDI along with other barcodes on the label. Participants indicated that this would be an important issue to consider in the development of labeling requirements.

In addition to piloting the integration of UDI across electronic data systems, the data from Mercy's pilot will be used in a data quality pilot conducted by FDA with Master Data Management consultants to inform the development of the GUDID. The Mercy data will become a subset of a larger dataset in FDA's assessment of device identification data. The analysis of the device identification data will then be used to inform strategies for remedying potential and existing data quality issues in the roll-out of the GUDID.

Next Steps

This meeting explored several critical considerations along the path to successful UDI implementation. Throughout the discussion, participants emphasized the importance of UDI as a pillar for many of the activities care delivery sites hope to be able to conduct, while recognizing that the full benefits of UDI will not accrue without broad adoption and implementation across the spectrum of stakeholders. Through a range of activities, including expert workshops and webinars, Brookings will continue to facilitate this conversation surrounding the benefits, challenges, and strategies for successful UDI implementation. These activities will ultimately help inform the development of a UDI Implementation Roadmap, which will convey the value of UDI implementation, guide relevant stakeholders in addressing key challenges, and serve as a foundation for policies supporting UDI adoption.