ENGELBERG CENTER for Health Care Reform at BROOKINGS

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Discussion Guide

Identifying Steps for Implementation and Integration of UDI within Electronic Data Infrastructure of Care Delivery Sites

Workshop Background

Medical devices equip providers and patients with the tools needed to manage and treat a range of conditions in hospitals, medical offices, patient homes, and other settings. As medical devices have become more sophisticated and care delivery sites less centralized, the need for an effective monitoring system to better understand medical device use and the associated outcomes patients experience has become critical. Stakeholders from across the medical device lifecycle have recognized this need and highlighted the potential role of electronic data systems within health care delivery sites in facilitating this understanding. Administrative and clinical data systems are two broad categories of these electronic data systems that have particular importance for this effort. Each type of system provides important benefits for health care delivery sites and an opportunity to capture more device-specific information as part of the routine delivery of care.

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, when it comes to medical devices, current 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. This, coupled with error-prone manual device information entry, can make it difficult, if not impossible, to specifically identify medical devices. With greater access to more specific device information, health care delivery sites can streamline their administrative systems, thereby, augmenting their ability to track medical devices and efficiently deliver care to patients.

Clinical data systems provide health care delivery sites with rapid access to an array of patient information. Specifically, electronic health records (EHRs), laboratory management systems, and other clinical data sources allow providers to record and access information on many aspects of a patient's current health status and background, including medications, allergies, and interventions. 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 can 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.

It is clear that the first step toward improving understanding of medical device use and associated patient outcomes involves the development and adoption of a standardized medical device

identification system. To achieve this goal, stakeholder groups urged Congress to mandate the establishment of such a system. In response, 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 comment through November 7, 2012, includes in its proposed 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. However, while the Proposed Rule provides an important step toward ensuring medical devices are consistently labeled, in order to successfully leverage the UDI system and effectively use it to conduct a range of activities, there will clearly need to be broad adoption and subsequent 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 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.

One of the recurring themes of the Work Group's discussion at this initial meeting was the importance of ensuring that UDIs are consistently and accurately recorded in electronic data sources, particularly within payer claims and the administrative and clinical systems of health care delivery sites. Informed by this discussion, Brookings held its first expert workshop on UDI implementation on October 15, 2012. This workshop brought together diverse experts to explore the opportunities and challenges associated with incorporating UDI into payer claims; materials from this meeting can be accessed on the Brookings website. Also emphasized at the initial Work Group meeting was the importance of meaningful integration of UDI into the electronic data infrastructure at health care delivery sites to enable an array of benefits, including streamlining the supply chain, providing access to device information to inform provider point of care decisions, and creating enhanced mechanisms for device safety surveillance and effectiveness evaluation. While acknowledging these potential benefits, participants recognized that the task of achieving this goal is not trivial and requires broad stakeholder input and focus.

Workshop Objectives and Overview

This workshop is designed as an opportunity for a diverse set of providers, vendors, medical device manufacturers, academic researchers, and other relevant stakeholders to weigh in on the potential barriers and paths forward for capturing UDIs in the electronic data infrastructure of health care delivery sites. To facilitate the conversation on these topics, this workshop is organized into three interactive

[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.

sessions in which a few lead discussants will start the conversation with remarks, followed by an open discussion among participants in the room. Before these sessions, a representative from Mercy Health System's supply chain division, ROi, will present a brief overview of their pilot efforts integrating UDI from end-to-end across their electronic data systems.

Session 1: Tracking UDIs throughout the Administrative Systems: Incorporating UDI into the Internal Supply Chain and Billing Processes

During this session, participants will explore the most pressing opportunities associated with incorporating UDIs into administrative systems and the important technical and motivational considerations related to achieving this goal. Particular attention will be paid to the supply chain and billing processes that may be influenced by UDI implementation. Potential discussion questions may include the following:

- Within health care systems or provider clinics, what are the most important administrative systems for UDI to be included in?
- What mechanisms could be used to incentivize adoption of UDI in these administrative systems?
- Who will bear the burden of ensuring accurate and consistent reporting of UDIs into supply chain management systems? How can this burden be minimized?
- What are some strategies for capturing UDIs in the internal supply chain while reducing data entry error?
- What are some of the potential challenges associated with capturing UDIs in the item master? What are some of the potential challenges associated with capturing UDIs in the billing system?
- What are the next steps that can be taken to jumpstart UDI recording within administrative systems of care delivery sites?

Session 2: Understanding Device Use and Patient Outcomes: Capturing UDIs in Clinical Data Sources

Stakeholders from across the medical lifecycle have identified the potential importance of incorporating UDI into clinical data sources within health care delivery sites. This session will allow participants to explore this possibility, with a special focus on important standards, policies, and workflow implications. Potential discussion questions may include the following:

- What are the most important clinical data sources for capturing UDIs?
- What are the incentives (e.g., meaningful use) and regulatory levers that can be used to drive UDI recording in these clinical data sources?
- What standards could facilitate UDI reporting in these clinical data sources? What timeline and level of effort is associated with incorporating UDI in each standard?
- What role can UDI play in facilitating interoperability between clinical data sources and registries?
- What policies could be put in place to enable and encourage recording of UDI in clinical data sources? What groups are responsible for those policies?
- How does UDI align with and/or support existing health care initiatives within care delivery sites?
- What members of the care delivery team should be involved in recording UDIs in clinical data sources?
- What are some ways to minimize error in documenting UDIs in clinical data sources?
- How should recording of UDIs be prioritized to ensure enough clinical detail within clinical data sources without overburdening providers and other health care system staff?

- With various care delivery sites at different points in their ability to capture UDIs in clinical data sources, what is the best strategy for approaching implementation? What are some ways to minimize the burden, especially for smaller provider practices and health care systems?
- What role can groups (e.g., patient/consumer advocacy groups, professional societies, quality improvement organizations) play in facilitating adoption of UDI? What are the best mechanisms for gaining their support?
- What role could quality metrics play in encouraging adoption of UDI recording within clinical data sources?

Session 3: Leveraging Information: Integrating Across the Electronic Data Infrastructure
Meaningful integration of data systems within a health care delivery site can help make possible many of the important benefits of UDI implementation. Building upon discussions earlier in the day, this panel will be an opportunity for participants to consider this goal and identify potential strategies, taking into account the experiences of pilot efforts. Potential discussion questions may include the following:

- How can meaningful integration of multiple data systems across a care delivery site be achieved in order to realize the benefits associated with UDI (e.g., relaying device information to providers at the point of care)?
- What are the short- and long-term objectives and associated steps needed to begin incorporating UDIs across the electronic data infrastructure? Which of these should be considered and implemented first?
- What will be the key challenges associated with integrating the electronic data infrastructure within care delivery sites? How can these issues be mitigated?
- What lessons can be learned from previous experiences (e.g., pilots) within integrated delivery networks (IDNs) and large health care systems? What best practices can be derived from these previous efforts?
- To achieve a fully integrated system, what stakeholder hand-offs are most important to consider? What are some ways to ensure that these transfers are handled efficiently?
- What role can UDI play in facilitating interoperability between administrative systems and clinical systems?
- What incentives could be used to stimulate integration across the electronic data infrastructure? Which of these incentives is likely to have the most impact?