ENGELBERG CENTER for Health Care Reform at BROOKINGS

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Discussion Guide

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

Workshop Background

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 providing physicians with new treatment options to address complex health issues. While these advances are noteworthy, there have also been recent examples of device failures leading to product recalls. For example, in 2011 St. Jude Medical recalled its Riata and Riata ST implantable cardioverter—defibrillator leads given premature insulation failure of the electrical conductor wires. At the time of this recall, an estimated 79,000 patients still had these leads.[1] Other prominent examples of device recalls include metal-on-metal hip implants and transvaginal mesh for pelvic organ prolapse. In cases like these, it is critical for actionable information to reach affected patients and their providers in a timely manner so that they can quickly understand the options available to them. This efficient flow of information is particularly 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. This workshop will consider the information needs of these patients and their providers and opportunities for improved patient-provider connectivity regarding implanted medical devices.

Patients and their caregivers have a wide spectrum of information needs related to medical devices. These needs 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 are likely to 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, it is clear that patients could play a more active role in their care if they had better access to information on the type of device they had or were about to receive. Having this information might 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. However, as described below, 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.

Providers also have diverse information needs with regard to medical devices, depending on 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 it, whereas a primary care physician caring

[1] U.S. Food and Drug Administration. (December 2011). FDA Classifies Voluntary Physician Advisory Letter on Riata and Riata ST Silicone Defibrillation Leads as Class I Recall. Retrieved March 8, 2013, from http://investors.sjm.com/phoenix.zhtml?c=73836&p=irol-newsArticle&ID=1640339.

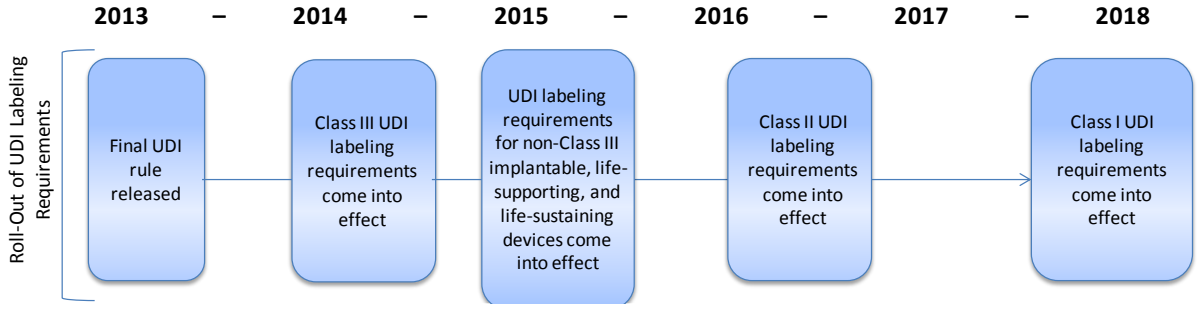
for a patient with an implanted device may only require information about the type of device and any related limitations or risks (e.g., whether a patient can safely undergo certain imaging studies). By having access to appropriate device information, physicians, nurses, physical therapists, home care 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 difficult for providers to efficiently access and communicate important device information as described below.

One of the primary challenges delaying development of 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 system for medical devices, Congress included provisions in the Food and Drug Administration Amendments Act of 2007 (FDAAA) mandating the United States Food and Drug Administration (FDA) to create a unique device identification (UDI) system that would enable identification of medical devices across the medical device lifecycle. 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, FDA published a Proposed Rule for the UDI system in the *Federal Register.*[1]

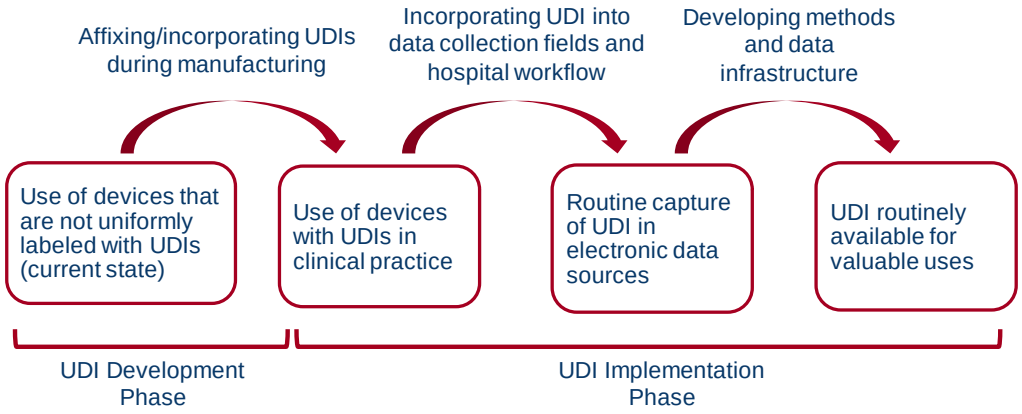
The Proposed Rule, which was available for comment through November 7, 2012, outlines proposed public health objectives, timeline, labeling requirements, and important exemptions and exceptions associated with UDI. It also details the components of the UDI, how the UDI should be generated and displayed (i.e., via plain-text and automatic identification and data capture forms), and the role of the accompanying Global UDI Database (GUDID), which will contain information on a set of standard fields submitted by manufacturers, such as brand, model, and clinically relevant size. Once the GUDID is operational, any interested party will be able to use a UDI to look up 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 resource to health systems, researchers, and other stakeholders invested in using UDIs to improve the supply chain, better understand device effectiveness, and conduct a range of other activities.[2] With certain exceptions, roll-out of these requirements will occur by device class (i.e., Class I, II, III) over a period of five years from the release of the Final Rule. Figure 1 shows an estimated timeline for roll-out of the UDI labeling requirements based on a 2013 release of the Final Rule.

Figure 1: Estimated Roll-Out of UDI Labeling Requirements



Currently, device 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 into their labeling mechanisms. This current lack of uniformity in device labeling has made it challenging, if not impossible, for other stakeholders to derive significant value from the available UDIs. FDA regulations will require UDIs to be assigned by device manufacturers. 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 Proposed Rule provides an important step toward ensuring medical devices are consistently labeled, 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 adoption of UDI by these stakeholders will require substantial motivation and effort in order to incorporate UDIs and associated standard data elements into health care electronic data systems and workflows. Once recorded routinely and stored electronically, it will be necessary to support the development of adequate data infrastructure and methods to ensure UDIs are useable by stakeholders.

Figure 2: 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. 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 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. 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.

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 safety information, easy access to important device information for patients and providers, and improved communication regarding devices between patients and providers. Although enabling each of these capabilities will certainly require 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.

Workshop Objectives

This workshop is designed to create an opportunity for patients and patient advocacy groups, providers, medical device manufacturers, academic researchers, and other relevant stakeholders to weigh in on 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 and providers. To facilitate the conversation around these use cases, this workshop is organized into three interactive sessions in which a few lead discussants will start the conversation with brief remarks, followed by an open discussion among participants in the room.

Session 1: Communicating Device Safety Information to Patients and Providers Using UDI

Efficient communication of device safety information is crucial to ensure, for example, that patients with devices are notified promptly of important safety information so necessary action can be taken, patients and their caregivers and providers generally understand the potential risks associated with use of a device, and recalled devices are not used. During this session, participants will explore the potential to leverage UDI and the GUDID in improving mechanisms for relaying safety information to providers, caregivers, and patients. Potential discussion questions may include the following:

- How can UDI and the GUDID enhance the ability for different stakeholders to push safety information out to patients and providers?
- What new opportunities (e.g., mobile apps) exist for facilitating the communication of safety information to patients and providers?
- What are some effective safety communication strategies from other industries that can be applied to medical devices? What role, if any, did unique product identifiers play in these recall strategies? How do patients prefer to be notified in the event of an issue related to safety regarding their devices?
- How can providers interact with their patients in a meaningful way to determine if a device safety concern applies to a particular patient? What new sources of information or information technology capabilities do providers need to support these interactions?

Session 2: Information Needs for Ongoing Care of Patients with Devices

As described above, physicians, nurses, physical therapists, home care workers, and other health care providers require access to device information in order to properly care for patients both before and after device implantation. Patients are also interested in accessing a variety of information related to devices, which could allow them to play a more participatory role in their care. This session will focus on the information providers need for routine care of patients with implants as well as the information needs of these patients. Participants will consider current frameworks for access to device information and workable strategies for facilitating access to important device information using UDI. Potential discussion questions may include the following:

- How can UDI improve the ability of providers, patients, and their caregivers to access needed device information?
- What current mechanisms for accessing device information exist for providers caring for patients with implanted medical devices? What current information gaps impede optimal ongoing care for these patients? How will the information needs of an implanting surgeon differ from those of a primary care provider?
- How can a provider quickly and efficiently access a patient's specific device information (e.g., in emergency care, while traveling abroad)?
- How do providers currently share patient information related to devices? What new opportunities (e.g., health information exchanges) exist for facilitating information transfer between providers? How can UDI improve vehicles for sharing device information?
- How can ongoing access to device information enhance continuity of care as part of new delivery models (e.g., accountable care organizations, patient-centered medical homes)? How can UDI be incorporated into efforts to drive adoption of these models?
- How can UDI facilitate the ability for patients to more effectively and independently understand safety issues related to their devices? For example, how can UDI be developed to allow patients to more easily detect problems with their devices or understand how their device may interact with other devices (e.g., in home care)?
- How should device information be made available using UDI so that patients and their caregivers have access to meaningful device information?
- How should GUDID data be exposed so that it is consumable for patient and provider access to device information? Are there additional data elements that should be considered for inclusion in the GUDID, in order to best meet the needs of providers and patients?

Session 3: Facilitating Enhanced Connectivity of Patients, Providers, and Others Using UDI
As patients increasingly share health information with each other, their families and caregivers, and their providers, it will be vital to understand and enhance the exchange of important, device-specific information. During this session, participants will draw on past experiences and pilots to identify potential approaches for using UDI to increase patient-provider connectivity and approaches for achieving broader connectivity of patients, caregivers, providers, manufacturers, public health agencies, and others. Potential discussion questions may include the following:

- How might UDI help to achieve the vision of improved communication between patients, distant care coordinators, providers, and other stakeholders in order to optimize care associated with medical devices? For example, how could patients be empowered to submit their own device information (e.g., adverse event reports via mobile apps) and providers be supported in efficiently communicating information to patients?
- How can UDIs be used to enable a seamless mechanism for patients to exchange important device information with other stakeholders in real-time? How can we build these capabilities into the existing health information technology systems? What data standards and data exchange methods will be necessary to enable these capabilities?
- What are the ways patients currently share information related to devices among themselves and potentially with caregivers in distant locations? How might UDI enhance these exchanges? How can UDI and improved patient connectivity support shared decision-making regarding medical devices?
- What pilot efforts might have important lessons to offer in this area?