ENGELBERG CENTER for Health Care Reform at BROOKINGS

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Draft Meeting Summary

Unique Device Identification (UDI) Implementation Expert Workshop: Accessing and Communicating Device Information - UDI as a Tool for Improved Patient and Provider Connectivity

Introduction

Medical devices, ranging from simple (e.g., tongue depressors) to complex (e.g., pacemakers), have substantially augmented our ability to manage and treat a wide variety of conditions. Advances in medical devices are enabling patients to live longer, more functional lives and are providing physicians with new treatment options to address complex health issues. Given their growing importance, there is broad recognition that manufacturers, providers, patients, and other stakeholders should be able to efficiently communicate actionable information throughout the medical device lifecycle (i.e., from production to point of use). Patients and providers have a particularly important stake in receiving this information as this communication could, for example, allow for potential safety concerns, recall status, and adverse events associated with a particular device to quickly reach intended recipients. This efficient flow of information is especially important for patients with or about to receive implanted devices (i.e., devices that are placed into a surgically or naturally formed cavity of the human body for 30 days or more), due to the potential need for urgent action to address safety concerns related to their continued use. As such, this discussion focuses on the information needs of these patients and their providers and opportunities for improved patient-provider connectivity regarding implanted medical devices.

Patients and their caregivers are likely to expect and seek a wide spectrum of information related to medical devices. The information needs of specific patients differ depending on a variety of factors, including whether a patient has already had or is planning to have a device implanted. For instance, prior to having a device implanted, patients may want to access general device information about the safety, effectiveness, and possible impacts on daily life prior to surgery. Patients who have already received an implant may want specific information about the device they received, especially when similar devices are the topic of national news, and prompt notification of any safety concerns with their device. Although patients' information needs vary, they could be empowered to play a more active role in their care with access to device information that is clear and personalized. For example, this information could help patients understand the importance of monitoring the performance of their devices, speak with their providers to learn how their particular device works, and understand what potential problems might arise and how they should report these to their providers. Although many patients assume that this information is readily available, current capabilities for specific and efficient communication of device information are limited, making it challenging for patients to take a more participatory role in their care with regards to devices.

Providers also have diverse information needs with regard to medical devices, depending on the type of provider and the point at which they interact with a patient. For instance, an implanting surgeon needs to have a very detailed understanding of the specifics of a device before implanting, whereas a primary care physician caring for a patient with an implanted device may require information about the type of device, any related limitations or risks (e.g., whether a patient can safely undergo certain imaging studies), and details regarding long-term maintenance of the device. Additionally, an emergency room

physician may require rapid access to whether or not a patient has a device and whether that device could be linked to any of the symptoms that patient is experiencing. By having access to appropriate device information at the point of care, physicians, nurses, physical therapists, home care workers, and other providers can make more informed decisions in the short- and long-term care of patients. Additionally, providers are uniquely positioned to relay important information regarding device use and associated patient experiences (e.g., via adverse event reporting). While providers are positioned to play this role, it is currently challenging for providers to efficiently access and communicate important device information.

One of the primary challenges impeding these capabilities is the lack of a standardized identification system for medical devices. Such a system could enable identification of medical devices and transmission of important information to and from relevant stakeholders as devices move from the manufacturer to the health system and are eventually used as part of patient care. While stakeholders involved in different stages of the medical device life cycle may have their own systems for identifying certain devices, communication across stakeholders is challenging and the device identification captured may not be sufficiently specific to allow detailed tracking. This stands in contrast to the system for drugs, in which identification and tracking is facilitated by the presence of the National Drug Code, which identifies drugs at a very specific level. 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. FDA regulations will require UDIs to be assigned by device manufacturers, with some manufacturers already fully incorporating UDI into their labeling mechanisms. However, FDA regulations do not extend beyond device manufacturers to those who order, use, bill, and pay for medical devices as they move from production to point of care. Thus, while the Final UDI Rule will provide an important step forward, the true value of a UDI system lies in its broad adoption and use by manufacturers, payers, providers, patients, and other stakeholders with important roles throughout the medical device lifecycle.

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. Over the past year, Brookings has engaged in a number of activities, including assembling a UDI Implementation Work Group, convening two expert workshops on selected issues and possible barriers to UDI implementation, and hosting two webinars to engage with broader audiences regarding UDI implementation. More information about each of these activities can be found

[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.

on the Brookings website. In collaboration with relevant stakeholders, Brookings plans to use the information gathered from these activities to begin developing a roadmap for successful UDI implementation that will convey the value of UDI implementation, guide relevant stakeholders in addressing key challenges, and serve as a foundation for policies supporting UDI adoption.

One recurring theme throughout each of the aforementioned meetings has been the importance of ensuring that a UDI system is developed in a way that facilitates seamless communication of device information, easy access to important device information for patients and providers, and improved mechanisms for sharing device information among patients, providers, and others. Although enabling each of these capabilities will require a clear plan to encourage uptake of UDI by an array of stakeholders (e.g., health care systems capturing UDI in electronic health records), participants emphasized that patients and providers are likely to benefit most from and therefore should have an important role in driving the development and adoption of such a system. To further explore these issues, on March 18, 2013, Brookings convened an expert workshop on the topic of "Accessing and Communicating Device Information: UDI as a Tool for Improved Patient and Provider Connectivity." This workshop brought together a diverse set of stakeholders to discuss the potential barriers to and paths forward for each of three major use cases related to UDI and the flow of device-related information to, among, and between patients, providers, and other stakeholders. Key themes from the discussion are summarized below.

Accessing, Communicating, and Sharing Important Device Information

Over the course of the day, participants put forward a vision for overall improved connectivity among stakeholders in which patients, providers, and other stakeholders can access useful and comprehensive device information; stakeholders are able to communicate safety device information; and stakeholders can easily share important device information. During this discussion, participants highlighted some of the key obstacles that will likely need to be considered and put forward a number of strategies to help realize this vision of improved overall connectivity. Prominent themes from that discussion are summarized below.

Challenges

Public Awareness: Participants expressed concern over the lack of public awareness surrounding the current challenges in device tracking and communication of important device information. Participants agreed that most patients and consumers assume that robust mechanisms for tracking medical devices and communicating important device information exist, and may not become aware of this deficiency until they encounter a problem with their device or are trying to determine if a particular safety communication affects them. Without strong public awareness regarding these issues, participants emphasized that it will be difficult to generate the necessary demand for improving these capabilities.

Increasing Patient Mobility: Another challenge put forth by participants is that patients are becoming increasingly mobile and changing their addresses, phone numbers, e-mail addresses, and other contact information more frequently, which can make it difficult for stakeholders responsible for notifying patients of important device information to do so over the course of a patient's lifetime. Although this challenge is not unique to patients with implanted devices, it is especially problematic as issues related to devices can often occur several years or decades after the initial device implantation, during which time patients may no longer regularly interact with the provider who inserted the device.

Variability in Information Needs: Additionally, participants indicated that conveying information uniformly to patients will likely be difficult as the level and amount of information patients will seek

depends on a number of factors. Examples of such factors include the patient type (e.g., passive, information seeking) and the impact the implant will have on daily activities. Participants specifically highlighted the limited levels of health literacy across patients and their caregivers as a key challenge in ensuring that patients understand the device information presented and are able to make informed decisions with their provider regarding potential next steps.

Limited Availability of Information: Participants also discussed a range of challenges that are likely to arise in ensuring device information is available. For patients, blogs and websites are a major resource for patients seeking information on what devices are safe, effective, and reliable. However, because there is no standard way to uniquely identify and share information regarding a particular device, there is little to no readily available information about specific device performance. Participants underscored this point by describing that on a particular patient experience sharing website, patients were only able to adequately identify their device five percent of the time. Participants also emphasized that establishing a standard with regards to the accessibility of device information will be difficult in part because there are no universal patient "rights" with regards to device information. Another challenge put forth was that stakeholders responsible for communicating valuable device information, particularly manufacturers, may be challenged with developing and conveying device information that is uncertain, evolving, and inconclusive. In doing so, they must strike a balance between reassuring patients and influencing patient decisions.

Provider-Specific Challenges: Participants described a number of provider-specific challenges related to accessing, communicating, and sharing important device information. In addition to the limited availability of device information, described above, the lack of specific device information as part of a patient's medical history (e.g., date patient had a particular device implanted) can make it challenging for providers to conduct a number of routine activities including quickly determining whether or not a patient has a recalled device. Unlike drugs where the prescribing physician is likely to regularly encounter the patient, participants discussed that implanting physicians are not usually involved in the long-term care of the patient. Additionally, any information that is present (e.g., device sticker in procedure notes) is not easily searchable, accessible, or transferable, leaving primary care physicians and other long-term care providers to either request this information be shared or try to retroactively determine whether a patient has a device and what kind of device they are likely to have. Current mechanisms for sharing information are limited by a number of factors, including predominantly paper-based record keeping practices, a lack of health information technology infrastructure (e.g., EHRs), inconsistent use of language and identifiers in these exchanges, destruction of paper records after a finite amount of time, long lag time associated with current record sharing mechanisms, and the time costs for providers in conducting any or all of the current information sharing activities. Moreover, although the discharge summary is a more widely read and easily shared document than many of these records, it does not usually contain any information that could uniquely identify the implanted device. These issues are further compounded in cases where the acuity of a patient's situation may force providers to make rapid treatment decisions with incomplete information.

<u>Strategies</u>

Engage Patients Early: One important strategy to motivate patients to use UDIs in a way that can improve access to information is to engage them early in their care. A simple strategy put forth by participants is to ensure that important device information, including UDI, is relayed to patients at the point of care. To drive patient participation and prompt providers to give patients important device information before and after surgery, for instance, participants proposed a "checklist" for patients to use during their conversations with providers that would include asking for the UDI of their implanted

device. Although participants indicated that there may be difficulty in giving a patient the UDI for their device prior to surgery due to the complexity of decisions regarding which implant to use, participants also highlighted the need to assemble a framework for these conversations as a starting point to drive recording of UDIs in the patient record and make patients and providers aware earlier of the UDI's importance as an identifier. Another strategy put forth is emphasizing the importance of the UDI as an important device identifier by suggesting that providers ask patients for their implanted device UDIs during routine visits. This would demonstrate to patients the importance of UDI as an important number for their implanted device, which could in turn help patients realize the value of including their UDI in future communications with providers or other stakeholders.

Motivate the Patients through Customized Information: Participants stated that educational materials and communication plans developed for patients should be plain, pragmatic, and comprehensive to allow patients to easily understand essential device information and make important decisions regarding their care. Additionally, participants put forth that customizing the information different kinds of patients receive could motivate patients to take a more participatory role in their care. For example, a patient who receives customized device information from a third-party website may be more likely to update their contact information to receive important safety communications. Participants also suggested that providers may have an important role to play in this effort by communicating specific device information to patients and their caregivers, linking specific device information to a patient's record during a procedure, and providing patients with device-specific educational materials, particularly if specific processes were built into provider workflows. However, participants indicated that even with increased provider involvement in these activities, translators may be necessary to help convey complex information to patients and their caregivers (i.e., at their health literacy level, in their preferred language).

Create Patient-Specific Solutions: To enhance patients' ability to receive and retain device information, a number of patient-specific tools will likely be needed. Participants put forth examples of such tools during the discussion, including wallet cards with smart-phone readable QR codes that link to the GUDID and interactive device information applications for smart-devices. Participants also suggested that the best approach may be multi-faceted, for instance, enabling a provider to scan a wallet card that would link that device to the patient's health record and enroll the patient in a program reminding them to update their contact information. Additionally, participants underscored the need for a device information portal or consumer page that would link various FDA device databases together (e.g., GUDID, recall database, adverse event reporting). Participants stated that a number of these databases will likely use UDIs to identify devices and that a single, centralized site would serve as an excellent tool for patients and their caregivers when seeking information. Participants added that this site could also engage patients in their care by providing customized device information to patients that choose to join, for example.

Build on Successful Approaches from Other Industries: Participants put forth that device information communication strategies developed for medical devices should build on successful approaches used in other industries. For instance, participants suggested automating communication of urgent information to the extent possible, citing current mechanisms used by the airline industry to notify passengers of their flight's status. Participants noted that automating these processes would greatly enhance the flow of information, help define and reduce some of the demands on stakeholders responsible for notifying patients, and allow patients to ensure that the information they receive is relevant. Participants also indicated more broadly that layering new technology for the communication of device safety information onto existing technology frameworks that may already serve a commercial purpose (e.g.,

OnStar) will likely increase the likelihood of success for these approaches. Another strategy offered for consideration was that device safety information from FDA and other sources could be condensed for providers to quickly and easily understand, mimicking current activities being conducted for drug safety information. Participants emphasized that this could help improve the workflow of providers by making complicated information available for rapid consumption.

Include UDIs in EHRs: Participants also emphasized the need for providers to ensure that UDIs are included in electronic health records (EHRs), particularly as part of meaningful use requirements. Participants indicated that by incorporating UDIs of implanted devices in EHRs, a more complete picture of patient-specific device use and experiences with these devices can emerge. This would give providers a richer set of clinical detail to make appropriate care delivery decisions. Additionally, participants discussed the potential for information from EHRs to be efficiently shared across providers, which in turn could offer primary care and emergency room physicians, for example, important information to make rapid treatment decisions in cases where patients are experiencing acute symptoms. However, participants indicated that although EHRs could enable these important benefits, it will be important to think through a number of concerns related to their use. One such concern is that because EHRs collect information on a patient level, establishing methods for aggregating the data and using it to conduct population level studies for postmarket surveillance purposes from EHRs will likely be important for stakeholders to think through. Participants also noted that because of the latency associated with issues surrounding implants, interoperability issues may also pose a significant obstacle for many of the enhanced capabilities EHRs would hope to achieve. These interoperability issues could be the result of the inability for disparate systems made by different vendors to communicate with each other or for old file types to be read by new systems, for example. Participants discussed that although UDI could help mitigate some of these challenges, UDI recording could present its own set of difficulties for providers. Specifically, participants drew attention to the workflow implications of recording multiple UDIs, indicating that while recording UDI in the operating room, for example, could enhance the ability to identify and communicate important device information it also may add additional steps and time for some providers. Additionally, participants noted that because several devices may be used in a single procedure and an implant may have multiple components, the costs and benefits of the level of granularity at which UDIs should be recorded will need to be considered.

Include UDIs in Medical Device Registries: Participants discussed the possibility of enriching medical device registries with UDIs as a potential solution to issues related to the access and communication of important information to patients, providers, and other stakeholders. By linking device use and patient outcomes, participants highlighted that these databases have the potential to track outcomes associated with devices, predict risks associated with particular devices sooner through extensive population studies, and improve patient safety by facilitating the communication of urgent safety information particularly if the data were made available to specific stakeholder groups (e.g., researchers, patients). Additionally, participants indicated that registries could be customized to capture the right kind of data for each device, and therefore avoid structured data issues associated with other data sources (e.g., claims, EHRs). Participants also offered that if registries were built in a way as to support efficient communication across disparate data sources, they could serve as a centralized repository of information for these data sources to pull from. However, participants recognized that registries will likely have a number of important issues to address. One such issue raised by participants is that registries are generally built to contain sets of information related to a particular device, further fragmenting important information. Participants discussed the example of a drug eroding the surface of an implant as the type of problem that a registry may not be able to identify because information about the drug and the device will likely be kept in two separate registries or data sources. Additionally,

participants indicated that if registries are made specifically for particular devices or by different groups, the lack of standardized datasets across registries will make it difficult to conduct informative comparisons and studies across registries. Participants also put forward the use of a simple registry or database to link a patient who opts in and their contact information with a specific UDI. This could then serve as the platform for communicating device information to patients, as well as make possible the collection of important information from patients. Participants added that a third-party website could potentially host this database and that patients could have access to the website to view and update their information.

Develop Manufacturer-Specific Strategies: Participants also suggested a number of manufacturer-specific strategies with regards to communicating device information. One such strategy was for manufacturers to explore the potential of dynamic labeling for devices. This would allow manufacturers to replace the static information currently available to stakeholders through the device label with updates as new information regarding the device and its use becomes available. Participants emphasized the importance of this and other strategies in enabling manufacturers to compete not just on the value of their products, but also on the quality of their communications.

Collect Information from Patients: In addition to providing and communicating important device information, participants emphasized the need for a bi-directional flow of information so as to collect information from patients and providers about their experiences with devices, particularly with regards to adverse event reporting. One strategy participants offered for collecting this information was to allow patients to automatically upload their device data and electronically log their experiences in their electronic or personal health records. This, in turn, could allow providers to check on a patient's status or receive an automated alert if there are any issues. Additionally, participants discussed the promise of UDI as a common identifier that could facilitate information sharing capabilities among providers, particularly as part of new health care delivery models (e.g., included in continuity of care documents, shared across health information exchanges). Participants also suggested the possibility of developing a cloud-based network where patients and their providers could upload, access, and exchange relevant device information.

Other broad strategies discussed during the meeting included linking data from EHRs to registries, incorporating UDI into claims to conduct Sentinel-like activities, and employing an incremental approach by beginning with a narrow scope that addresses the most pressing needs and gradually building capabilities.

Key Considerations in Selecting and Implementing Above Strategies

Participants described a number of important considerations to take into account in selecting and implementing these strategies. During the discussion, one framework put forth for selecting an appropriate medium (e.g., EHRs, registries) focused on the communication and access to safety information as this area will likely be of demonstrable value to the majority of stakeholders. Criteria for this framework included the time of risk, the magnitude of risk, and the expressing action. In implementing the above strategies, participants also discussed the need for widely used and uniform patient identifiers to enable the above use cases by appropriately linking device information to patient details. Additionally, participants emphasized the need to thoroughly consider patient privacy, particularly at a time in which increasing attention is being paid to cyber security threats. Participants emphasized that this consideration will be particularly important because much of these strategies will require strong patient support, which hinges on trust regarding the safety of their information. To sidestep some of these issues, participants offered that patients may be inclined to voluntarily enroll if

they could quickly understand the value of sharing their information. Participants described that this is consistent with an observed rise in the amount of information patients are deciding to share in order to access some benefits (e.g., patient enters information online to automate making an appointment with their doctor). However, participants also noted that there may still be unwillingness on the part of patients, for example, to partake in a registry or offer their health records for postmarket surveillance or research purposes. In response, participants put forth the model of the health immunization databases, stating that if a public health need generated a strong demand for access to medical device information in the same way that it did for health immunization information, that this need may supersede some of the participation and privacy issues. These and other considerations will likely be important in implementing a successful strategy to ensure that these valuable uses are realized.

Next Steps

This meeting began an important conversation around the ways that UDI can assist in overcoming the challenges associated with moving from the current state, in which capabilities to communicate, access, and share important device information are limited, to a robust system that efficiently enables these activities across the medical device lifecycle. However, it is important to recognize that UDI alone will not resolve the associated issues; rather, UDI can serve as a tool to facilitate strategies for achieving these valuable uses, particularly if a plan for UDI implementation is designed with these end goals in mind. In order to realize this vision, it is clear that a range of stakeholders will likely need to be engaged in this effort. In particular, there will need to be a thoughtful consideration regarding what groups like FDA and the Office of the National Coordinator for Health Information Technology can do, what providers and patients will likely do, and what mechanisms to fund such efforts exist to find the points at which incentives across various stakeholder groups align. Additionally, a clear value proposition must be articulated to key stakeholder groups and the public in order to ensure the success of UDI implementation. With this in mind, Brookings hopes to use the input gathered from a variety of activities to develop a UDI Implementation Roadmap, which will be used by a range of stakeholders to articulate the value of UDI for specific groups and support the adoption of UDI in such a way as to enable many of the intended benefits.