ENGELBERG CENTER for Health Care Reform at BROOKINGS

July 16, 2012

Meeting Summary

Unique Device Identification (UDI) Implementation Work Group Kick-Off Meeting

Introduction

Medical devices play an integral role in enabling a range of diagnostic, preventive, and therapeutic interventions in hospitals, medical offices, patient homes, and other settings. Given the extent of their use, there is broad recognition of the importance of having an effective system for monitoring the use of medical devices and patient outcomes associated with their use. Although significant steps have been taken to enable such monitoring for drugs, critical gaps remain in the ability to gather specific information on devices. One of the major challenges in this area is the lack of a standardized identification system for medical devices that would be analogous to the National Drug Code (NDC), which provides a common language for identification of specific drugs. Without such a standardized identification system for medical devices, it is much more challenging, if not impossible, to understand whether potential safety concerns are limited to specific devices, initiate efficient communications to providers and patients who might be affected by a device recall, and conduct a range of other activities that rely on specific information regarding device use.

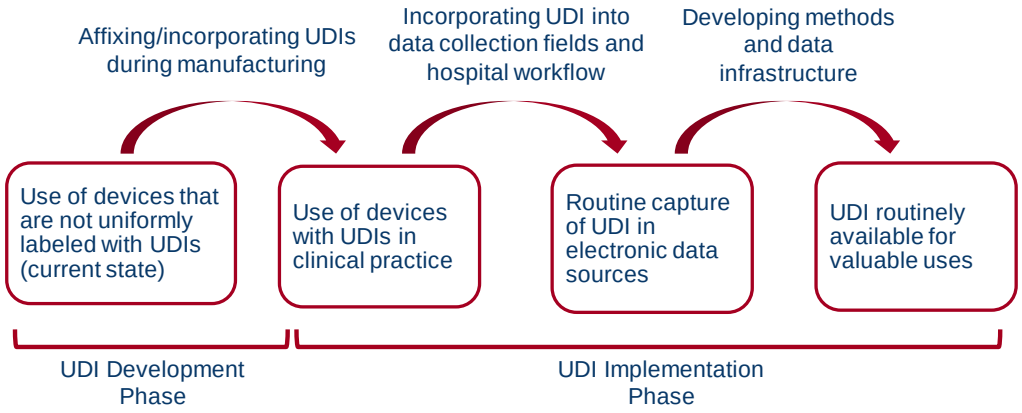
In response to growing calls for the development of a standardized medical device identification system, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA). FDAAA mandated the United States Food and Drug Administration (FDA) to create a Unique Device Identification (UDI) system that would enable tracking and identification of medical devices across the medical device lifecycle (i.e., from production through use in clinical practice). In response to this mandate, FDA organized public meetings and workshops, conducted pilot studies, and issued calls for comments on key issues relating to UDI. FDA then actively worked to incorporate input gathered from stakeholders, and on July 10, 2012, published the Proposed Rule for the Unique Device Identification System in the *Federal Register*.[1] The Proposed Rule, which will be available for comment through November 7, 2012, outlines the public health objectives, timeline, labeling requirements, and important exemptions and exceptions associated with UDI. It also details the components of the UDI, how the UDI should be generated and displayed (i.e., via plain-text and automatic identification and data capture (AIDC) forms), and the role of the accompanying Global Unique Device Identification Database (GUDID), which would provide detailed device information to stakeholders and the general public.

While the release of the Proposed Rule is an important step forward, its proposals, if adopted in the Final Rule, only ensure that UDIs will be developed and included on labels for relevant medical devices and that accompanying device information will be available to the public. The true value of a UDI system, however, lies in its broad adoption and subsequent use by manufacturers, distributors, payers, providers, and other stakeholders with important roles throughout the medical device lifecycle. Figure 1 illustrates major steps that would need to occur along the UDI development and implementation pathway in order for the value of UDIs to be realized. After UDIs are developed and affixed on medical

[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.

device labels, substantial motivation and effort will be required by key stakeholders to incorporate UDIs into electronic data collection fields and hospital workflows. Once recorded routinely and stored electronically, it will be necessary to ensure that adequate data infrastructure and methods are available to ensure UDIs are useable by stakeholders. Examples include efficiently linking UDIs to other parts of the patient medical record, real-time linkage with device information such as recalls, and linkage to other databases used for medical product safety surveillance and effectiveness evaluations.

Figure 1: UDI Development and Implementation



The Engelberg Center for Health Care Reform at Brookings is collaborating with FDA and Chickasaw Nation Industries, Inc., to explore the most pressing opportunities and challenges in achieving the goal of successful UDI implementation. During the first year, Brookings will engage in the following activities:

- Assemble the UDI Implementation Work Group to advise on issues related to the implementation of UDI, explore potential strategies for resolving them, and identify topics in need of further exploration;
- Convene three expert workshops on selected issues and possible barriers to UDI implementation, identified by the work group, that would benefit from more in-depth consideration; and
- Hold two webinars to engage with broader audiences regarding UDI implementation.

In collaboration with relevant stakeholders, Brookings will use the information gathered from this effort to begin developing a roadmap for successful UDI implementation. This roadmap will convey the value of UDI implementation, guide relevant stakeholders in addressing key challenges, and serve as a foundation for policies supporting UDI adoption. Brookings expects that development of a complete roadmap will be a multi-year effort, involving more opportunities for workshops and other stakeholder engagement.

To begin the conversation around opportunities and challenges associated with UDI implementation, on July 16, 2012, Brookings held an in-person kick-off meeting of the UDI Implementation Work Group. This meeting brought together representatives from key groups, including device manufacturers, payers, electronic health record (EHR) vendors, academics, clinicians, and others with a vested interest in UDI implementation. Over the course of the day, participants identified important use cases, explored major challenges and strategies surrounding UDI implementation, and considered topics that could benefit from additional focus during subsequent expert workshops and webinars. Key themes from the discussion are summarized below.

Use Cases

Once UDIs are available on medical device labels, incorporated into appropriate data collection fields and health system workflows, and supportive infrastructure and methods are in place, UDI could be used for a variety of different purposes. Participants considered the most likely and important use cases or enhanced capabilities that arise from UDI implementation. While participants identified a wide range of potential use cases (Figure 2), a few received the most attention during the discussion and are described below.

Figure 2: UDI Use Cases Identified by Meeting Participants

Use Case	Brief Description	Direct Stakeholder Groups
Safety surveillance and effectiveness evaluation	Ability to organize data, track device use, and evaluate meaningful outcomes (longitudinally track patients, conduct epidemiological studies, etc.)	Device Manufacturers, FDA, payers, providers/health systems, patients
Supply chain management (internal and external)	Greater efficiency in tracking devices throughout the device lifecycle from point of production to point of care (includes inventory management)	Device manufacturers, providers/health systems
Recall communication	More effective identification of recalled products and associated patients and targeted communication of recall information to relevant parties	Device manufacturers, FDA, providers/health systems, patients
Provider access to device information	Empowerment of providers with increased access to information about devices that may be used to care for patients and devices already in use (i.e., implanted devices) to inform selection of interventions, reduce medical errors, and improve quality of care	Providers/health systems, patients
Device reimbursement	Ability for more specific and appropriate charges and payments for medical devices	Providers/health systems, payers, patients
Investment planning	Better information to support long-term planning for major device investments	Providers/health systems
Biomedical equipment management	Increased ability to efficiently track location and status of biomedical equipment	Providers/health systems
Patient access to device information	Improved transparency of device information for patients to increase general knowledge of their devices	Patients
Fraud detection	Identification of improper device use and billing	Payers, providers/health systems
Anti-counterfeit detection	Detection of imitation devices (e.g., at border control, in health systems)	Device manufacturers, FDA, providers/health systems
Regulatory compliance	General implementation and response to regulatory requirements	Device manufacturers, FDA
Emergency preparedness/response	Improved ability to match stock of devices with personnel trained in their use; rapid identification of devices as part of medical countermeasures	Providers/health systems, FEMA

Safety surveillance and effectiveness evaluation

Like other medical products, medical devices may have potential risks that do not emerge in pre-market studies. After devices are approved or cleared for marketing and experience with them begins to accrue, it is important that ongoing safety surveillance, continued evaluations of effectiveness, and device use in clinical practice are conducted. Although efforts are underway to improve device surveillance through programs such as FDA's Medical Device Epidemiology Network Initiative, current mechanisms of device surveillance rely largely on voluntary reporting by consumers or health care professionals. One major issue related to voluntary reporting is that reports are often incomplete and do not contain information

that would allow linkage with a specific device. Certainly, if UDIs were included as part of voluntary reports, this could allow more efficient aggregation of adverse events related to a particular medical device. Participants also underscored the potential for UDI to facilitate active surveillance methods that utilize data from electronic sources, such as claims or EHRs, assuming that UDIs are routinely recorded in these sources. Safety and effectiveness of some implantable devices are also currently monitored through active registries; however, without UDIs in place, it is challenging to efficiently obtain longitudinal follow-up, through collection of electronic health care data, on patients who were recruited into the registries. Enhanced capabilities to monitor device use and understand associated outcomes, especially with regard to identifying risks and benefits associated with specific populations, could contribute to a more complete safety and effectiveness profile for devices and enable more appropriate and timely remedies when potential safety concerns are identified.

Supply chain management

The ability to efficiently communicate device information throughout the supply chain is critical. Participants underscored the potential for UDI to improve internal and external supply chain management of devices, from production to point of care, by enabling better mechanisms for conveying pertinent device information. Within the internal supply chain (e.g., within a particular health system), UDI may allow for more accurate and specific inventory records and quick capture of device information using AIDC. This, in turn, may support more comprehensive and efficient identification of recalled devices. At present, inventory and recall management can be challenging due to the use of non-unique device identifiers that may simultaneously identify two or more disparate devices. This, coupled with error-prone device information capture, can create wasteful redundancies and make it difficult, if not impossible, to specifically identify recalled products. With regard to the external supply chain, participants explained that streamlining communication by using a common identifier across each stage of the medical device lifecycle can enable more efficient and accurate identification of important product information, such as storage instructions and recall status. These improvements can reduce excess costs associated with ineffective supply chain management and provide other benefits to the health system and the public.

Recall communication

In the event of a medical device safety recall, manufacturers issue statements, which FDA helps distribute, notifying the general public of the recalled item and the reason for its recall. Without a UDI system in place, the specific devices affected by a recall are often unclear to relevant stakeholders. If manufacturers were able to issue a recall for a particular device specifying the associated UDI, health care systems would then be able to query their inventory systems for that UDI and efficiently identify the recalled product and affected patients. Health care systems could then use this information to more proactively notify patients of the recall status of their medical devices. Providers could also make use of real-time recall information at the point of care, potentially reducing the number of patients exposed to implicated devices. Outside of clinical settings, participants suggested that patients with potentially recalled devices would find value in being able to independently identify recalled devices through the use of UDI and the GUDID.

Provider access to device information

Providers must make a range of decisions about which medical devices are best suited to a patient's needs, how to use the devices they have selected, and how to assess the status of devices that patients are already using. However, providers do not currently have access to sufficiently comprehensive and contemporary information about these devices. If providers had the ability to quickly and efficiently query the GUDID with specific UDIs at the point of care (e.g., via communication between the provider's

decision support tool and the GUDID), this could become an important new resource in decision-making. In particular, providers could benefit from real-time access to detailed information about device characteristics, storage instructions, pertinent recalls, and other features. In the case of used medical devices, providers may also find information regarding a device's history useful.

Participants also discussed providers' need for access to specific information regarding the devices a patient is already using, particularly in the case of implanted devices. For example, it could be especially important for a provider to know exactly which implanted device his or her patient has as part of routine follow-up care or if the patient is in need of revision surgery. Participants indicated that having such information readily available to providers could significantly reduce medical errors and improve the quality of care delivered.

Challenges

Participants emphasized that realizing the benefits associated with UDI implementation may be challenging. Throughout the meeting, participants discussed potential obstacles along the path to successful UDI implementation, including both technical and motivational challenges. The following were major themes from the discussion.

Technical Challenges

Appropriate UDI assignment and recording

Participants identified a number of issues related to appropriate assignment and recording of UDIs that would need to be addressed in order to ensure successful UDI implementation. First, participants emphasized that a single medical procedure often involves the use of multiple devices and speculated as to whether UDIs for each device would need to be recorded (e.g., in EHRs, on claims forms). Participants suggested that it will be necessary to strike a balance between burdensome recording of numerous UDIs and ensuring that the appropriate information is captured regarding a procedure. Participants also acknowledged that devices routinely undergo configuration changes associated with updated materials, design, or software and may have accessories or spare parts. Clarity regarding what types of configuration changes warrant the issuing of a new UDI and how to handle accessories and spare parts will likely be important. Finally, participants raised the challenge of whether and how to retroactively assign UDIs to legacy devices or devices with long life spans that are already in use. The Proposed Rule begins to shed light on this issue by indicating that legacy devices will not be retroactively labeled with UDIs; however, further discussion may be necessary to fully resolve the challenges posed by continued use of legacy devices without recording of UDIs.

Information technology infrastructure

Many of the use cases put forth by participants can only be achieved if there is appropriate information technology infrastructure in place throughout the medical device lifecycle. In particular, participants emphasized the role of health information technology, which has the potential to enable efficient capture, storage, and exchange of patient health information, and association of this information with UDIs. Appropriate changes would need to be made to existing EHR systems to facilitate collection and integration of UDIs with other patient data. Participants suggested that modifications to existing electronic systems should also be made to streamline workflow in order to avoid creating an undue burden on providers and hospital staff.

Once fields are created for UDIs in EHRs and other systems, providers and other health system staff will need a mechanism for efficiently capturing UDIs as devices are used in patient care. As mentioned above, the Proposed Rule specifies that the UDI shall be provided in both plain text and AIDC formats on

the medical device label. Automatic identification and data capture formats, such as bar coding and radio frequency identification technology, can facilitate the rapid capture of UDIs (e.g., by enabling UDIs to be read electronically through a network connection), potentially saving a great deal of time and avoiding error introduced by human data entry. The Proposed Rule is technologically neutral, leaving the decision about what form of AIDC is most appropriate to manufacturers. If health systems and providers do not already have readers for these AIDC formats, participants indicated that purchasing such readers could translate into an additional financial burden. This could be particularly problematic if there is not harmonization among manufacturers in terms of the AIDC format used for UDIs, necessitating the purchase of multiple reader types by health systems and providers.

Once UDIs are captured, the information technology infrastructure will also need to enable UDIs and related device and patient information to be leveraged for the use cases described above. Among other capabilities, this will require interoperability among systems and data sources, both within and outside of the health system.

UDI incorporation into claims

Electronic claims data are increasingly being used for a range of activities, including active medical product safety surveillance, effectiveness research, and evaluation of patterns of care. Enriching claims data with UDIs could help facilitate several of the use cases described above. However, participants acknowledged that making changes to claim forms and claims processing systems is not trivial. Rather, such changes are typically costly and burdensome to enact, and as such, it may be challenging to gain the support of payers. Participants suggested that if the Centers for Medicare & Medicaid Services (CMS) were to adopt the policy that UDIs must be reported on claim forms and made corresponding changes to its claims forms and processes, this would likely encourage other payers to follow suit. However, some participants cautioned that enacting such changes to CMS's system would be a lengthy process, requiring numerous amendments to an already complex claims processing infrastructure. Important questions were raised regarding whether or not requiring UDIs on submitted claims would also need to be associated with reimbursement policy changes as facilities are typically reimbursed using a global average rate per case system rather than being specific to the exact device used in many surgical procedures. These and other challenges would need to be resolved in order for UDIs to become integrated into claims data and available for use in surveillance and research activities.

Other technical challenges discussed at the meeting include data protection (e.g., ensuring patient privacy) and device security, lack of information about existing data sources and their ability to contribute to our understanding of devices, and appropriate attribute development for building the GUDID.

Motivational Challenges

Lack of stakeholder knowledge, understanding, and support for UDI implementation

Among the motivational challenges discussed, lack of stakeholder knowledge regarding UDI and its potential benefits was one of the most significant. While relevant stakeholders may be aware of the movement to adopt a UDI system, many are unaware of its potential impact on areas such as patient safety and supply chain management. As a result, key stakeholder groups may not express the same level of support for UDI implementation as they might with a full understanding of its potential benefits. For example, without broad stakeholder support within health care systems, successful UDI implementation could be hampered by reluctance to capture UDI information as part of the routine delivery of care or record such information in EHRs and other systems. Similarly, without understanding potential benefits and uses of UDIs, payers may be unwilling to invest in redesigning claims transaction

systems and data warehouses to accommodate the inclusion of a new field for UDIs. Participants suggested potential approaches to promoting better stakeholder awareness and adoption of UDI, which are described below in the "Strategies" section.

Concern that UDI implementation could disrupt care delivery
Participants suggested that UDI implementation may not be embraced by health systems and providers due to concerns regarding potential disruption to the clinical workflow or the sequence of processes involved in initiating and completing a procedure. Currently, providers often document a procedure or a patient visit afterward so as not to interrupt the delivery of care. However, this can lead to significant gaps in recorded information and delays in documentation. Participants highlighted the important role that AIDC technologies could play in expediting the process of capturing UDIs during a procedure, thereby reducing disruptions to the workflow and ensuring that valuable device information is captured efficiently.

Other motivational challenges raised by participants included potential financial burden for stakeholders, with a potentially greater burden for smaller companies, and a desire for rapid UDI implementation balanced against a need to ensure that UDI implementation achieves longer-term objectives.

Strategies
Participants proposed both technical and motivational strategies to address some of the challenges raised during the meeting and encourage broad stakeholder implementation of UDI. The following strategies recurred throughout the discussion.

Technical Strategies
Include UDI in claims
To provide an incentive for providers to record UDIs, participants suggested that payers could require reporting of UDI as a mandatory field on claims forms. This would effectively require health systems to create a process for providers to keep track of the UDIs used in procedures in order to ensure reimbursement. As described above, having UDIs as part of claims data would facilitate a host of new research and surveillance activities that are already occurring with claims data for drug evaluations, but could be very important for evaluating device safety and effectiveness. In addition, some participants indicated that inclusion of UDIs on claims could assist payers in exploring differential payments, wherein the payment for a particular procedure would vary depending on the specific device that was used. Another potential benefit for payers might be in the area of fraud prevention and detection, as the UDI would make it more difficult to misrepresent procedures done and specific devices used.

Use quality measures and IT standards to incentivize UDI adoption
Routine tracking of device use offers opportunities for hospitals and providers to improve the quality of care delivered. In order for this to happen, quality measures and information technology standards must link device use to outcomes through the incorporation of device-specific performance measures. Participants emphasized the power of these metrics in shaping behavior and suggested ways in which these tools could be employed to encourage UDI adoption among health systems and providers. If UDIs were integrated into quality measures (e.g., with a process measure regarding the percentage of the time UDIs are recorded when a procedure is done involving a device) and the results were made public and used to inform CMS reimbursement, this could become a strong incentive for adoption of UDI. Participants also discussed the potential inclusion of UDI as part of meaningful use standards. Meaningful use refers to the set of standards, defined by the Office of the National Coordinator for

Health Information Technology (ONC), meant to help providers collect, store, and share electronic patient data securely and effectively in EHRs. To encourage adoption of EHRs, CMS outlines meaningful use standards criteria which, if met, render health care providers eligible to receive financial incentives. Meaningful use is currently being implemented in three stages, with Stage 3 focusing on improving quality, safety, and efficiency. If reporting of UDI were included as part of Stage 3 meaningful use standards, providers could be compelled to record UDIs in EHRs in order to remain in compliance with meaningful use standards and receive the CMS incentives. This adoption of UDI recording by providers, if done in a way that minimizes provider burden, could then enable routine device tracking and improve the quality of care they deliver while. In addition to improvements in the ease of tracking device performance that UDIs could enable, participants suggested that another effective Stage 3 meaningful use standard might be that providers should be equipped to immediately notify patients if their device is recalled. In complying with this standard, providers would need to rely on having UDI recorded in the EHR, which could increase UDI adoption among this stakeholder group.

Other technical strategies discussed during the meeting included identifying a trusted third party to maintain a database linking UDIs and patients, recording UDIs in the device data log, and conducting pilots, simulations, and feasibility testing.

Motivational Strategies

Educate and engage relevant stakeholders

In order to achieve broad stakeholder support for UDI, participants drew attention to the need to educate and engage stakeholders on UDI and the enhanced capabilities that could arise from its implementation. Participants suggested creating and distributing educational materials that concisely relay information about UDI and its importance. Participants emphasized the need to present stakeholders, especially leadership within health care systems and providers, with the clinical and economic value that can be attained from successful UDI implementation. For example, participants discussed the potential for UDI to drive down costs within a health care system and suggested that such savings could be a key motivator encouraging active adoption of UDI. One way of conveying the value of UDI implementation might be to prepare testimonials from health systems that have already adopted other forms of unique device identification, perhaps with accompanying data regarding the improved efficiencies these systems experienced.

Additionally, this meeting strongly suggested that engaging patients in this effort is crucial. Like providers, patients often desire and would benefit from having more complete information about the devices used in their care. Patients may be particularly interested in having more information about implanted devices that are in place over a long period of time. With patient access to the GUDID and UDIs of devices they may be using, there is the potential for patients to have more independent access to device information and, once they are aware of this potential, patients may begin to demand that their providers capture UDI information. If this happens, providers are likely to perceive additional value in recording UDIs in EHRs and supporting broader UDI implementation efforts at their institutions.

Prepare relevant stakeholders for UDI Implementation

Participants discussed the need to prepare stakeholders for changes that will be associated with UDI implementation. Specifically, participants suggested an incremental approach to UDI implementation coupled with the use of change management processes. Participants noted that change management processes may need to be tailored to individual stakeholder groups and organizations in order to achieve full UDI implementation, given that each stakeholder group may have different needs and challenges that are important to consider. Change management could be employed to help prepare

stakeholders for UDI implementation by creating flexible and dynamic plans that outline the short- and long-term objectives of and threats to successful implementation. Key aspects of the change management process described by participants included identifying a vision, understanding stakeholders' needs and challenges, ensuring effective communication across stakeholders, and creating incentives to drive stakeholder adoption.

Other motivational strategies discussed at the meeting include employing a scorecard system for UDI implementation and promoting harmonization across countries.

Defining Successful Implementation

After considering challenges and strategies, participants began to define the features of a successfully implemented UDI system. Four key features emerged from this discussion:

1. UDI is used as the common language between stakeholders, enabling efficient and effective data communication across the medical device lifecycle;
2. UDI is used as the primary identification and reporting code throughout the internal and external supply chains, increasing efficiency, reducing the likelihood of human data entry errors, and enabling instant relaying of information;
3. UDI fields are included in electronic data sources (e.g., EHRs, claims), coupling clinical detail with device information and enabling timely identification and communication of safety issues; and
4. UDI capture is seamlessly integrated into the point of care workflow, minimizing disruptions to care delivery by employing AIDC technology as much as possible.

While it will likely take many years to achieve successful UDI implementation as defined during this meeting, the following section describes the immediate activities that will be undertaken to move toward this goal.

Next Steps

The UDI Implementation Work Group kick-off meeting illustrated the capacity of UDIs to enable the capture and use of specific medical device information for a range of purposes across the medical device lifecycle. The full benefits of UDIs, however, will not accrue unless broad adoption and implementation occurs across the spectrum of stakeholders. Through a variety of activities, Brookings will continue to facilitate dialogue among these stakeholders. Brookings will hold monthly calls with the work group, seeking members' further input on challenges UDI implementation may face and strategies to address those challenges. Brookings will also convene three expert workshops bringing together thought leaders and stakeholders to explore some of the key challenges and strategies nominated by the work group. While topics for these expert workshops have not yet been determined, some potential topics include integrating UDI in claims forms and incorporating UDI as a Stage 3 meaningful use standard. Brookings also plans to hold webinars that will be used to communicate to a broader audience regarding the potential for UDI. With broad stakeholder input over the first year, Brookings will begin developing a framework for the UDI Implementation Roadmap, which will be completed in subsequent years and used by a range of stakeholders to support UDI implementation efforts.