



Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation

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About the Engelberg Center for Health Care Reform at Brookings

Established in 2007, the Engelberg Center for Health Care Reform at Brookings is dedicated to providing practical solutions to achieve high-quality, innovative, affordable health care. To achieve its mission, the Center conducts research, develops policy recommendations, and provides technical expertise to test and evaluate innovative health care solutions.

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Executive Summary

The U.S. Food and Drug Administration (FDA) is establishing a national unique device identification system to adequately identify medical devices through their distribution and use. When the system is fully implemented, the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form. Device labelers must also submit certain information about each device to the FDA-administered Global Unique Device Identification Database (GUDID). The database, which will serve as a reference catalog of information about every device with an identifier, will be publicly accessible to allow all stakeholders—provider systems, payers, clinicians, patients, industry, FDA and others—to search, download, and use information in the GUDID. The UDI system, which will be phased in over several years, represents a landmark step towards improving patient safety, modernizing device postmarket surveillance, and facilitating device innovation. These promised benefits will only be fully realized with the adoption and integration of UDIs into the health care delivery system.

Adoption and use of UDIs across the health care system by provider systems, patients, payers, health information technology (HIT) developers, and many others can lead to significant improvements in the ability to deliver high-quality, high-value health care to patients. As the standard for communicating specific device information across major health care sectors, UDIs can unlock important information about devices at critical points in the delivery of care and facilitate optimization of device safety and effectiveness. For example, recording UDIs at the point-of-care (POC) in electronic health records (EHRs) and in claims data could significantly enhance the nation's ability to conduct medical device safety surveillance and manage recalls. Other benefits include: efficient identification and communication of device safety concerns, active learning about the long-term quality and performance of devices, facilitation of premarket device approval/clearance and expanded indications for existing devices, data collection to support better value, increased reimbursement

transparency, and more accurate and efficient supply chain processes. These activities are more readily conducted for pharmaceuticals because of the widespread use of National Drug Codes (NDCs) as the standard mechanism for communicating specific pharmaceutical information across the health care system.

The benefits of UDI implementation across the health care system are significant and, while the path to full implementation is complex, there are relatively straightforward steps that can be done now to begin realizing many of them. For example, two high priority steps that can be taken in the near term include enabling providers to scan and record UDIs into EHRs at the POC and motivating patients who receive device implants or use other major devices to demand the UDIs from their providers. A national “Know Your UDI” campaign can be an effective way to increase awareness of the importance of UDIs to patients and consumers.

Additional strategies include integrating UDIs into hospital inventory management and billing systems, and incorporating UDIs into administrative transactions. Further, integrating UDIs into easily accessible patient and consumer tools, such as personal health records (PHR) and mobile applications, would enable patients to receive safety alerts, obtain information about their devices, and potentially communicate patient experiences with devices. These capabilities may be valuable to patients and improve their experience within the health care system.

This roadmap includes examples of health care organizations that have already begun to take many of these steps, highlighting the benefits and costs of UDI adoption and use. For example, case studies by Mercy Health and the California Department of Health Care Services have demonstrated the benefits of unique device identification across health systems and administrative transactions respectively. Learning from their experiences and building on them can provide a framework for better care delivery and medical device interventions.

While UDI capture for the majority of devices, including devices transiently associated with patients (e.g., magnetic resonance imaging machines and infusion pumps), will bring significant value to the health care system and should be a priority, we focus this roadmap on the high-risk implantable devices, a device group of great public health importance and one that can inform the multitude of issues presented. Below is a summary of recommendations.

Summary of Recommendations

Integrate UDIs into Provider Systems

- Provider systems should incorporate UDIs into their electronic health records
- Adopting automatic identification and data capture (AIDC) technology can facilitate more efficient and accurate UDI capture in clinical settings
- Provider system executive leadership should sponsor a comprehensive strategy to guide operational and technical implementation of UDIs within their system
- Provider systems should automate important safety reporting with UDIs
- Provider systems should deploy pilot studies to highlight specific use cases and the return on investment for implementing UDIs across the three major data systems (e.g. supply chain, clinical, and revenue management)
- Provider systems should integrate the flow of UDIs across supply chain, clinical, and revenue-cycle management systems to more efficiently realize the benefits of UDIs
- The Office of the National Coordinator (ONC) and the Centers for Medicaid and Medicare Services (CMS) should support the incorporation of UDIs into EHR Certification Criteria and Stage 3 Meaningful Use (MU)

Integrate UDIs into Administrative Transactions

- Include the device identifier portion of the UDI as a situational element at the claim detail level for high-risk, implantable medical devices
- Link medical device registries to claims data integrated with UDIs
- Commission a payer-led pilot project to demonstrate primary and secondary benefits of UDIs in claims
- Include the DI portion of the UDI in payment and remittance advice
- Pursue the compliance and development of the DI portion of the UDI as a Health Insurance Portability and Accountability Act (HIPAA) code set to replace Common Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System (HCPCS) for medical devices

Integrate UDI into Patient-Directed Tools

- Patient advocacy groups, FDA, and other strategic partners should develop awareness among patients to request the UDIs of their medical devices from providers (i.e., “Know Your UDI” campaign); efforts could be led by patient advocacy organizations
- Patient and provider checklists and questionnaires should include the capture of UDIs for high-risk implantable medical devices
- PHR developers should integrate UDIs into PHR implementations.
- Consumer medical application developers should work in collaboration with patients, patient advocacy groups, and FDA to integrate UDIs into their web resources and applications.
- Patient advocacy groups, the National Library of Medicine (NLM), and the FDA should work in collaboration to develop tools that increase the accessibility and openness of federal databases containing UDIs and medical device information

Part 1: Background and Value of UDI Implementation

SECTION 1

Introduction

Medical devices are essential for the diagnosis, management, and treatment of a wide variety of conditions, enabling patients to live longer, more functional lives. The FDA Center for Devices and Radiological Health (CDRH) is charged with ensuring the safety and effectiveness of a great diversity of medical devices including implantable prosthetics, MRI machines, and *in vitro* diagnostics. Although FDA-approved devices are the global gold standard for device safety, recent failures in devices such as cardiac defibrillators and metal-on-metal hips have called public attention to the inadequacies in our system for assessing the continued safety and effectiveness of these devices once in use. Medical devices, especially implantable devices, may be permanently attached to a patient over their lifetime. As a result, tracking of these devices over long time periods becomes vital.

Postmarket surveillance of devices is more challenging relative to drugs and biologics due to fundamental differences between these types of medical products. For example, medical devices are diverse; they can be permanently implanted or temporarily attached to patients, they may have embedded software, emit radiation, or, in the case of *in vitro* diagnostics, they may include drugs or monoclonal antibodies. The FDA definition of a device encompasses a wide variation of entities, while excluding therapeutics relying on chemical action (see Glossary). These challenges are exacerbated by the iterative nature of device development and relatively short time a specific model of the device is marketed, the lengthy tracking period (especially for an implanted device), and challenges to optimizing device use due to the need for clinician training and technology adoption.

In addition, there is no robust system that can longitudinally collect data on medical devices and unambiguously link devices to individual patients so that important notifications can be sent to the care team and patient about problems associated with their devices. These difficulties are directly related to the lack of a standard for unique device identification. These constraints not only impede safety surveillance, management of adverse events, and analysis of device-specific clinical outcomes needed to measure quality and longtime safety of particular medical devices, but also impact overall transparency of postmarket surveillance of medical devices and even the nation's ability to facilitate premarket device approval/clearance and expand indications for existing devices (all of which depend upon a robust surveillance system).

I. Policy Background

The United States is in the midst of a major overhaul of its healthcare system and the basic models in which care is provided and funded. Actions taken by several independent entities responsible for promoting the nation's healthcare, including the current administration, the FDA and the Institute of Medicine (IOM), have collectively set in motion a cascade of changes to address persistent gaps in our healthcare system, including the postmarket surveillance of medical devices. A seminal 2001 IOM report underscored the importance of improving the HIT infrastructure, with a particular emphasis on EHR adoption.¹ This was followed by two 2011 reports outlining how progress in science, informatics, and care can align to create a "learning healthcare model" where the system collects data seamlessly to generate evidence for best practices.² Recognizing the need to modernize the nation's healthcare system, the Health Information Technology for Economic and Clinical Health (HITECH) Act (February 2009), provides incentives to promote an electronic system for healthcare operations by authorizing incentive payments through Medicare and Medicaid to eligible professionals.³ The goal was not only to implement EHRs, but also the "meaningful use" (MU) of EHRs and health information exchange (HIE). MU aims to use certified EHR technology to improve quality, safety and efficiency, and to reduce health disparities by setting MU objectives and criteria in describing the requirements to incentive payments.⁴

Of particular interest in MU is the barcode requirement for drugs along with electronic medication administration record (eMAR) tracking guidelines. Once such a tracking system is available for devices, these incentives can be extended to encapsulate the use of devices as well.

The Patient Protection and Affordable Care Act (ACA, March 2010) focused on provisions to expand coverage, control healthcare costs, and improve healthcare delivery.⁵ The current fee-for-service payment model for health care services is widely thought to be one of the major causes in driving up U.S. health care costs; the ACA creates several new Medicare programs intended to improve health care quality using “pay-for-performance” payment strategies. In this new system, providers will find that gathering evidence for the quality of care becomes crucial to maintain their competitive edge.

Paralleling these developments have been notable changes in the medical device space. Recognizing the need for need for better postmarket surveillance and patient access to device-specific information, Congress included provisions in Section 226 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), directing FDA to create a unique device identification system that would enable tracking and identification of medical devices. The Safety and Innovation Act (FDASIA), signed into law in July 2012, refined the requirements by stipulating certain deadlines. Under Title VI of the Medical Device Regulatory Improvements Section 605 of FDASIA, the FDA is required to establish a program to routinely and systematically assess information regarding device recalls and to use that information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. Sections 614 and 615 under the same title required FDA to issue a final rule for establishing a unique device identification system, taking into account patient access and to expand the extant postmarket risk and data analysis system for drugs (i.e., the Sentinel System) to include medical devices.

CDRH has been taking steps intended to improve regulatory processes related to the development and use of medical devices. In September 2012, CDRH released a report titled “Strengthening Our National System for Medical Device Postmarket Surveillance” and an updated report in 2013, which proposed five specific actions to improve the national system. These actions included:

- “Establishing a multi-stakeholder Medical Device Postmarket Surveillance System Planning Board;
- establishing a UDI system and promoting its incorporation into electronic health information infrastructure;
- promoting the development of national and international device registries;
- modernizing adverse event reporting and analysis; and
- developing and using new methods for evidence generation, synthesis and appraisal.”⁶

CDRH further declared that the system should specifically provide timely, accurate and systematic device information based on benefit/risk assessment throughout the marketed life of the device via standardized, structured, high quality electronic health data. In addition, the system should also be able to, in near-real time, identify potential safety signals from various privacy-protected data, reduce the cost and burden of device surveillance, and enable using this postmarket data to provide evidence to support pre-market requirements. The report also acknowledges the need for a robust system to complement current tools used for medical device postmarket surveillance. The Sentinel System is one such current tool and is a long-term program designed to build and implement a national system for monitoring the safety of FDA-approved drugs and other medical products using electronic data from routine care.⁷ As described in more detail in Section 2, the Sentinel System utilizes administrative claims data and some electronic clinical data from major commercial health plans in the U.S. in a national distributed data system. Because this system relies on unique identifiers to identify specific medical product exposures (e.g., NDC codes for drugs), the absence of unique identifiers for devices has rendered the system less useful for broad medical device safety surveillance.

The foundation for such a national postmarket surveillance system would be privacy-protected, routinely collected electronic health information containing UDI and device-specific registries in selected product areas complemented by additional data sources (e.g. adverse event reports, administrative and claims data). Such a system would have broad patient capture, real-world generalizability, scalable and reusable infrastructure, continuous accrual of information for near real-time analysis, and use structured data with standardized nomenclature and definitions.

The Brookings Institution, in collaboration with CDRH, is convening a multi-stakeholder National Medical Device Postmarket Surveillance System Planning Board. The Planning Board is tasked with identifying high-level governance structure, practices, policies, procedures, and business model(s) necessary to facilitate the creation of a sustainable, integrated medical device postmarket surveillance system that leverages and complements existing and on-going efforts. A final report of the Planning Board's recommendations is expected in early 2015. The Duke Clinical Research Institute and under the auspices of FDA's Medical Device Epidemiology Network (MDEpiNet) and in collaboration with CDRH is convening a Medical Device Registry Task Force. The Task Force is charged to: identify registries that could contribute to the national system described above; leverage registries to meet multiple needs such as quality improvement, comparative effectiveness research, and reimbursement; identify registry best practices; and identify "priority medical device types for which the establishment of a longitudinal registry is of significant health importance; and develop strategies for the use of registries to support premarket approval and clearance."⁸ Together the Planning Board and Registry Task Force will support the development of infrastructure that will be successful, in part, by leveraging the integration of UDIs across the health care sector.

II. UDI Final Rule

In response to the FDASIA, in September 2013, FDA published the Final Rule for a Unique Device Identification System that outlines how and when device labelers (which are also often the manufacturers, see Glossary) must include UDIs on device labels and packages, and in certain cases, directly on devices themselves.⁹ A UDI (see Appendix A: Unique Device Identifier Basics) is a unique numeric or alphanumeric code that comprises two parts: the device identifier (DI) and a production identifier (PI). The rule specifies that each UDI be provided in a plain-text version and in a form that uses automatic identification and data capture (AIDC) technology. These UDIs will be issued under a system operated by an FDA-accredited issuing agency. Compliance dates for UDI implementation will be phased in based on the existing risk-based classification of medical devices:¹⁰

- September 2014 for devices classified by FDA at the highest risk level (Class III)
- September 2015 for implantable, life-supporting or life-sustaining devices
- September 2016 for moderate risk (Class II) devices
- September 2018 for low risk (Class I) devices

Following this same timeline, device labelers must submit data on the DI portion of the UDI and a standard set of basic identifying elements for the device to the FDA-administered Global Unique Device Identification Database (GUDID) (see Appendix B: Global Unique Device Identification Database). The GUDID is designed to be a publicly accessible reference catalogue of device information for every device with an identifier, with data intended to be searched, downloaded, and used by all stakeholders in the ecosystem. It is important to note that the GUDID will not contain any proprietary or patient information.

III. UDI Implementation

The UDI Final Rule primarily deals with device labelers' development of UDIs, their placement on device labels and packages, and submission of this information to the GUDID. As illustrated in Figure 1, full UDI implementation will require other stakeholders, including physicians, hospitals, payers, and patients to integrate UDIs to their respective systems. Distributors and provider inventory management systems should

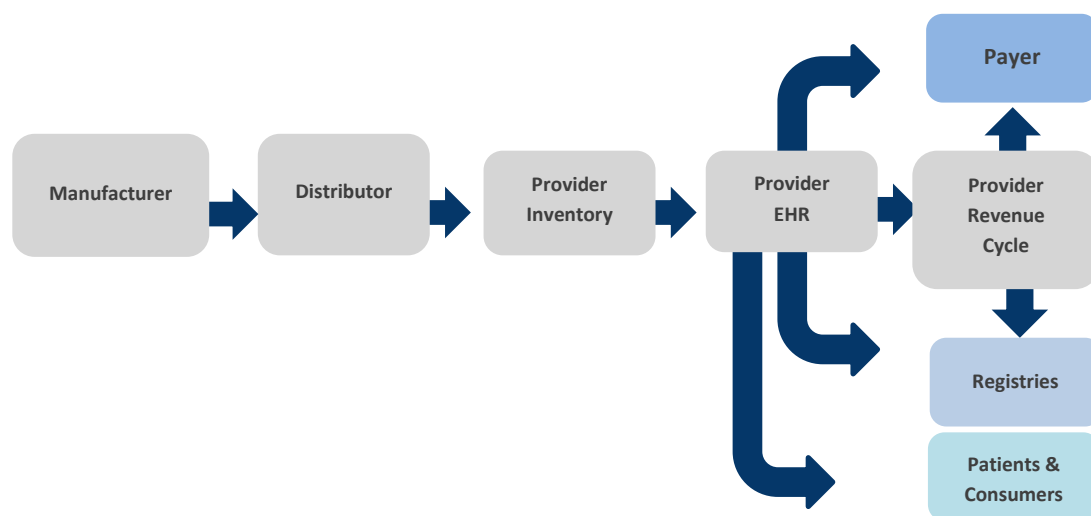
have the ability to capture and transmit UDIs so that device-specific information can flow seamlessly from manufacturer to provider. From there, UDI capture at the POC is critical since this is where the device information is connected to individual patients who receive treatment with that particular device. The main data repository in which providers can capture UDIs are via patient EHRs. UDIs captured via EHRs can link specific devices to individual patients which can then be transmitted to payers for reimbursement purposes, to registries for safety surveillance and tracking device effectiveness, to providers who require patient and device intervention histories (e.g. interventional radiologists), and to patients to provide up-to-date information regarding their implanted devices.

These steps align well with the Institute of Medicine's recommendation to "improve the capacity to capture clinical, care delivery process, and financial data for better care, system improvement, and the generation of new knowledge,"¹¹ as well as the goals of enhanced quality of care and patient safety through advancement of EHR and health information exchange (HIE). In line with these IT advancements, special attention should be paid to the technical and workflow aspects of UDI implementation and integration of databases so that UDIs can flow seamlessly to facilitate recording and storage of specific device information into electronic health care databases, including EHRs and personal health records (PHRs), registries, and health insurance claims.

Currently, efforts are underway to create a field for UDIs in EHRs. Incentives provided through the MU criteria outlined by the ACA will play an important role in motivating providers to adopt UDIs via their EHR systems; UDIs will enable providers to generate the evidence regarding the quality of care provided to patients through medical devices. UDIs will not only equip providers with the ability to track which patient has what device and to communicate more effectively with patients regarding the devices they use, but will also facilitate assessment of the quality of these devices and their value in terms of patient-specific clinical outcomes. UDIs will also permit transparency to the process, allowing payers to be more cognizant of the specific devices they reimburse.

At a population level, device-specific information can be collected for meta-analysis across provider systems and via registries. These changes driven by UDI implementation will greatly benefit patients by improving the quality of care, reducing cost and empowering patients by providing up-to-date knowledge regarding their medical devices and allowing them to be well informed when making shared decisions with their providers.

Figure 1: Overview of the Transmission of Medical Device Data through Health Care Systems



IV. Roadmap Structure

In order to help stakeholders successfully adopt UDIs, FDA charged the Brookings Institution with developing a roadmap for integrating UDIs across the healthcare ecosystem. The Engelberg Center for Health Care Reform (ECHCR) at the Brookings Institution, under a cooperative agreement with FDA and Chickasaw Nation Industries (CNI), LLC engaged stakeholders to begin determining important elements of a successful UDI implementation strategy. A work group of diverse expert stakeholders was convened to inform ECHCR's UDI implementation activities in July 2012. This group identified key use cases, strategies, challenges, and features of successful UDI implementation. At the meeting, the UDI Work Group members identified three themes that needed in-depth study: UDIs in claims, UDIs in the electronic data infrastructure of care delivery sites, and UDIs as a tool for improved patient and provider connectivity. The foundation for the roadmap for UDI implementation targeting different stakeholders is based on recommendations of the work group.

The target audience of this roadmap is stakeholders contemplating or actively pursuing the adoption of UDIs into their systems and enablers that can help create such a system. This interdisciplinary group comprises not only major stakeholders such as provider organizations, payers, registries, clinicians, patient interest groups and patients, but also consists of government entities such as ONC, the Agency for Health Research and Quality (AHRQ), and CMS, standards organizations such as HL7, and EHR vendors, etc. The goal of this roadmap is to illustrate the value of UDIs across the medical device healthcare ecosystem, demonstrate the value for each major stakeholder, identify challenges to integrating UDIs into the each stakeholder system, and provide mitigating strategies and recommendations across all major stakeholder groups. Due to the enormity of the task and the level of detail involved in implementing UDIs across all classes of devices, we focused on effective UDI implementation for high-risk implantable devices across the healthcare ecosystem.

The roadmap is laid out with the following organization: Section 2 (Benefits of UDI Achieving Successful UDI Implementation) demonstrates the value of implementing UDIs across all healthcare stakeholders. Section 3 discusses integration of UDIs into provider systems and identifies the deficiencies in the existing system for linking specific devices to individual patients and subsequently measuring clinical outcomes. The section demonstrates how the adoption of UDIs can mitigate these challenges and highlights the value that can be derived by UDI implementation across clinical, supply chain and revenue cycle systems. It also provides key strategies for UDI implementation; analysis of case studies of successful integration of UDIs at provider sites show that leadership, operational and technical strategies are all equally important. A case study of a provider system successfully integrating UDIs is included in the appendix. Section 4 discusses integrating UDIs into administrative transactions. Currently, billing data contain the most comprehensive records on individual patient encounters. Due to the lack of interoperability within and across provider systems, patient EHRs are not capable of communicating events such that devices can be tracked over time as patients move between providers. Therefore, the capture of UDIs through claims data provides useful information linking patients to specific devices across provider systems and over time. Section 5 explores various tools that can be employed to access UDI information by patients and consumers. Section 6 contains conclusions and a storyline of two hypothetical patients Woody Smith and Linda Hayes and their hypothetical encounters with UDI-affixed devices across the healthcare system. These scenarios are intended to provide a better picture of how patient experiences and care can be improved with UDIs. We outline clinical scenarios for Woody, who is in need of a knee replacement and Linda who already has a pacemaker and needs to replace the wires of her pacemaker through different stakeholder settings, to highlight and make actionable an idealized depiction of successful implementation of UDIs across the entire healthcare ecosystem. This concluding section is followed by an appendix and a glossary.

SECTION 2

Benefits of Achieving Successful UDI Implementation

The unique device identification system has the potential to bring significant value to the health care system by enhancing the ability to deliver safe and high quality care. Large health systems and payers can benefit from improved medical device tracking across settings, improved efficiency, and opportunities for cost reduction. Virtually all stakeholders, including such diverse groups as the patients, clinicians, health systems, payers, FDA, other federal agencies, researchers, supply chain personnel, HIT developers and especially patients, can benefit from enhanced postmarket surveillance, development of evidence of risk-benefit across the total product life, recall management, and transparency. While many benefits span multiple stakeholder groups, full implementation and utilization of UDIs will bring value to all major sectors of the health care system. Just as a vehicle identification number (VIN) can enable a consumer to make more informed decisions before purchasing an automobile, support consumer access to specific safety and recall information, and facilitate reporting of potential safety problems,¹² the value of UDIs derives from their role in unlocking and enabling the transfer of critical information about medical devices.

By linking devices to important information on device attributes, quality, performance, and cost from a variety of potential sources, use of UDIs across the health care system can support safer and higher quality care with devices. More specifically, UDIs can facilitate transfer of information to support decision making at the point-of-care (POC); improve the efficiency and effectiveness of recall management and safety communication; enable more robust population-based evidence development on device safety and effectiveness; facilitate premarket device approval/clearance and expanded indications for existing devices; provide opportunities for improved reimbursement and purchasing models that drive towards better value; and enable more efficient supply chain processes and health care operations management.

The benefits of UDI implementation across the health care system are significant and, while the path to full implementation is complex, there are relatively straightforward steps that can be done now to begin realizing many of them. For example, encouraging and supporting patients to request UDIs from their providers and enabling providers to record and gain access to UDIs at the POC can go a long way toward realizing the benefits of UDIs. In parallel, system wide progress toward more integrated and interoperable health systems, including continued adoption and utilization of HIT, increased interoperability between HIT systems across settings, and continued development of clinical data storage standards will further help to support UDI integration and uses.

In expectation of national progress on these fronts, this section details the specific use cases and potential benefits that UDI adoption and implementation could bring. These benefits are summarized in Table 1 on the next page.

Table 1. Benefits of UDI Implementation

BENEFIT THEME	ADVANTAGES
Enhanced Ability to Deliver Safe and High Quality Care to Patients	<ul style="list-style-type: none"> • Provider access to critical device information • Patient access to device information and shared decision-making
Improved Recall Management	<ul style="list-style-type: none"> • Improved recall process • Efficient communication of safety information (i.e., alerts) to patients and providers
Evidence Development to Support Safe and High Quality Care	<ul style="list-style-type: none"> • Medical device safety surveillance • Medical device comparative effectiveness and patient-centered outcomes research • Tracking of medical device utilization patterns and analyses of appropriateness of care • Improved ability to support ongoing quality initiatives • Support for medical device innovation
Improving Transparency, Reimbursement and Value	<ul style="list-style-type: none"> • Increased medical device reimbursement transparency • New opportunities for value-based purchasing and other support for enhanced value
Improve Efficiency in Health Operations Management	<ul style="list-style-type: none"> • Improved supply chain integration and management • Identifying networked and telemetric medical devices • Emergency preparedness and response • Fraud detection • Anti-counterfeit detection

I. Enhanced Ability to Deliver Safe and High Quality Care to Patients

The most fundamental benefit that UDIs can bring to patients and providers is their ability to unlock information critical to delivering safe and high quality care to patients. As the volume and diversity of digital medical information available at the POC increases exponentially, managing the information flow efficiently and effectively to inform POC decisions becomes increasingly challenging. For medical devices, uncoordinated and often missing information on devices can contribute to lost opportunities for patient education, suboptimal care coordination, lack of shared decision-making, potentially missed device failures, or safety issues, and other problems that lead to poor outcomes. Currently, information specific to a particular manufacturer's model of device is difficult to obtain, partly due to the lack of comprehensive accumulation of evidence on the performance, value, and patient experiences with the particular devices when used in clinical practice (see later in this section), or if such information is available, it is difficult to obtain efficiently because there is not a single standardized identifier that could be used as the key to accessing the information. Successful UDI implementation presents a pathway towards enabling the development of better evidence on device safety, performance, and quality, as well as an opportunity to seamlessly communicate device information to and between providers and patients.

In this section, we discuss how UDIs could lead to safer and higher quality of care by enabling efficient access to information about devices and their uses to patients and providers. For providers, this includes enabling more efficient access to critical information about specific devices and about patient-linked device history for improved care coordination. For patients, this includes more efficient access to device information that could lead to improved shared-decision making.

Provider Access to Critical Medical Device Information

Information needs before, during, and after clinical encounters differ among providers, especially when it comes to medical devices, depending on their clinical focus and specialty. For example, specialists who implant devices surgically may seek information on a specific manufacturer's device version or model that is crucial before or during surgery (e.g., size, expiration date, components made of latex). The UDI itself would serve as the key that the clinician could use to obtain this specific information. For candidate devices that the surgeon might be considering, the surgical suite and/or hospital's clinical software could be linked to the facility's device inventory, to the GUDID, and to other external information via UDIs. This could enable the surgical staff to have real-time access to unambiguous, accurate, and standardized device attributes and other relevant information such as recalls or safety alerts. The capability to record the specific UDI of the utilized device as a searchable field in the EHR would give subsequent providers more efficient access to specific device information when needed.

In the context of subsequent care, primary care providers, emergency department clinicians, and other providers who care for patients who have or use medical devices may need real-time information on recall status, signs of potential device malfunction, and other maintenance considerations at the POC. In many cases, the provider in the outpatient settings may have limited experience with particular devices or have incomplete medical history on the patient under their care. If the UDI of the device in question was already recorded into searchable fields in the patient's medical history and/or hospital discharge sections of the EHR, important device information could be quickly obtained by the clinical staff through online information sources. This could reduce staff time spent tracking down the device brand name, manufacturer, serial number, lot number, etc., from a sticker in the procedure notes or by contacting the surgeon who performed the procedure (if known). Further, background research on the specific device could be conducted more accurately and efficiently if relevant information were obtainable via a known UDI. This would enable clinicians to more quickly diagnose and/or prevent potential device-related problems as well as to better coordinate follow-up care. In this sense, UDIs can alleviate problems with medical records being incomplete, unclear, or in a problematic format.

The scenarios described above illustrate how UDIs could enable more efficient access to device-specific attributes and recall status, which will help to improve the quality and efficiency of care. Furthermore, routine usage and recording of UDIs into the EHRs, claims data, and other electronic data sources will enhance opportunities to develop population-based clinical evidence on the safety, appropriate uses, patient experiences, and outcomes attributed to specific devices. These data would become more readily accessible by clinicians and patients, who would have improved ability to make more informed decisions. More details on these aspects are covered in the "Evidence Development to Support Safe and High Quality Care" section.

Patient Access to Device Information and Shared Decision-Making

Current research and initiatives have highlighted the strategic value in keeping patients informed and engaged with their own medical care.¹³ Recent efforts such as patient portals and the Federal Blue Button campaign have positioned patient engagement as a core goal to long-term health care improvements.¹⁴ Building on these efforts, the recording, storage, and retrieval of UDIs could increase the ability of patients to document their experiences with devices and to utilize UDIs to access publically available information specific to their devices. With this information, patients could become more active participants in their care and participate in shared decision-making.

One of the key challenges to increasing engagement is addressing varying levels of information need. For example, patients who are about to use or have implanted a new device may seek information on a specific device's performance, safety and lifestyle considerations, etc., in order to set realistic expectations. Once patients have a device, they may become alarmed if they learn that there is a Class I device recall for a particular device that may or may not be the same as the one they have. For either example, by knowing the UDI, patients could seek out recall or other lifestyle information that is specific to the device's version or model by using blogs and other Internet sources. Development of effective patient-directed and consumer friendly tools, such as patient portals and mobile applications, that allow bidirectional information flow (i.e., that utilize UDIs to record and provide relevant device-specific information) and have appropriate privacy protections, could enable patients and consumers to become more informed and engaged. Taken further, if patients see direct value in such information, this could generate positive feedback that leads to increased demand for device information and for their providers to document and record UDIs. As in the VIN example for automobiles, UDIs would have a direct role in helping to ensure that this information is tied to a specific version or model device.

However, the availability and usefulness of the information to patients will depend on how well manufacturers, researchers, and patient advocacy organizations leverage the accumulating information on devices and patient experiences to prioritize research and data analytic activities toward topics that are most meaningful to patients. These activities and making the results accessible to the public will be more manageable with UDIs.

As this information becomes more routinely collected and appropriately shared, it could be used to develop better population-level evidence on actual patient experiences with devices. Such results could provide feedback to patients to further inform their care and inform device developers for continued product improvement. With appropriate privacy standards and procedures in place, this information could lead to better higher-quality care for patients.

It should also be noted that long-term and sustainable gains made from UDI adoption and implementation in the institutional and private sector could be most supported and magnified by increasing the patients' and the public's knowledge of UDI and its benefits.

II. Improved Recall Management

Recent examples of critical device failures have called public attention to the need for an improved system of medical device safety surveillance and recall management. One such example was St. Jude Medical's 2011 recall of the Riata and Riata ST implantable cardioverter-defibrillator leads resulting from premature insulation failure of the electrical conductor wires. At the time of this recall, an estimated 79,000 patients still had these leads.¹⁵ A 2011 Government Accountability Office Report highlighted findings regarding a recalled pacemaker with a seal that degraded and exposed the device to moisture. In this case, 1,732 of 23,987 relevant devices failed to be recalled due to missing records.¹⁶ Other examples include DePuy's 2010 ASR hip system recalls prompted by international total joint replacement registry data and patient morbidity from a wide variety of metal-on-metal hip implants.^{17,18}

Without UDIs to quickly identify affected devices, the recall process will continue to remain complicated, laborious, and costly. The recall process not only corrects device defects, but notifies end users of potential risks and steps to minimize the impact of the device failures, as defined in FDA's regulation. At this time, when a recall occurs, manufacturers issue statements describing the cause of the recall and the devices affected, and for high risk devices, they will often publish serial and lot numbers of the devices being recalled. FDA then distributes these statements to medical professionals and the general public. This is an ineffective way to reach all patients or medical personal who may come into contact with the affected patients. Full UDI adoption and implementation into data infrastructure is essential for improvement.

Many recalled devices have not yet reached patients, and therefore require the supply chain personnel to search stock inventories for affected devices. By providing unique and unambiguous identifiers, the integration of UDIs into supply chain data systems will enable the majority of recalled devices to be quickly identified before being exposed to patients. Some recalled devices may reach the operating room (OR) or surgical suite, and it is essential for the clinical staff to identify recalled devices prior to patient exposure. Use of AIDC technologies like RFID and barcode scanners in the ORs and surgical suites at the POC would allow clinical staff to be immediately notified if a device had been recalled prior to its use in a procedure. This capability would depend on integration of UDIs with real-time device recall information within the clinical software used within hospitals.

Finally, for the few device recalls that affect devices that have already reached patients, all patients with the devices must be notified quickly. This is a significant burden on clinicians and their office staff. Patient mobility makes delivery of safety messages to patients with recalled medical devices problematic because manufacturers often have outdated contact information. If UDIs are scanned at the POC and documented in the POC system and EHR, this system could be queried via UDI to generate a patient list, thereby avoiding significant time and cost burden while improving accuracy and appropriately maintaining privacy. In addition, if UDIs are included in the administrative transactions such as claims, payers could help identify all members with a specific recalled device in near-real time, regardless of provider and setting, and issue personalized notifications. Coordination among payers, providers, and manufacturers could ensure a much more effective and efficient recall process with the use of UDIs; however, this is dependent on proper recording and storage of UDIs in a searchable form within supply chain, clinical and administrative data systems. Patient-directed tools such as the FDA MedWatcher mobile application could also greatly benefit the process by leveraging UDIs to disseminate important safety messages to patients and the public.

III. Evidence Development to Support Safe and High Quality Care

A key element to delivering safe and high quality care to patients is the ability to learn from clinical practice. Development of better evidence on safety, effectiveness and other outcomes meaningful to patients is essential for informing patient and provider decision-making on the best care for a particular patient. In the last decade, increased attention has been placed on the ability of the U.S. medical community to deliver safe and high quality care. The landmark Institute of Medicine (IOM) reports, *To Err is Human* and *Crossing the Quality Chasm*, highlighted concerns about medical safety and quality issues within the U.S. health care system.^{19,20} These reports asserted that the nation needed to improve the effectiveness of health care by addressing wasteful and harmful medical practices.

However, delivery of highly effective, efficient, evidence-based care is constrained by current difficulties in using electronic clinical information for the development of better evidence. The lack of effective integration and standardization of electronic clinical information across the health care system has led to calls for the development of a system that has the capacity to generate and use scientific evidence in the delivery of care,²¹ or what the IOM calls the “learning health care system.”²² As a result, stakeholders have been engaged in efforts to establish efficient mechanisms for tapping into underutilized electronic health information, thus enabling a broad spectrum of valuable uses. These efforts are at risk for missing much needed information regarding medical devices in the absence of widespread implementation and adoption of UDIs. Documentation of UDIs during routine medical care across health care databases, including EHRs and administrative transactions, is needed to enable longitudinal tracking of important device outcomes.

In this section we identify five areas of population-based evidence development that can improve the quality of care patients receive with medical devices, including: (1) medical device safety surveillance; (2) comparative effectiveness and patient-centered outcomes research on medical devices; (3) tracking of medical device utilization patterns and analyses of appropriateness of care; (4) improved ability to support ongoing quality initiatives; and (5) facilitation of continuous product improvement.

Medical Device Safety Surveillance

With the input and active participation of key domestic and foreign stakeholders, FDA is building a framework to strengthen the nation's device postmarket surveillance system. The goal of the enhanced system is to improve the ability to quickly identify poorly performing devices, accurately characterize and disseminate information about real-world device performance, including the clinical benefits and risks of marketed devices, and efficiently generate data to support premarket clearance or approval of new devices and new uses of currently marketed devices. A cornerstone of this strengthened system is the incorporation of UDIs into EHRs, clinical information systems, claims data sources and registries, potentially making vast amounts of previously untapped clinical information available to facilitate total-life cycle performance and safety assessments of medical devices. The system, as envisioned, will augment a number of existing data sources and surveillance strategies that work to accumulate evidence concerning medical device postmarket safety.^{23,24} These approaches rely on various methods and techniques tailored to the specific device and public health need, but can be limited by a lack of integration and timeliness.

Medical Device Reporting: Each year, the FDA receives several hundred thousand medical device reports (MDRs) of suspected device-associated deaths, serious injuries, and malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products. The FDA's Manufacturer and User Facility Device Experience (MAUDE) database houses MDRs submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities, i.e., hospitals, ambulatory facilities, nursing homes and outpatient centers) and voluntary reporters such as health care professionals, patients, and consumers. Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete or inaccurate data, under-reporting of events, lack of denominator (exposure) data, and the lack of report timeliness. Inclusion of UDIs by submitters of adverse event reports would lead to greater accuracy in reporting by eliminating uncertainty about the identity of the device, resulting in improved analysis and more rapid action to address safety issues.

Postmarket Studies: Medical devices approved by FDA under the pre-market approval (PMA), protocol development product (PDP), and humanitarian device exemption (HDE) applications can be required by FDA to show continued evidence of safety and effectiveness through post-approval studies ordered at the time of approval.²⁵ Typically, post-approval studies (PAS) are used to assess device safety, effectiveness, and/or reliability in the real-world setting, including long-term effects. The PAS can also be used to assess the learning curve, the effectiveness of training programs and how well the device performs in certain groups of patients.

FDA can also require that manufacturers of certain Class II or Class III devices conduct postmarket surveillance studies (often referred to as "522 studies" for Section 522 of the Food, Drug and Cosmetic Act) when the FDA has evidence that failure of such devices may pose serious adverse health consequences or by the nature of their use.²⁶ During 522 studies, sponsors develop and initiate a plan to conduct postmarket analysis of medical devices with appropriate study design and methodology agreed upon in coordination with FDA. Study approaches vary widely and may include non-clinical device testing, analysis of existing clinical databases, observational studies, and, rarely, randomized controlled trials.

Medical Product Safety Network: In 2002, the FDA launched the Medical Product Safety Network (MedSun) as an enhanced surveillance network of about 250 hospitals nationwide that work interactively with the FDA to better understand and report on device use and adverse outcomes in the real-world clinical environment. MedSun utilizes a Web-based system that facilitates the secure transmission of adverse event data from participating facilities to the FDA. Partnering hospitals participate in medical device surveys, assess recall effectiveness, conduct educational forums, and submit high quality, actionable reports.

Medical Device Registries: Medical device registries also comprise a specialized role in postmarket surveillance. Medical device registries collect and maintain structured data on diseases, conditions,

procedures or devices for specific populations.²⁷ Registries can derive information from various electronic health data sources, and are usually maintained and governed independently from the systems and organizations participating in the registry. As an example, the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) developed the Transcatheter Valve Therapy (TVT) registry as a benchmarking tool to track patient safety and real-world outcomes related to the transcatheter aortic valve replacement (TAVR) procedure. The TVT Registry is designed to monitor the safety and effectiveness of the TAVR procedure through the capture and reporting of patient demographics, procedure details, and facility and physician information.²⁸ In addition to tracking patient safety data and outcome data, the registry also provides useful information to regulators and payers. For example, the FDA recently expanded the use of transcatheter valve therapy based on data from the TVT Registry.²⁹

Registries must capture a wide variety of data elements in a standardized way, such as the device type and version number, the components that comprise the device, the provider that prescribed the device along with his or her experience and training, and the various types of issues that can affect device performance.³⁰ Without this information consistently captured, or easily accessible, information sharing and reporting become increasingly difficult.

Sentinel Initiative: A promising initiative by the FDA to engage in active surveillance is the Sentinel Initiative (Sentinel), launched in 2008. Sentinel is a distributed network of payer and provider organizations that work collaboratively with the FDA to collect and query privacy-protected data (primarily from administrative transactions and some clinical data) to track and monitor medical product adverse events. The Sentinel System is being actively used to assess potential safety concerns on prescription drugs and vaccines using data from over 126 million Americans.³¹ Despite Sentinel's early success, it lacks adequate coverage of medical devices due to the absence of manufacturer and brand-specific identifiers for medical devices in administrative transaction and clinical data. The Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) mandated that the Sentinel system expand to include medical devices.

Safety Surveillance using Administrative Transactions: Incorporating UDIs into administrative transactions such as claims will provide a valuable supplemental source of data for postmarket surveillance systems, where historically such data have been underutilized for analysis of medical devices. Administrative transactions present unique opportunities due to the centralized collection of administrative transaction data among payer organizations, as opposed to the more fragmented provider system HIT environment. The future utility of Sentinel for medical devices will largely depend on UDI adoption into administrative transaction systems among payers. Collection of UDIs by provider systems and payers should supplant the need to engage in the costly and time-consuming process of cross-mapping between the currently fragmented medical device identification standards.

Standard identification of specific medical devices will be a notable enhancement for current postmarket surveillance approaches and a critical component in the FDA's framework for building a national postmarket surveillance system. Integration of UDIs into existing and future strategies, both public and private, will play a pivotal role in building active, timely postmarket surveillance support for medical devices. Current identification standards for medical devices either encompass entire classes of medical devices (e.g. HCPCs, CPTs) in one code or vary significantly among manufacturers (e.g., catalogue numbers). Researchers will be able to more accurately monitor device performance for exact types and brands of medical devices with UDIs. The informational value of UDIs will be highly dependent on the clinical data, administrative transactions, registries, and patient-directed tools that are able to both collect and link UDI with relevant patient health information.

Medical Device Comparative Effectiveness and Patient-Centered Outcomes Research

Medical devices that are approved to be marketed and sold for clinical use in the U.S. often have limited evidence supporting their safety, performance quality, and value in real-world settings. Regulators often

depend on randomized clinical trials (RCT) to provide evidence of medical product safety and effectiveness, but RCTs often are inadequate in predicting or measuring real-world performance, quality, and value. Such assurances are even weaker for medical devices where approximately 1 percent of medical devices are required to submit to RCTs for regulatory approval in the U.S. The majority of medical devices that are approved by the FDA are either exempt from premarket review or go through the 510(k) process where clearance is based on substantial equivalence to a predicate device, typically without extensive new evidence requirements. This leaves stakeholders with even less information on the safety and effectiveness of a medical device.

Comparative effectiveness research (CER) has provided much needed evidence on the impacts of these interventions on outcomes meaningful to patients, clinicians, and sometimes payers in the real-world clinical setting, thus filling many evidence gaps. Using observational study methods and utilizing longitudinal clinical and administrative data from EHRs, claims, registries and other sources, CER provides an efficient and lower cost way of developing evidence from actual clinical practice. The IOM believes it is likely that by 2020, “90 percent of clinical decisions will be supported by accurate, timely, and up-to date clinical information, and will reflect the best available evidence.”³² However, without implementation and use of UDIs, this could be an unrealistic goal for medical care with devices.

Despite increased attention to CER on the national stage to transforming health care practices, economic, structural and policy-related challenges remain. To address these challenges, the American Recovery and Reinvestment Act of 2009 (ARRA) appropriated \$1.1 billion to support a national CER infrastructure. This initial investment seeded the Patient Protection and Affordable Care Act’s (ACA) establishment of the Patient-Centered Outcomes Research Institute (PCORI), and authorized the Federal Coordinating Council (FCC) for Comparative Effectiveness Research to prioritize and coordinate CER activities across federal agencies. AHRQ, academic research, patient advocacy efforts, and the establishment of the PCORI have emphasized making CER more patient-centered, an approach also known as patient-centered outcomes research (PCOR). PCOR seeks to enhance CER by providing answers that will specifically inform patients and caregivers to facilitate their own health care decision-making. PCOR focuses on data that measure value and on patient-centered metrics that are specifically captured to assess the patient experience.

Unfortunately, these efforts have not been as widespread for devices since many existing data sources of electronic health information are deficient of identifiers for the specific version or model of medical devices. Consequently, current methods for many large-scale studies of medical devices require active and costly data acquisition, including manual review of records for device information that is often buried in PDFs, unstructured text, and hand-written notes. Capturing UDIs and linking them to relevant device and patient information in electronic health information such as EHRs, PHRs, and claims during routine care could substantially lower the cost of CER studies, while increasing their scale and value.

High quality CER on medical devices could improve patient and provider treatment decisions that can directly benefit decision-making and the quality of care patients receive. For example, factors that might otherwise be obscured, such as minor differences in medical devices (e.g., size, shape, materials) or how a particular device affects a specific cohort of patients (women, overweight, etc.) may be more efficiently captured through the availability of UDIs. Evidence from CER on devices also generates additional benefits that include designing better care coordination and disease management programs, informing clinical practice guidelines, and informing payer coverage decisions.

Prospective observational studies have also been used specifically to provide earlier access to promising medical devices while developing better evidence that can be used to support coverage decisions by CMS and private payers. Medicare’s Coverage with Evidence Development (CED) is a tool that has been used for such purposes. CMS codified CED into policy in order to provide Medicare beneficiaries with access to promising treatments and procedures, but for which little clinical evidence existed within the senior population (which is typically underrepresented in trials). Within CED, physician payment under a provisional coverage determination for the technology is provided conditional on participation in a registry designed to

capture the outcomes of treatment. As evidence accrues, CMS can choose to either: discontinue provisional coverage; apply a National Coverage Determination (NCD), expanding full coverage to the entire Medicare population; or potentially grant coverage for a small subset of patients in which the treatment is shown to be effective.

To date, the CED has been hampered by a number of challenges that have significantly limited success. In general, there has been limited infrastructure for collecting the additional data needed to develop better evidence. Individual CED programs have had to be bootstrapped to other existing efforts in order to be implemented, and have faced difficulty in assembling a coalition to support the effort; without leveraging existing resources, CED programs impose significant additional costs on the manufacturers and provider systems involved in setting up and sustaining the infrastructure. CED could be more efficiently conducted by acquiring the ability to link registries to claims and EHR data (as in the TAVR case); such an enhancement could reduce provider burden and reduce the costs for registry maintenance. UDIs could help improve the applicability and usefulness of these additional data sources by including the ability to identify specific versions or models of devices and linking them to outcomes.

Tracking of Medical Device Utilization Patterns and Analyses of Appropriateness of Care

While CER and PCOR involve the design and conduct of rigorous research studies that formally test hypotheses comparing two or more interventions, electronic health data offer many other opportunities to gain important insights into the quality, value, and cost of care. The usefulness of these data depends on the context of use, the decision-maker using the data, and the methods applied to the data. The data can range from simple rate counts of the numbers of patient using particular devices to evaluating the impact of devices on important outcomes. For example, if UDIs were stored in their respective data systems, large health systems, payers, and manufacturers could track the volume, frequency, and context of use of specific medical devices within the populations they care for or manage. This could lead to more informed decisions on resource allocation. Linking exposure to specific medical devices to clinical and economic outcomes could further help identify gaps in care, patient populations for whom particular medical devices lead to better care, and measure the impact specific devices have on total cost of care. Cost-effectiveness analyses of specific devices could help providers and payers make more informed decisions about developing programs intended to improve outcomes and lower total costs.

Limited efforts to capture comprehensive medical device information at the POC and across organizations have also been a barrier to tracking medical device utilization patterns. UDIs could serve as a foundational standard on which to build point-of-use systems across supplier and delivery systems. AIDC technologies like RFID and barcode scanners can reduce the burden of tracking how and when medical device are used across multiple systems.

Improved Ability to Support Ongoing Quality Initiatives

The current trend in health reform by payers and providers has moved from fee-for-service (FFS) payments that reward volume and intensity toward alternative payment models (APMs) that reward better outcomes for patients at lower overall cost. With the parallel rapid formation of accountable care organizations (ACOs), providers are taking on more financial risk if their care does not result in better outcomes and associated reductions in waste. Success of these efforts is directly dependent on collecting and using data from routine practice that can be used to measure outcomes, track quality improvement, and determine overall costs of care. For procedures that involve implanted devices, the ability of providers and payers to track and report the impact of specific devices on quality measures and outcomes could be directly enabled by the adoption and implementation of UDIs within EHRs and claims databases. This ability could also support the development of new APMs, such as bundled payments, that are specifically tied to particular medical devices.

Recently, the Office of the National Coordinator for Health Information Technology (ONC-HIT) released in a “notice of proposed rulemaking” that UDI capture would be a component of future voluntary EHR certification. This development might enhance certain quality initiatives if UDIs can serve as a key identifier

able to link medical devices and various clinical data for quality assessment. Such recognition and incentives from the federal government help the long-term sustainability and inherent value of UDIs as a tool to advance the quality of health care.

Support for Medical Device Innovation

Currently, most of the regulatory evidentiary requirements for device approval occur in the premarket space. Postmarket data can sometimes be used to supplement pre-market information in order to satisfy evidentiary requirements for product approval of a similar device or to expand the device label to a larger population, thereby reducing the time and cost of developing a medical device. Under certain circumstances (unmet needs), some of the premarket requirements for a novel device can even be shifted to the postmarket. Regulators apply stringent premarket requirements prior to approval in part because of the presently inadequate measures for postmarket surveillance and the inability to gather reliable information while the device is being used in the real-world setting. This scenario is further exacerbated by the inability to uniquely identify specific devices and link them to patient information with relevant clinical outcomes. Therefore, in the current environment, it is difficult to prove the quality and effectiveness of a particular device while it is in use.

FDA's vision for the future of device postmarket surveillance depends on the creation of a national system that not only generates information to quickly identify poorly performing devices and other safety problems and accurately characterizes the real-world clinical benefits and risks of marketed devices, but also facilitates the development of new technologies, new devices, and new uses of currently marketed devices through evidence generation and analysis. Examples of how such a system could support innovation include producing data to serve as the comparison group in device performance studies, identifying new patient populations that benefit from device therapies, leveraging the expansion of labeled device indications to new groups, and demonstrating the relative safety of a device type to support down classification and a reduction in the premarket evidentiary needs.

IV. Improving Transparency, Reimbursement and Value

Reimbursement by payers for medical devices that are used during hospital procedures is usually provided by a single bundled payment for the procedure itself, which is intended to cover all medical services for the procedure, including any medical devices used. Traditionally, Medicare payment for hospital-based procedures that involve implantable or other types of devices is based on Medicare-Severity Diagnosis-Related Groups (MS-DRG). The MS-DRG system is predicated on a set of fixed payment rates based on the average treatment costs for a group of bundled services defined by specific diagnoses and other clinical characteristics.³³ Private payers typically follow Medicare payment methodologies or other methodologies that include some form of global payment rate for a bundled set of services. For procedures in the outpatient setting, Medicare uses the Ambulatory Payment Classifications (APC) system to provide payments of services billed. Private payers also use the APC or related fee-for-service payments.

Regardless of the payment methodology used by the payer, billing codes are necessary for the provider to communicate to payers what procedures were actually performed. The International Classification of Diseases, Clinical Modification (ICD-9-CM) Procedure codes and hospital revenue codes are billing codes used for procedures in the inpatient settings, whereas the Healthcare Common Procedure Coding System Level II (HCPCS) codes, which are based on Common Procedural Terminology, 4th edition (CPT-4), are primarily used in outpatient settings. In a few cases, such as in drug-eluting stents, HCPCS codes can be used for payment for specific brand devices (and therefore their identification can be captured in the claims data), but for the vast majority of devices, these procedure codes are not specific to the actual devices used. As a result, these procedure codes cannot be used to link specific devices with the associated procedures, which hinders subsequent efforts to correlate specific devices with safety, effectiveness and value outcomes.

As an important consequence of the lack of specificity of procedure codes for specific devices, hospitals and clinics are at financial risk if the negotiated reimbursement for the procedure does not cover the cost of the specific device used, as the cost for different makes and models of devices used for the same procedures can vary widely. This situation can create unintended incentives for facilities to use lower cost devices without much evidence on the performance or effectiveness trade-offs, if any.

If UDIs were included in the administrative transactions, such as the claims process, payment schemes could be reformed to provide payment that account for the specific devices used. This would increase transparency between providers and payers and identify potential areas to reduce waste, particularly for high-cost implantable devices. For example, this could alleviate some of the financial risk that hospitals incur when using covered devices since they would be reimbursed for that specific device. For payers, this could provide an opportunity to reimburse specifically for lower cost devices that have equal performance and outcomes to the higher cost alternative. For patients, this could also improve transparency in the value and cost of care they receive, since their explanation of benefits (EOB) could include the specific devices used, their cost, and how much the health plan covered. An indirect benefit of including UDIs into the claims transaction process would be the accumulation of device-specific data within the claims that could be used to track outcomes, quality and cost, and to support ongoing initiatives aimed at improving value. Optimally, payment for the actual cost of devices and reductions in the use of medical devices with substandard patient outcomes could represent significant value for the health care system. Furthermore, use of UDIs by payers could also create opportunities to enter into new purchasing agreements directly between manufacturers and payers, potentially allowing for negotiated discounts if there were data accumulated to demonstrate value.

V. Improved Efficiency in Health Operations Management

Providing high-quality and patient-centered health care is becoming increasingly dependent on the efficiency of medical delivery supply chains and operations. Before a medical device has any contact with a patient, it must traverse an exceedingly complex and opaque supply chain. The prevalence and range of uses for medical devices has increased as more stakeholders escalate the sophistication of their operations and clinical offerings. Despite these developments, there have been few efforts by provider systems to integrate distribution, supply chain, delivery logistics and administrative transactions. Such efforts are largely hindered by the lack of digitized medical device information and data synchrony across the value chain.

UDIs present clear advantages in the ability to link medical devices with their clinical use, supply logistics and cost. Operational efficiencies gained from being able to track both high-cost and high-volume medical devices will be critical in a health care environment that increasingly emphasizes quality along with risk-sharing, pay-for-performance, and bundled payments.

In this section we identify six primary use cases to illustrate the role of UDIs in improving efficiency in health operations management, including: (1) improved supply chain integration and management; (2) identifying networked and telemetric medical devices; (3) emergency preparedness and response; (4) improving fraud detection; and (5) anti-counterfeit protection

Improved Supply Chain Integration and Management

Medical device distributors, group purchasing organizations (GPOs) and provider systems utilize supply chain data systems to communicate with each other regarding inventory management. Efficient systems integration across the supply chain is vital for enabling health care systems and providers to track inventory and optimize supply quality and volume in order to minimize disruptions in patient care.

Current provider system supply chain operations suffer from inefficiencies caused principally by a lack of data standards and process automation. Few provider systems have access to a unified supply chain standard for medical device identification and product attributes. Distributors and provider systems will often develop expensive proprietary standards and systems or rely on subjective estimates of inventory levels in an effort to

avoid costly surpluses or dangerous deficits in supply. In addition, capture of medical device information is often manual and error-prone. Such limitations mean supply chain administrators often have difficulty in accurately and reliably tracking the acquisition, use, location and quality (e.g., expiration date) of medical devices across the different divisions of the organization.

By employing a standard way to communicate the identification of a specific device's make, model, expiration date, etc., UDI integration into the supply chain could improve the speed and accuracy of data entry (e.g., with AIDC technology), data cleaning and adjudication, elimination of redundancy or use of duplicative identifiers, more accurately predict demand, optimize inventory turnover and maintenance, and better determine specific medical device return on investment. The ability to accomplish these activities more efficiently and accurately would allow providers to provide optimal care to their patients.

Optimizing UDI integration within the supply chain will require implementing the requisite automatic identification and data capture (AIDC) technology. UDIs coupled with AIDC and point-of-use technology would allow administrative and clinical staff to quickly capture and collect data on the medical devices in their system without the need for manual entry or paper ledgers. Adoption of AIDC technology reduced inventory loss at one major health system to 1 percent, where the average is often 15-20 percent.³⁴ In a pilot demonstration, Mercy Health was able to electronically manage the expiration dates of their medical devices, shifting from a system in which boxes were marked with color-coded sticky notes to an electronic system that produces reports of the inventory closest to expiration for immediate use (see Appendix C: Mercy Health Case Study). This, in turn, provided significant cost savings to the system, and helped strengthen support for an integrated approach to UDI adoption.

Another study by a large provider system and medical device manufacturer to integrate medical device data standards observed 30 percent reduction in outstanding days payable and 73 percent reduction in data inconsistencies through the adoption of a single unified standard on purchase orders.³⁵ With UDI integration into the procurement process, provider systems will be able to link medical device cost data, logistics, and utilization for improved insight into how their devices are used across the system. These data can then be analyzed to assess device purchasing and usage trends, with the intent to forecast future demand. This improved value assessment flows to the patient, leading to higher quality, patient-centered health care.

Emergency Preparedness and Response

Furthermore, improved inventory maintenance and management would be of vital importance for emergency preparedness. Integrating UDIs into supply chain and emergency logistical software could improve the ability to match medical devices with emergency personnel trained in their use, enhance the ability to query and locate medical device inventory, and rapidly identify devices as part of medical countermeasures. A provider system that is able to integrate UDIs into EHRs would be better equipped to provide emergency medical services, and to retain medical device tracking ability after the emergency event for provider follow-up. This UDI-enabled tracking could help to reduce or mitigate any treatment errors or suboptimal treatment, as variability in care often increases during public health emergencies.³⁶

Identifying Networked and Telemetric Medical Devices

Advanced technology groups and industry analysts predict that industries will increasingly incorporate "Internet of Things" (IoT) technology to connect physical objects with a synonymous virtual object that can be tracked, modified and analyzed across networks.³⁷ IoT technology enables devices to respond to dynamic environments and provide autonomous feedback to monitoring systems in real-time.

Care delivery sites consist of an amalgam of both analog and digital systems that are often unconnected and unsynchronized. This fragmentation of systems prevents adequate measures to safeguard against machine failure, human error, and data loss. One investigation into medical device internal time synchronization found that of 1,700 medical devices at four world-class medical institutions, 20% were off by more than 30 minutes,

with an average error of 24 minutes across all devices. Such disparities in time have important implications for the timing of critical medical interventions.³⁸

Though difficult in the absence of interoperable data and communication standards, linking medical devices to centralized and synchronized suites of IoT technology could unlock a number of methods to enhance care coordination and medical outcomes. Such suites or integrated clinical environments (ICE) could improve real-time safety notifications for life-critical devices, management of chronic disease, and elderly support systems for at-home care.^{39,40} Tagging medical devices with radio-frequency identifiers (RFID) or other AIDC technologies could assist in efforts to log, maintain, and locate medical devices and equipment across provider systems. Networked and interoperable medical devices could also enable manufacturers and vendors to conduct continuous product improvement analysis on the delivery and performance of their products and services.

Establishing these networked and interoperable systems requires a system for classifying and identifying specific medical devices and their attributes. UDIs could serve as a standard identification system for each unique medical device that interacts with medical device delivery operations or services. IoT technology is expected to exponentially increase the amount of data available to store and analyze. Structuring this data using UDIs as a key identifier could simplify how medical devices are integrated into IoT systems.

Fraud Detection

Fraudulent billing regarding the use of medical devices represents a critical issue for payers and provider systems seeking to improve their systems. Resources that are absorbed in compensating for fraudulent medical device usage increase the waste present in the national health system. The U.S. government has recovered over \$23 billion dollars since 1997 from fraudulent medical usage, including medical devices, through the Health Care Fraud and Abuse Program (HCFAC).⁴¹ CMS has led highly publicized efforts to curb waste, fraud, and abuse in medical device billing, particularly for durable medical equipment (DME) primarily used in home settings.⁴² Medical device fraud can be perpetrated in numerous ways, and often involves forged documentation, up-billing for more expensive equipment not used, and minimal or no verification of medical necessity. These tactics often exploit billing and authorization procedures because of the lack of verification and authentication at the point-of-use. In addition, detection of overbilling and fraud is data intensive. Even as data analysis methods improve and fraud detection accuracy increases, the timely identification of fraudulent activity is critical, but remains hindered in a non-digital environment. EHR adoption should continue to assist in making fraud detection easier; however, gaps will remain if left unaddressed. UDIs will be a valuable tool for stakeholders to fill those gaps in protecting their resources and patients from fraud.

Payers and provider systems should find UDIs to be a preventative and proactive tool to combat fraudulent billing and inappropriate use of medical devices. Since fraud detection can be a data intensive process, UDIs can serve as a key identifier for linking medical devices across stakeholder medical IT systems, thus enabling more in-depth analysis and inspection. When paired with administrative transactional data, such as claims, UDIs could improve fraud detection efforts to target medical devices that are not justified as a medical necessity. Payers, in particular, have an incentive to capture UDIs to unambiguously identify medical devices used in a patient's care, which can otherwise be problematic if billing codes are too nonspecific (e.g. Healthcare Common Procedure Coding System). Medical record auditing measures can also be improved in both speed and accuracy with the combination of EHRs and UDIs. Pairing a patient's medical record with their UDI means that providers take a more active role in assessing which specific medical devices their patients are receiving and for what purposes. Auditors can more easily access these records because they are digital and can utilize central UDI repositories like the FDA's GUDID to verify device version or model. Pilot projects exploring the value of UDIs have already reported valuable gains in preventing and reducing fraud by linking billing codes found in claims with medical device purchases by providers.⁴³ Increasing the fidelity and quality

of medical device information will only serve to enhance transparency and deter malicious agents from exploiting the system.

Anti-Counterfeit Detection

Device integrity and effectiveness underpin the foundational relationship of trust between patients and the manufacturers and provider systems that deliver the care they receive; counterfeit medical devices sever this trust. Counterfeit medical devices include devices that either mimic an approved device or make fraudulent claims towards their effectiveness or condition.

UDI implementation presents a pragmatic solution to identify devices that may be counterfeit. If UDIs are fully adopted across the supply chain, the absence of a unique identifier for any medical device could alert stakeholders along the medical device value chain of possible counterfeit activity. Stolen devices that are being illegally resold could be flagged in a manner that far exceeds the speed of counterfeit mitigation measures used today.⁴⁴ The GUDID might also be leveraged to quickly identify the extant supply of legitimate medical devices.

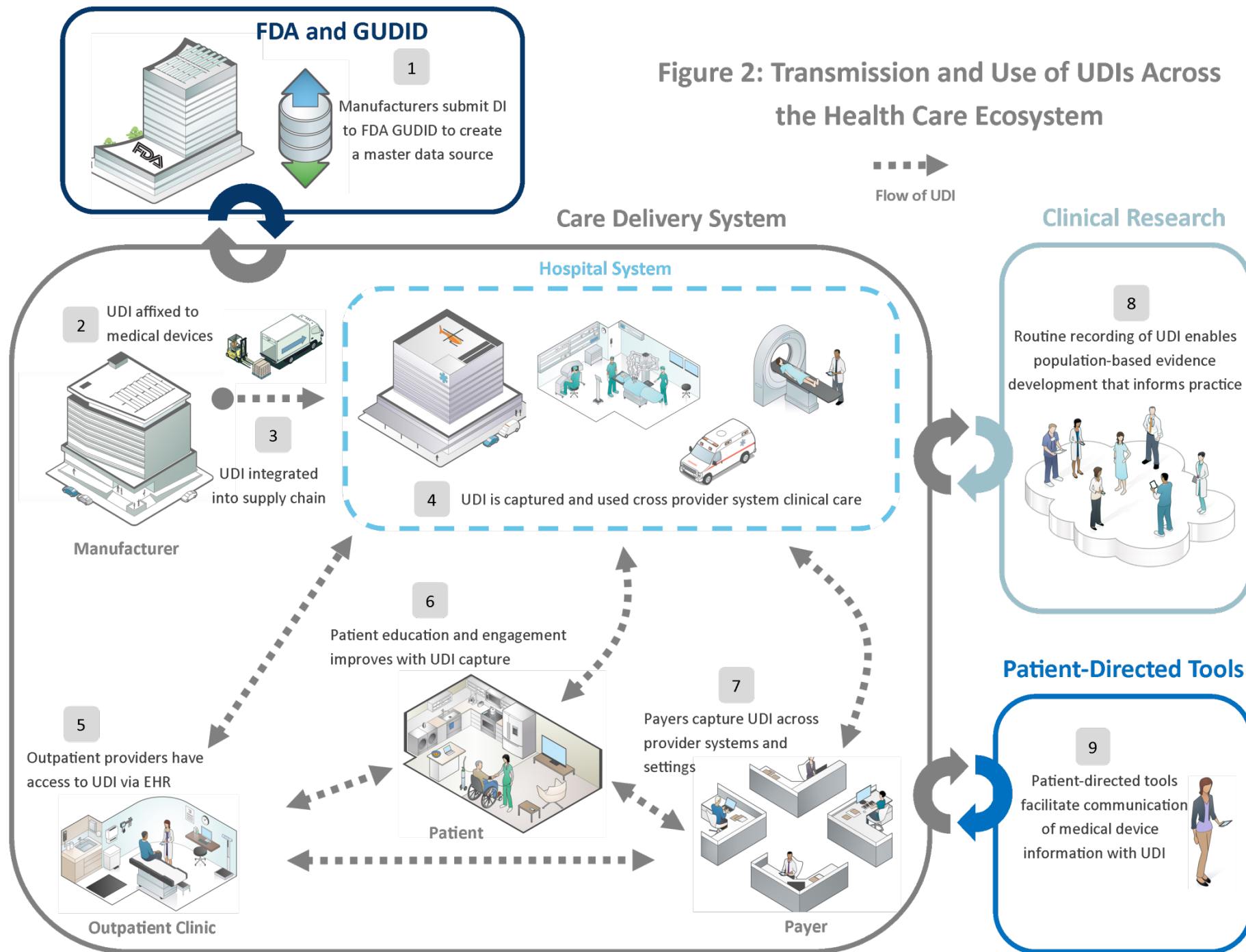
With over half of all medical devices coming in from across US borders, verifying medical device integrity in transit is a global endeavor.⁴⁵ UDIs could be used in conjunction with other anti-counterfeit technology such as the FDA's Counterfeit Detection Device CD-3 to bolster screening efforts at the border and beyond. UDI could serve as a component to verification standards by establishing crosslinks with the GUDID and manufacturer databases for device authentication. As medical devices become increasingly ingrained into patient's lives, stakeholders should look to use UDIs as a central tool to protect against the threat of counterfeit devices.

Part 2: Strategies for UDI Implementation

The point where manufacturer compliance with UDI regulations ends is where the need for implementation strategies begins for health care stakeholders who stand to benefit from UDIs. Section 3 covers the distinct strategies for implementing UDI across the health care system, including integrating UDIs in provider systems; administrative transactions; and patient-directed tools. In an optimal scenario, simultaneous perusal of each specific strategy would aid in the capture and utilization of UDIs across the total breadth of the nation's health care system. This framework is depicted in **Figure 2** on the next page.

In this framework, UDI is envisioned to form the technical foundation for linking medical device information across the regulatory, care delivery, clinical research, and patient domains.

Figure 2: Transmission and Use of UDIs Across the Health Care Ecosystem



SECTION 3

Integrate UDIs into Provider Systems

Medical devices are an essential component of provider systems that deliver safe and high-quality health care to patient populations. Provider systems face the complex and difficult task of identifying, acquiring, utilizing, maintaining, tracking, determining value and seeking reimbursement for a wide-variety of medical devices to meet patient needs. Each provider system maintains supply chain, clinical, and revenue-cycle management data systems that, while differing in technology, sophistication, and scale between provider systems, fulfill specific functions within each provider. Standardizing and synchronizing medical device data across these functional systems is a current limitation.

Supply Chain Data Systems

Efficient supply chain function and inventory management are fundamental to ensuring safe and timely delivery of medical devices to patients. The ability to quickly survey which items are in stock, may need replenishment, are close to expiration, and need to be removed due to recall, are some of the important activities that supply chain systems are designed to accomplish, but are currently challenged to achieve partly due to the lack of standardized identification for medical devices.

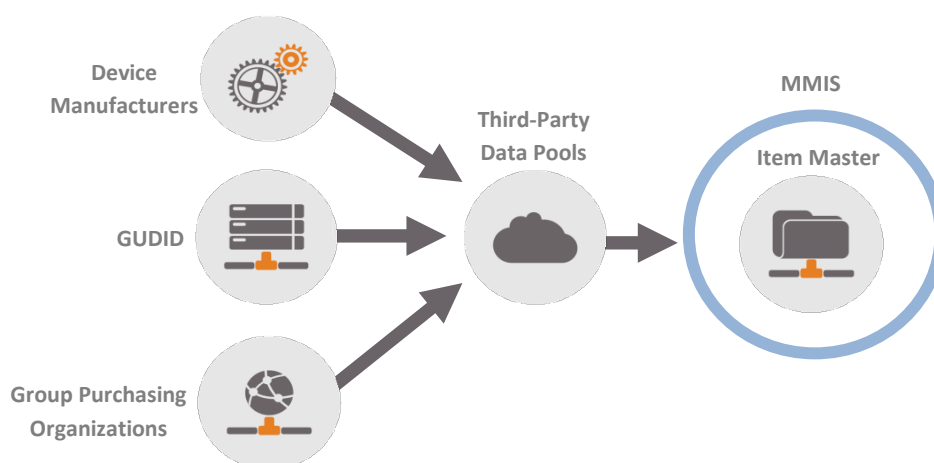
Medical devices typically first enter provider systems through procurement and supply chain systems. Supply chain data systems facilitate management of the provider's internal supply chain, track the movement of items within a care delivery site, allow for appropriate and accurate purchasing, and perform a host of other necessary functions. Efficient communication across the internal supply chain is crucial to enabling provider systems to monitor their inventory, ensure the quality of their stock, and manage recalls effectively.

Larger provider systems often develop highly scalable and structured enterprise resource planning (ERP) databases that organize their medical device information for track and trace ability at the point of care. ERPs and related database systems are largely synonymous with “supply chain data systems” in this roadmap; however, the rationale underlying subsequent strategies can be applied to less sophisticated systems with reasonable adaptations.

The principal components of a supply chain data system include the item master and materials management information system (MMIS). The MMIS serves as the platform for provider system supply chain activities and draws medical product information from the item master, which acts as a data repository. The item master serves as a primary source of information for items and materials used regularly throughout the provider site, including medical devices. Item master databases are populated and maintained generally by supply chain personnel within a particular provider site and may have anywhere from hundreds to tens of thousands of regularly procured items. Development and maintenance of item masters can also be contracted out to third-party developers. Third-party developers work to maintain the quality of data in the item master and send regular updates to the provider system item master. As shown in Figure 3, supply chain data can originate from many sources including device manufacturers, GPOs, and soon the GUIDID. Third-party developers are making increasing usage of web or cloud-based technology to manage and aggregate this diverse medical device information off-site and online to ensure data synchrony, consistency, and rapid updates.

Once a device arrives at the care delivery site, typically a non-standardized identifier is scanned or manually entered into the MMIS. The MMIS system then draws associated product information from its item master. In the case of many implanted devices (e.g., cardiac pacemakers), the device is brought to the POC by a distributor or manufacturer representative and its data are not entered into the item master, but instead captured, occasionally for clinical and billing purposes.

Figure 3: Synchronizing Medical Device Data with Cloud-Based Solutions



Clinical Data Systems

Once medical devices arrive at the POC, a variety of clinical data systems are involved in the administration and use of medical devices on patients. EHRs, operating room software suites, laboratory management systems, and other systems all play an important role in allowing physicians, nurses and others at the POC to quickly record and access information related to patient health status and medical history. HIT systems such as clinical data warehouses, which collect information pulled from the EHR and other administrative databases, and health information exchanges (HIEs) that facilitate the storage and transmission of patient data, increase the efficiency of data flow through the clinical data infrastructure.⁴⁶ For example, some provider systems allow patients to enter information upon patient arrival (e.g., age, gender, smoking status) and tie that information to a unique patient ID that is printed on a wristband. The patient ID is then scanned at any location within the provider site that the patient visits and pulled into the EHR. The EHR then serves as an aggregator for clinical and patient information.⁴⁷

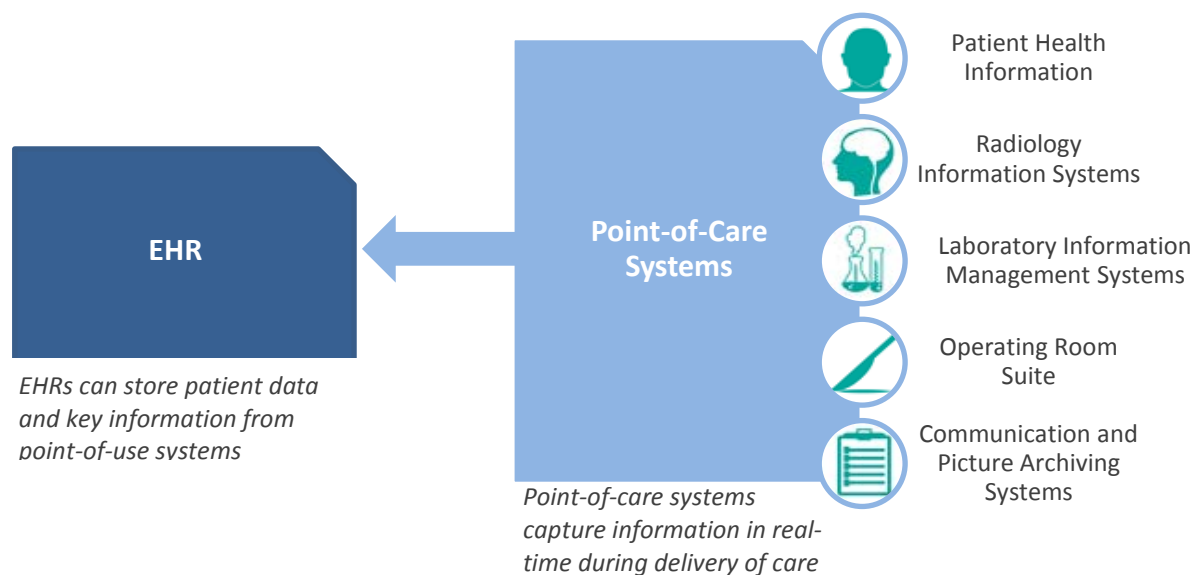
STAKEHOLDER EXPERIENCE

Difficulty in Identifying Implants in Revision Total Hip and Knee Surgeries

Total hip and total knee arthroplasties (THA/TKA) are common orthopedic procedures that involve implants with multiple components. With a more active population receiving these implants, aging baby boomers, prevalence of osteoarthritis and other factors, the rates of revision THA/TKA are expected to rise. Access to device-identifying information from primary THA/TKA impacts surgeons' ability to identify failed implants for revision THA/TKA. In a study conducted by Wilson et al., an estimated 41 hours of physician and staff time annually are expended on identifying failed implants (with median surgeon time as 20 minutes per case and median staff time as 30 min per case). This underscores the inadequacy of processes to attain specific device information. Ready availability of UDIs for implanted devices as part of the patient data and clinical data systems would streamline efforts to identify failed implants in revision THA/TKA, reducing the amount of time and resources expended on these efforts currently. complications and improve patient health.

As shown in **Figure 4**, diverse systems that each support important functions allow the site to efficiently conduct a wide range of care delivery activities. In addition, clinical data repositories, and health information exchanges, which facilitate the exchange of patient information across these systems, can support secondary functions including quality improvement, research, query-based care and clinical operations.⁴⁸ Ideally, this information should follow the patient over the course of their care.

Figure 4: Relationship between POC Systems, EHRs and the Patient Dataset



The benefits of successful EHR adoption have been widely discussed and recognized, and significant investments in incentivizing adoption have been made across the health care system. Yet, many EHR implementations lack the functionality to store device-specific identifiers or supplemental device information. Some EHR vendors include optional modules to capture medical device information, but the information captured is often limited and the module's optionality discourages use by front-line clinical staff. This prevents providers from accessing important medical device information as they would be able to do for drugs and biologics.

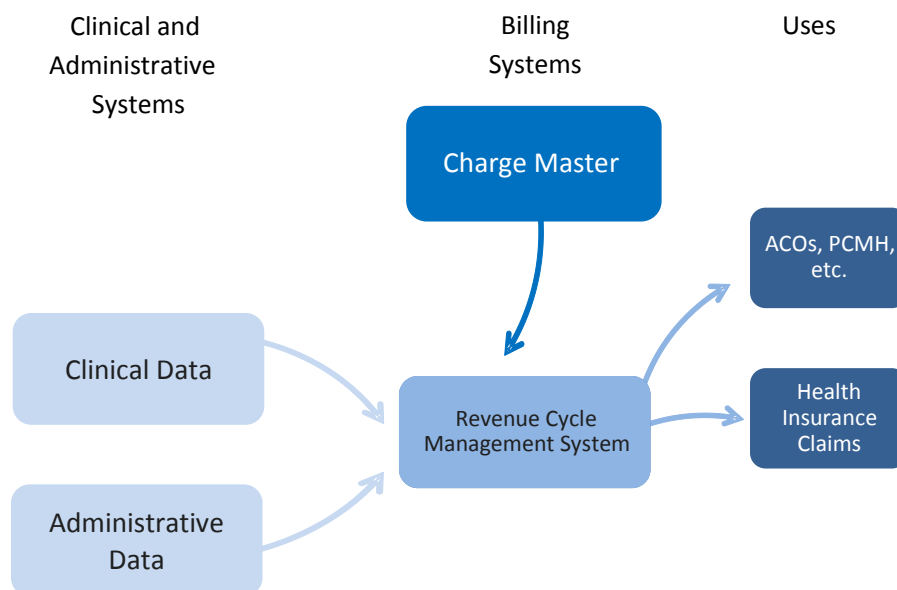
Revenue Cycle Management Systems

Accurate billing is an important function for provider systems to ensure that appropriate payment is received for the procedures, services and supplies provided. The principal systems that support billing activities include the charge master and revenue cycle management system. These components help to manage revenue, measure internal utilization, generate reports, and ensure overall compliance.

The charge master serves as the basis for the revenue-cycle management system, and is a comprehensive and hospital-specific listing of each item that could be billed to a patient, payer or other provider system. Each item in the charge master has an associated charge code that generates a price for that procedure, service or supply. Provider systems rely on a combination of internal codes and administrative transaction code sets (e.g., CPT, HCPCS) that are unable to identify specific devices, but rather group them into broad classes under one code within the charge master.

The revenue-cycle management system at a provider site utilizes the charge master data to perform eligibility verification, claims generation, and patient billing among others. Data from the charge master are then pulled into a revenue-cycle management system, along with some clinical data (e.g., procedure performed) and supply chain data, all acting as the foundation for activities in the billing environment, such as generating a final claim or bill (**Figure 5**).

Figure 5: Overview of Integrated Billing System



I. Challenges to Provider Systems

Improvements to the delivery of care to patients and strategic decision-making will rest on the ability of provider systems to link the flow of medical devices with their data from the supply chain through clinical and revenue-cycle operations.⁴⁹ The unavailability of specific and standardized medical device data, along with limited interoperability between provider data systems, hinders the exchange of accurate and timely medical device information. While comprehensive solutions for barriers that impede HIT interoperability are outside the scope of this roadmap, the gap in medical device data standardization underpins many of the challenges that face each of the principal provider data systems.

Inability to Link Patients with Specific Medical Devices

At the POC, clinical data systems have limited capability to link medical devices to patients, and therefore are unable to track and measure clinical performance of interventions involving specific medical devices. EHRs often lack fields to incorporate device-specific information. When available, medical device information is difficult to access and transmit (e.g., due to unstructured notes, multiple proprietary standards). In addition, efforts to quickly obtain patient information in an array of situations, including revision surgeries, diagnostic imaging (e.g., MRI) and emergencies, are complicated and burdensome.

Medical device recalls represent an acute scenario where the decoupling of patient health information and specific medical device information slows the management and corrective action of the recall. While implanted devices are generally tracked through an implant log, this information is often not electronic or easy to query. In addition, clinical outcomes analysis on the performance of different models and brands of medical devices is nearly impossible without capturing uniquely identified medical devices. Opportunities for patient engagement and medical information transparency are also limited when the data are unavailable or inaccessible in EHRs.

Lack of Device Transparency in the Supply Chain

Many provider systems lack inventory and operational transparency and hence lack the capability to track devices as they move within their systems from the stock room to the POC and then to billing. Provider systems may find it difficult to accurately determine the identity, volume and disposition of their medical devices in stock. Adoption of uniform standards for medical device data is rare and most provider systems must contend with fragmented standards or expend resources developing their own proprietary standard. Lack of specific

identifiers increases the possibility that item masters may simultaneously identify two or more different devices. One report by the Department of Defense found that 30 percent of catalogue numbers found in provider supply chain data systems could not be matched to the correct manufacturer and 20-25 percent lacked the product brand name.⁵⁰ In many instances, medical devices, such as high-risk implantable devices, may bypass supply chain systems entirely. These devices are often brought to surgical suites on a contingency basis by distributors and manufacturer representatives, and are thus only captured in clinical and billing data systems. These occurrences further complicate efforts by provider systems to account for their inventory utilization and track and trace the device across their system and beyond the hospital.

Inefficient Maintenance and Resource Management

Several full time employees and resources are commonly required to cleanse medical device data for the MMIS. The absence of unique and standardized identifiers introduces the risk of incorporating multiple entries for the same product (possibly introduced by small format variations or mistyping), indexing multiple distinct items with duplicate identifiers, and incomplete device information. This leads providers to expend significant resources and time to ensure the quality of data in the item master and accurately map these non-unique, variable identifiers to inventory. Significant time can be spent conforming current medical device inventory information to a provider system's proprietary standard or applying a secondary identifier.

These errors and inefficiency can lead to distortions and disruption in managing the supply chain. Overstocked items can incur heavy inventory management costs to the provider, while scarcity can delay patient care. Obsolescence of expired devices is an additional cost to provider systems in the form of wasted resources and inappropriate use of expired medical devices on patients. Measures of specific medical device utilization are also complicated in an environment where specific medical devices cannot be readily identified.

Error-Prone Manual Data Entry

Difficulties in specifically and accurately identifying medical devices are compounded by error-prone manual entry of information into data systems.⁵¹ In clinical data systems, medical device identification information that is recorded on patient health records and claims is likely to be unstructured, contain errors, or be incomplete. Errors in handwritten and typed entries of medical data have been shown to be considerable; 5-13 percent of these errors occur regardless of level of medical training.^{52,53} This can have serious consequences when provider systems must quickly notify their patients when a medical device has been recalled or when trying to follow the patient longitudinally. At reimbursement, manual data entry for billing transactions and reconciling discrepancies can occupy 20 percent of staff time.⁵⁴ Due to the lack of unified standards and barcodes for medical devices, provider systems find little incentive to adopt AIDC technology to automate collection of medical device information. Point-of-use system adoption in provider systems lags behind other industries, inhibiting automated capture of medical device data in clinical and billing systems.

Limited Capability to Engage in Medical Device Quality Tracking for Payment

As providers seek payment for the medical devices they use during the course of care, they have little incentive or opportunity to uniquely identify devices for reimbursement. Generalized billing codes for broad classes of medical devices obscure the differences among each type of device. Recent trends in payment models, such as capitated, bundled and pay-for-performance have been reactions to increasing health care expenditures, and have subsequently shifted more costs toward provider systems. Many provider systems are now tasked with linking patient outcomes, costs and reimbursement with medical devices. The inability to link patient data with device-specific outcomes limits the capacity of these models to utilize specific medical device information for quality improvement purposes.

Lack of Internal and External Data Synchrony and Interoperability

The lack of interoperability between supply chain, clinical, and revenue-cycle data systems impedes and complicates routine activities within a provider site. Changes in medical device data in the supply chain are often not reflected in the provider's clinical and billing systems, decoupling medical devices from the flow of data. As health care reform and novel payment models push provider systems toward improving patient outcomes and controlling costs, the need to align systems and promote frictionless information exchange between provider

data systems will increase. Non-standardized and non-unique medical device information propagates duplicate and incomplete information across the major data systems. This fragmentation also creates significant barriers against developing solutions for a common syntactic and semantic framework for external health information exchange and use. Limits to external data exchange between provider systems and research institutions prevents continual evidence generation and safety surveillance that is needed to ensure that patients across the nation are receiving the highest-quality medical device interventions possible.

STAKEHOLDER EXPERIENCE

Healthcare Transformation Group (HTG) Industry Item Master

Recognizing the need for more efficient supply chain processes in health care, HTG, which comprises Mercy Health, Mayo Clinic, Kaiser Permanente, Intermountain and Geisinger, is seeking to develop an industry item master. The group has chosen GS-1 as their UDI standard, and has begun encouraging, and in some cases enforcing, compliance with the standard as part of doing business with vendors. To further drive standardization across the health care system, HTG is working with manufacturers to encourage their contribution of device information to an industry-wide item master. Fruition of this and other efforts, if combined with data from the GUDID, would represent an important step towards the vision of a universal and reliable data source – a repository from which health care systems could retrieve standardized product information. This would significantly reduce the burden on health care systems in creating and maintaining item masters. It would also facilitate the tracking of devices that are brought to the POC by company representatives and that are not found in the provider’s item master.

II. Value of Integrating UDIs into Provider Systems

UDIs can enable a number of valuable activities within provider systems, which are currently challenging, if not impossible to conduct in the absence of UDI. The value of UDI implementation is discussed in Section 2, but a brief summary of value for provider systems is captured in **Figure 6**.

Figure 6. Value Use Cases of UDI Implementation into Provider Systems

DIRECT VALUE	INDIRECT VALUE
<ul style="list-style-type: none"> • Patient access to device information and shared decision-making • Provider access to critical device information • Efficient communication of safety information to patients and providers • Medical device safety surveillance • Comparative effectiveness and patient-centered outcomes medical device research • Tracking of medical device utilization patterns and analyses of appropriateness of care • Improved ability to support ongoing quality initiatives • Improved recall process • Improved supply chain integration and management • New opportunities for value-based purchasing and other support for enhanced value • Emergency preparedness and response 	<ul style="list-style-type: none"> • Anti-counterfeit detection • Increased medical device reimbursement transparency • Fraud detection • Identifying networked and telemetric medical devices • Support for medical device innovation

With access to specific device information through the use of UDI, provider systems can augment safety, quality, and efficiency in care delivery to patients. The incorporation of UDI into the POC data system would allow, for example, a cardiologist to log the UDI of a pacemaker implanted into a patient via the catheterization laboratory software suite. This information can then be made available for transmittal to the EHR. Although the cardiologist may be involved in the initial implanting of the device and some immediate follow-up, primary care physicians and others will likely play a large role in the patient's long-term care. As such, UDI inclusion in the patient's EHR will enable downstream providers to access information about the patient's device at any point after the procedure. This has value in on-going care, revision procedures and in response to safety alerts or recalls. Patients themselves will likely benefit from long-term access to this information accessible from the site of their procedure or their PHR. Device data obtained at provider organizations is the necessary first step for availability of data for use in postmarket surveillance.

Provider systems can also begin to experience a wide range of benefits from using UDIs across the care delivery site, particularly all the way to billing. UDI incorporation into MMIS systems which can communicate with clinical and billing systems creates an opportunity to streamline and improve inventory management processes. If providers at the POC were able to scan a consumed device or product, the system would specifically decrement that product in stock. Supply chain personnel would therefore gain an exact accounting of, for example, where the most dollars are being spent at the POC. In addition, supply chain personnel would be able to more efficiently ensure the fidelity of data within their item master. Moreover, because UDIs can be readily partitioned into production and device identifiers, MMIS systems (discussed in greater detail below) can be more easily programmed to receive data from the item master.

By incorporating UDIs into billing systems, provider systems can also gain deeper insight into the link between device use and cost, as well as to bill appropriately for medical device use. UDI implementation could facilitate improved management of the inventory by synchronizing products listed in the charge master and the item master, supporting better revenue cycle and supply chain management. As medical devices are used in the course of the patient's care, providers will be able to support more effective billing of the device and reduce inefficiencies.

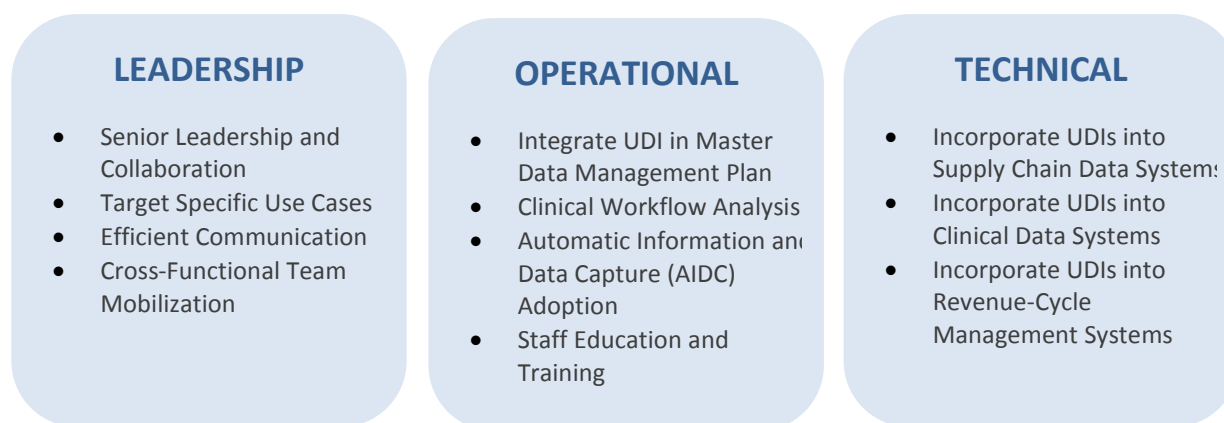
Importantly, implementation and electronic capture of UDIs would support cross-collaboration between different departments in provider organizations (i.e., clinical, materials management, and billing) surrounding use of devices and device data. The ability of the provider organization to assess device use and clinical outcomes, device utilization and procedure reimbursement and total cost of care for procedures would be enhanced. Population health management surrounding devices and engagement in device postmarket surveillance through availability of data would be supported as well.

III. Strategies for Integrating UDI into Provider Systems

Comprehensive strategies for successful UDI implementation in provider systems will require the aligning of resources and goals among the major functional groups found in each provider system, which can be reinforced through aligned adoption by their external partners. A multipronged approach would be highly beneficial, taking into account the leadership, operational, and technical components of implementing UDI in provider systems, as depicted in **Figure 7** on the next page.

In the following sections, we will explore the changes necessary for providers to experience the value of successful UDI implementation through (1) the leadership, operational and technical strategies for incorporating UDI (**Figure 7**), and (2) crosscutting strategies for providers with varying levels of HIT implementation.

Figure 7: Strategies for Provider System UDI Implementation



Strategy Development and Sponsorship by Senior Leadership

Senior provider leadership will play a key role in driving UDI implementation by providers. Provider leadership can be supported by external partners such as vendors, manufacturers, suppliers and patients, all of whom interact in the provider environment. These interactions are constructed upon various business relationships, supply chains, contracts, and human capital that are not confined to one particular health system or hospital. In developing a strategy to implement UDI across the provider system, senior leadership within the provider system and relevant external partners should convene and discuss the necessary steps to move forward with UDI implementation. Provider systems should also identify specific leaders who will sponsor the UDI implementation project through completion.

Target Specific Use Cases

Each provider system is distinctive and the value they anticipate deriving from adopting UDIs may be highly situational. Leadership for each provider system should develop a straightforward planning and implementation strategy that clearly articulates which valuable use cases of UDIs will be prioritized, which specific systems and processes will be affected, and how UDIs will be implemented. Prioritizing which specific use cases to target (Section 2) will be an organization-specific exercise, as each provider system seeks to align its core mission and vision with its own value assessments. Most definitions of value in health care coalesce around the idea of “health outcomes achieved per dollar spent”; however, outcomes are measured differently across provider systems and are “inherently condition-specific and multidimensional.”⁵⁵ Additionally, the measurement of outcomes by individual providers is highly dependent on the provider’s ability to capture them. In many instances, providers are only able to assess medical device outcomes within a narrow time window after interventions such as implantation surgeries. Provider systems that quickly identify key use cases as well as metrics for successful outcomes using UDIs will have increased likelihood for effective implementation.

Promote Bidirectional Communication

The most arduous barriers to new health care strategy implementation can often be traced to the failure of leadership to generate a dynamic team-based environment that includes stakeholder input from all levels of the organization and focuses on a well-communicated strategic direction.^{56,57} UDI implementation will impose technical, operational, and financial burdens on the various departments of provider systems. To overcome these barriers, successful implementation of UDI will require provider system leadership to clearly articulate its strategy across the various functional units (e.g. information technology, clinical, supply chain, and revenue-cycle management systems) of the organization and why UDI matters. Provider system leadership should communicate that changes would be expected across the provider system not just for UDI, but for other standards and processes that UDI will affect as well. Clear channels of bidirectional communication between leadership and the functional units should be opened to encourage feedback throughout the implementation process. Since each provider system is different, each functional unit will have to consider a variety of specific challenges and opportunities in order to successfully implement UDI.

Cross-Functional Team Mobilization

Provider system leadership should seek out functional unit leaders who can lead UDI implementation. Establishing a cross-functional team with project ownership increases the likelihood that important functional considerations will be included into the strategic model of UDI implementation, increasing the value of UDI for each functional unit affected. As an example, cross-functional collaboration could prevent a scenario in which clinicians might find it difficult to assess and appreciate the future value of UDI when the argument for adoption is presented in the language and context of an IT- or supply chain-led project or vice-versa. The value of UDI implementation and associated processes must be communicated to each major organizational stakeholder. Preferably, this cross-functional team should maintain ownership over the UDI strategy and implementation, and perform continuing value analysis to evaluate the benefit of UDI implementation. Broad stakeholder buy-in and continued ownership should discourage detrimental project isolation of UDI implementation, since failure in this instance becomes collective. Cross-functional teams should be able to support all phases of UDI implementation, from introduction to achieving valuable use cases.

V. Operational Strategy

Integrate UDI into Master Data Management Plan

Provider systems must increasingly manage and extract value from the clinical, supply chain, and revenue management systems that are producing exponential amounts of data. Developing a plan for how and where UDI will be managed within provider data systems will be critical to leveraging UDI across each of the targeted use cases and to prevent UDI from being lost in the flux of data. To manage this data, many organizations have developed master data management plans (MDMP). MDMPs assist in organizing data through delineation of the critical data entities, policies, standards, processes, and functions to create a single source of truth to be used across the organization. MDMPs help reduce duplication, ensure data consistency, and streamline processes by having each data system extract from a master file. UDI will serve as the core regulatory-compliant data for medical device product information and will function to increase the quality and consistency of device information.⁵⁸ Incorporating UDI into a provider system's MDMP should help institutionalize its importance and provide a rigorous framework for its management, whether the UDI resides in an item master or elsewhere.

Clinical Workflow Analysis

Introduction of new health information technology into provider systems carries with it enormous potential for improving care delivery; however, a number of institutional and sociotechnical barriers exist, which can limit the return on investment (ROI) from new tools.⁵⁹ To improve consistency and reduce incidences of error, provider systems operate with procedural workflows or standard operating procedures (SOP) to guide their staff and physicians. Additions of new technologies can be disruptive to legacy workflows and systems, and, if unresolved, can negate the positive benefits of the technology.

Workflow analysis is an analytical tool used to examine the relationship between a new technology such as UDIs and the relevant institutional and sociotechnical considerations in order to derive value and improve the organization. Aligning clinical workflows with data flows is vital for establishing advanced HIT systems to support UDI implementation. Clinical workflows are established processes in clinical care of patients that describe a series of tasks, how they are accomplished, by whom, in what sequence, and at what priority.⁶⁰ Data flows involve the movement of information from one system to another. (A detailed description of the interaction between clinical workflows and health IT systems specifically regarding the integration of UDI into provider systems is illustrated under "Incorporate UDI into Clinical Data Systems" [page 39] in this section.) Leadership at care delivery sites would benefit from engaging stakeholders involved in both the clinical workflows and the data flows in order to ensure a seamless capture and flow of UDI across systems. Understanding priorities, potential barriers, communication and education needs and designating leadership in these areas will be critical for success. While the focus initially will be on clinical data systems and their associated workflows, in tandem with the supply chain workflow, providers should be prepared to reevaluate workflows related to medical device information across the entire organization, including in the supply chain, revenue-cycle management and patient interactions.

Automatic Identification and Data Capture (AIDC) Adoption

Adoption of AIDC technology could play an important role in increasing the safety and accuracy of medical device information obtained at the POC and exchanged throughout the provider system. UDIs, captured at the POC using a bar-code scanner or radio frequency identification device (RFID) could help streamline the capture of key device characteristics for the patient medical records and reduce the potential for errors associated with manual recording.⁶¹ This will be especially important in fast-paced specialties (e.g., emergency medicine) where there might be insufficient time to record UDIs manually, but will also be important generally as unexpected patient needs arise, which may preclude time needed for manual documentation by the clinical team. Due to the necessity of UDI data capture across many different systems such as POC, surgical device software, supply chain data systems, EHRs, and billing systems, its effects should be expected to propagate across numerous workflows that could benefit from standardized AIDC technology.⁶²

Staff Education and Training

Staff education and training efforts will be critical to the success of executing an effective clinical strategy for UDI implementation. Investing in communication and education of clinical leadership on UDI value and implementation will be imperative to gain support. In addition, investing in training programs tailored to the needs of providers at the POC (e.g., lab technicians, nurses and operating room physicians) provides a mechanism to convey the value of implementation and ensures that staff is adequately trained to capture UDI at the POC. Without efforts to educate and train the organization, and especially frontline staff, the adoption of UDI and affected workflows will be fraught with impediments or ultimately fail. Even a well-developed clinical strategy for adopting UDI faces challenges of technophobia, lack of prior physician engagement, weak functional relationships between IT divisions and clinical practice, data use opacity, and suspicion regarding a new technology's value to clinical performance, among others.⁶³

Adaptation of the organizational educational and training mechanisms should be ongoing as adoption progresses. The value of UDI will be different for successive phases of implementation. Reduction in staff time spent on manual entry, lessened paper records and availability of UDI in electronic records may be apparent initially. Recall management and adverse event reporting might also see early benefits. Whereas clearer documentation of device use at the POC, error-reduction and supply chain efficiencies may be noted in early stages, the ability to capture supply chain cost-savings could take longer. Expanded use of device data internally or in support of postmarket surveillance is another area that may take time to develop. Provider systems may find it beneficial to track adoption using a formal method of analysis such as building a technology adoption curve. Such analysis can be used to benchmark progress and key milestones that take into account the resources, time and personnel necessary to achieve those goals, both to start up and to maintain UDI implementation.⁶⁴ Whichever approach is taken, provider systems should be prepared to assess the evolving effectiveness and maturity of their education and training efforts to make sure that they optimize the implementation of UDI in their systems.

VI. Technical Strategy

A. Incorporate UDI into Supply Chain Data Systems

Highlight Potential for Significant Cost Savings

In an already challenging fiscal environment, provider systems are searching for areas where they can cut costs without affecting quality. One area in particular that can provide a strong incentive for providers to adopt UDI is in the supply chain, largely due to the ability of UDI to improve quality and reduce wasteful inefficiencies. As discussed in the inset box (below), although there will be costs associated with initial adoption and implementation of UDI into the provider system, the enhanced capabilities for the supply chain can provide significant savings to care delivery sites.

STAKEHOLDER EXPERIENCE

Mercy Health

Prior to implementation of UDI in the catheterization laboratory setting, Mercy Health System (Mercy) performed annual physical inventories to ascertain the value of all supplies for their General Ledger. In one Mercy facility, the value of the physical inventory according to their automated system was approximately \$800,000. Once UDIs were implemented and each device's unique identifier was scanned, the value of the inventory was found to be approximately \$1.9 million. The improved accounting of the facility's inventory allowed Mercy to manage the inventory value down to \$1.56 million in 6 months and resulted in significant cost savings for the health system. Additionally, Mercy was able to electronically manage the expiration dates of medical devices. Supply chain management shifted from a system in which boxes were marked with color-coded sticky notes to the sophisticated capability to produce reports which targeted inventory closest to expiration for immediate use. This was another source of cost savings to the health system, which strengthened support for an integrated approach to UDI adoption among leadership.

Incorporate UDIs into Item Masters

Once accessible and widely distributed, UDIs could serve as a key identifier for medical devices, replacing catalogue and serial numbers in the item master. Before incorporating UDI into the item master, several factors need to be considered. For example, because of the lag time associated with rollout of UDI and the concurrent existence of legacy items which will not be retroactively labeled with UDIs, hybrid systems that can support both UDI- and non-UDI labeled devices will likely be necessary for an extended period of time. In addition, as shown in Figure 3, the item master may need to retrieve and integrate information from multiple databases. While the GUDID (FDA) serves as the primary repository for device information by storing the DI, the item master may need to be augmented with supplemental information from catalogs and other manufacturer materials, as well as with additional information such as supplemental attributes and recall information. With greater access to supplemental device attributes and other important information, stakeholders can access a wealth of clinical, operational and financial information. Once UDIs are incorporated into the item master and integrated with clinical systems, device scanning at the POC will allow UDIs to populate into clinical systems. Subsequently, device information can be disseminated to other stakeholders from the patient EHRs.

Implement Pilots of UDI Adoption that Demonstrate Supply Chain and Clinical Coordination

Small pilot studies initiated at provider sites could be the most compelling way to demonstrate the value of UDI implementation and to provide a clear understanding of tangible on-the-ground benefits to provider systems. Provider systems should investigate collaborative pilot models that could include manufacturers, group purchasing organizations and HIT vendors. These pilots should target specific service lines where there would be observable impacts. For example, pilots implementing UDI in a catheterization lab or other small care delivery setting would enable supply chain personnel and others to quickly understand some of the issues that must be addressed, iterate strategies, and experience the early wins associated with implementation. This, in turn, can motivate implementation in larger scale settings, such as the operating room. If smaller pilots are not feasible, provider systems should examine case studies from other health systems that have already adopted UDI, particularly if these studies are accompanied by supporting data regarding the improved efficiencies that these systems experienced.

Develop Industry-Wide Standards for AIDC Technology

Another issue that may cause additional challenges for provider systems will be the Final Rule's neutrality regarding labeler selection of AIDC technology. Neutrality could increase the burden on care delivery sites, since multiple types of AIDC readers may be needed to enable consistent recording of UDIs. One approach to reduce this burden would be efforts from manufacturer and labeler consortiums to set an industry-wide standard for AIDC technology adoption. If labelers agreed on one or a limited number of AIDC technologies as part of representing the UDI on a device label, this could alleviate some burden on care delivery sites by reducing the

types of AIDC reading systems they must purchase.⁶⁵ Additionally, manufacturers could offer provider systems that are purchasing devices a suite of AIDC technology options in order to ensure that devices procured meet the AIDC needs of provider data systems.

B. Incorporate UDI into Clinical Data Systems

In order to fully reap benefits from adopting UDIs in terms of improving quality of care, reducing cost, and increasing patient satisfaction, it is vital that the UDIs are captured at the POC, with the ability to pull associated information from the GUDID, supplemental attribute databases, and the supply chain. Provider systems should focus on investments in AIDC technology at the POC to capture UDIs affixed on devices or labels. In addition, providers can work with EHR vendors to develop an implant field to capture UDI and leverage current HL7 and MU initiatives. As a first step, providers could focus on a specific clinical area as in the Mercy Health case study (see Appendix C: Mercy Case Study). A comprehensive integration across all clinical areas and across the entire provider system (i.e., procurement, POC and revenue cycle) might not initially be practical or feasible. In order to pursue provider system adoption of UDIs across clinical data systems with limited interoperability, it will be important to consider a number of strategies, the most compelling of which are discussed below.

Driving EHR Incentives and Adoption

With a number of efforts to incentivize EHR adoption underway, a unique opportunity exists to ensure that UDI is a standard element in EHR implementations (see Section 1). EHR certification criteria and MU objectives have covered a wide variety of areas related to improving quality, streamlining systems, and reducing the potential for errors. One area of particular interest has been capturing treatment procedures for drugs and biologics through EHRs. While significant progress has been made in this area, tracking medical devices and their use remains largely untouched, partly due to the inability to uniquely identify medical devices. With the finalization of the UDI rule, however, an opportunity exists for stakeholders to enable the capture of medical device use as part of the clinical record. To drive UDI incorporation into EHRs, two complementary regulatory opportunities exist: 1) UDI inclusion in the EHR certification criteria, and 2) UDI inclusion as part of meaningful use incentive programs. Furthermore, there are several existing initiatives that can further support these opportunities for interoperability. CMS' 2014 Clinical Quality Measures incentivize providers to improve clinical health outcomes, clinical processes, and operational efficiency. In addition, AHRQ's Patient Safety Initiative, in coordination with FDA's Adverse Event Reporting, seeks to reduce the frequency of adverse events and streamline their reporting.

Incorporate UDI into EHR Certification Criteria

To drive adoption of UDIs in EHRs, a direct path lies with incorporating UDIs into the EHR certification technology standards being developed by ONC. This could accelerate UDI adoption by ensuring that EHRs are able to support UDI capture appropriately, efficiently, and in a reportable way, eventually allowing them to be leveraged for additional uses. As a result of a joint collaboration effort between ONC and FDA, the Proposed Rule for the 2015 Edition of the Standards and Criteria for EHR Certification, released in February 2014, included a certification criterion focused on EHR's ability to record UDI information about implantable devices as part of a patient's "implantable device list." The EHR would allow a user to record and access the UDI(s) of implantable device(s) and other relevant information. In addition, the EHR would need to be able to separate the device identifier (DI) and production identifier (PI). The discussion of UDIs in the Final Rule serves as the basis for inclusion in several criteria, including: Implantable device list; transitions of care; data portability; view, download, and transmit to third party; and clinical summary.⁶⁶ However, in September 2014, ONC ultimately decided to retract the entire proposal, effectively eliminating the criterion recommending that EHRs be able to record UDI information. During the public comment period, ONC received pushback from hospitals and vendors who argued that the technical change ONC was requesting were too arduous. In addition, making UDI adoption into EHRs optional was perceived to have limited value since the benefits of UDI would more likely be realized if its capture was a requirement across certified EHR implementations.

Incorporate UDI into Stage III Meaningful Use

Recognizing that UDI adoption within the certification criteria should be a requirement, ONC support for UDI integration within EHRs is critical. As such, it should recommend a field for UDIs as part of the associated

certification criteria when CMS issues its proposed Stage III MU objectives. These objectives are currently under development and are expected in 2017. The two federal advisory committees administered under ONC, the HIT Policy and HIT Standards Committees, play a particularly important role in this effort. Under the HIT Policy Committee, several subcommittees have been formed to provide in-depth exploration into specific topic areas. The Meaningful Use Workgroup makes recommendations to the HIT Policy Committee around the short- and long-term definition of MU, mechanisms for EHRs to support MU, and ways for provider systems to demonstrate MU. This workgroup is examining the potential for including UDIs in their recommendations to the HIT Policy Committee around Stage III MU. Currently, the group is exploring the potential for UDIs as a menu objective for recording of UDIs associated with implanted devices upon implantation. The proposed objective for the purposes of the incentive program was 80 percent recording of UDIs within the EHR reporting period.⁶⁷

Incorporate UDI into Standards for the Electronic Exchange of Clinical Information

Another opportunity to incentivize UDI capture in EHRs and enhance interoperability lies in the Health Level 7 International (HL7) standards. HL7 is an American National Standards Institute (ANSI) accredited organization and a standards development organization recognized by the Health Information Portability and Accountability Act (HIPAA), which is focused on the exchange, integration, sharing and retrieval of electronic health information. HL7 develops two standards that would benefit by enrichment with UDI: the HL7 Clinical Data Architecture (CDA) for clinical documents and the HL7 v2.x, v3.0 for data exchange messaging. The CDA provides a structure for exchange for important clinical documents, such as the discharge summaries and progress notes.⁶⁸ Since these documents are widely read and shared across providers and patients, the inclusion of UDI into the standards for these documents would enhance the level of information the provider or patient is able to access. Currently, HL7 is looking to exchange the entire human readable form of the UDI as a UDI data type or a simple string. Depending on whether privacy is a concern in the particular application, HL7 is providing guidance regarding the transmittal of UDI (e.g., human readable, full string). Where possible, HL7 is also indicating that implementers should consider validating the DI against a database (e.g., GUDID) in real or near-real time as part of the input validation process.⁶⁹

Standardize Capture of UDI at the POC

Provider systems vary greatly in their use and assortment of medical devices administered to patients. Each care setting, including operating rooms, ambulatory settings, emergency rooms, and outpatient clinics, has unique contexts in which devices are used, and, as such, has its own specific needs regarding device information (e.g., meaningful attributes for the care context, level of granularity for information capture). This necessitates the creation of tailored, yet standard, approaches to implementation for each care setting. Leaders within each discipline and care setting will need to prioritize which medical device will need UDIs captured and when. For example, in a total knee replacement, there may be different parts of the implant made by different manufacturers. Protocols for orthopedic surgeons, operating room nurses, and other providers at the POC should indicate which of these components will need to be captured in the clinical data systems. Professional societies are uniquely positioned to lead this charge by identifying and prioritizing which device UDIs will need to be captured in the context of routine procedures. In developing this standardized protocol and list, software vendors for specific POC systems could begin to implement these changes to support UDI capture.

Develop Flexible and Networked Clinical Data Systems

Provider data systems must parse through an array of data sent from many devices in order to uniquely identify the device, its location, and a link to the individual patient identifier. This information must be integrated by the provider system's HIT and be made accessible to the clinical staff as well as the patient. In the case of a malfunction, for example, the ability to understand which device malfunctioned, the nature of the malfunction, and the device's location is important. Providers will benefit from open and flexible systems that can assimilate different types of information (e.g., patient ID and location ID), and provide actionable information for care delivery site staff. To bolster the flexibility and networking capability of their HIT systems, provider systems should explore the use of web-based cloud architectures, RFID technology, and flexible data exchange technology such as application programming interfaces (APIs). A key challenge in this regard will be networked devices. Since the Final Rule was silent regarding incorporation of UDI reporting within the electronic data

produced by medical devices themselves, provider systems will need to work with manufacturers to include the UDIs in this context. Pilots should be conducted to help provide a compelling business case, and standards, such as those used for electronic data interchange.

Adopt Appropriate AIDC Technology

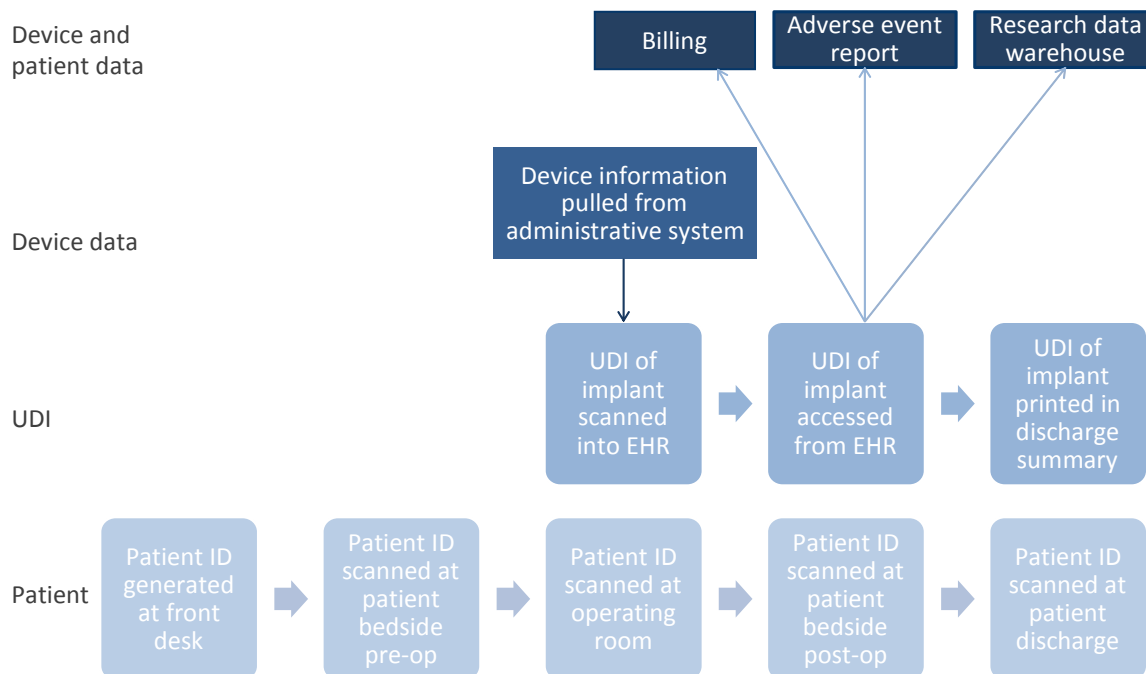
To ensure that the UDI is appropriately captured and supports more streamlined workflows, provider system adoption of AIDC will be extremely important. FDA mandated that the affixed UDI be recognizable by AIDC technology; therefore, to gain optimal benefit, providers should invest in AIDC technology for scanning and capturing the UDI across their systems. While the Final Rule is technologically-neutral with regard to AIDC technology so as to leave room for innovation in the field, the lack of clarity for labelers could lead to confusion regarding adoption of various AIDC technologies. Without manufacturer and labeler agreement regarding AIDC technology selection or the ability to specify which AIDC technology is compatible with which manufacturer products, this ambiguity could lead to greater implementation pains for provider systems and consumers. Since provider systems stand to gain a great deal from effective AIDC technology adoption, particularly with regards to improving workflow, investing in AIDC readers that meet the needs of their clinical staff will be imperative.

Ensure Interoperability Across Provider Data Systems

Interoperability between systems and standardized data capture will be beneficial for the seamless flow of the UDIs across the provider system and beyond. However, the current HIT infrastructure contains a diverse set of systems that have little to no ability to communicate with one another. This is a result of the siloed structure of care delivery sites and the various vendors that produce systems for each silo. Repetitive, wasteful processes across the care delivery site create inefficiencies that could be improved with better communication across systems. It will not be sufficient to include UDIs in each of these siloes; rather, UDIs must be captured as structured data elements that can then be easily passed to other systems.

HIT interoperability in health care is a major undertaking not confined to integrating UDIs across health care systems. Existing infrastructure and mechanisms to support, for example, developing continuity of care documents (CCDs), could be leveraged for UDI adoption. If UDIs were captured into an interoperable system, a number of valuable uses, such as supply chain optimization, efficient identification of patients affected by a recall, and enhanced billing capabilities, are more likely to be obtainable. For example, a provider could scan and capture a UDIs at the POC, triggering a pull of information (e.g., device attributes) from the item master, supply chain systems, and reference databases such as the FDA's GUDID. This information could then be passed to other systems, such as a clinical data warehouse, or be used for adverse event reporting (shown in Figure 8). Further development of these mechanisms could ensure more efficient transfer of UDIs and third-party supplementary product attributes across clinical systems that can accommodate security requirements and ensure more open architectures. This would enable clinicians and other providers to access important information and make more informed decisions in the short- and long-term care of patients.

Figure 8: Diverse systems must be interoperable in order for benefits of implementation to accrue



Enable Automation for Clinical Process Requiring UDI Information or Reporting

If captured into clinical data systems, UDIs could also be incorporated into automated reporting of clinical alerts and adverse events. Such reporting could increase patient safety and reduce the amount of time and resources used by provider systems to maintain these functions. Similarly, if providers participate in a device registry, the ability to automatically upload information to the registry from the POC and/or clinical data source would free up additional time and resources.

C. Incorporate UDI into the Revenue-Cycle Management System

Adopt UDIs to Support Emerging Care Delivery and Payment Models

There is a shift among provider systems away from fee-for-service to new care delivery and payment models (e.g., bundled payments, accountable care organizations, patient-centered medical homes). Providers seeking to succeed in these new models will need to generate evidence for the link between outcomes and cost to be able to demonstrate improved quality, as well as take steps to improve the efficiency of the care they provide. UDI use and integration in electronic data systems provide opportunities to support this need for data on medical devices and device-requiring procedures.

Require UDI in the Claims Forms

Claims forms, submitted to private or public payers, serve as the primary mechanism through which providers are paid for a procedure, service or supply provided. The billing system acts as the aggregator for information important to report on the claims and codes appropriate for reimbursement. If UDIs are ultimately required for reporting high-risk, implantable medical devices in claims, interface of the clinical data and billing systems would support this information need. This would serve as a strong incentive for providers to incorporate UDI into their billing systems, as well as across the electronic data infrastructure.

VII. Diverse Care Delivery Sites with Varying Levels of HIT Adoption

UDI Implementation within Varied Care Settings

The health care delivery system is composed of a wide range of settings, including large hospital systems, community health clinics, outpatient clinics, ambulatory settings and pharmacies. At each care delivery point,

there will likely be varying levels of HIT adoption that are both specific to the needs of the care delivery site and in line with the available resources. This disparity will likely be most pronounced concerning the sophistication of capabilities in HIT, with a continuum of capabilities ranging from high developed electronic infrastructure to predominantly paper-based processes. While UDI incorporation into data systems will facilitate a wide range of valuable uses, smaller provider systems that have not moved to adopt HIT systems can also begin to derive value from recording UDIs. In particular, including UDIs in the patient record, whether paper-based or electronic, can improve the availability of information that both the provider and patient can access. Recording UDIs can also help support provider system activities ranging from gathering more specific information regarding a patient's medical device to quickly assessing a patient's device maintenance needs.

Stakeholder Engagement

Provider systems can also share strategies regarding implementation. As more experience with UDI implementation begins to accrue, a forum where provider systems with various levels of HIT and UDI adoption can share their experiences, what challenges they encountered, and what workarounds they developed, would be helpful in supporting implementation efforts. Demonstrating value will be an important motivator for provider systems who need further support of the value of adoption. Provider systems who have already adopted UDI and have begun to experience the benefits are well positioned to help build up provider system demand for incorporating UDI into the electronic data infrastructure. In particular, if provider systems can convey the value of UDI implementation through case studies, testimonials, and accompanying data regarding the improved efficiencies these systems experienced, other provider systems should be motivated to adopt and can learn from the early adopters' implementation experiences. The value propositions for UDI implementation, particularly in a challenging fiscal environment, will need to be made clearly, and targeted education efforts with stakeholders will be important, specifically among physicians, nurses, chief information officers, chief operating officers and chief medical officers.

VIII. Recommendations

- 1. Providers systems should incorporate UDIs into their electronic health records:** Documenting UDIs in EHRs represents one of the highest value targets for provider systems, given the ability of EHRs to aggregate vast amounts of clinical and patient data. Provider systems should work with HIT vendors to build a field for UDI into their EHRs. Provider systems should also engage in workflow analysis and planning to anticipate the circumstances when UDI capture will be required, voluntary, or unnecessary and the impact UDI capture will have on operations.
- 2. Adopting automatic identification and data capture (AIDC) technology can facilitate more efficient and accurate UDI capture in clinical settings:** To facilitate the primary recommendation above, AIDC technology will help streamline provider workflows and facilitate the UDI's electronic capture. Provider systems should certify that the AIDC technology they invest in is compatible with the majority of the medical devices they intend to capture. Further consultation with medical device manufacturers and labelers may be needed to verify the type of AIDC technology needed.
- 3. Provider system executive leadership should sponsor a comprehensive strategy to guide operational and technical implementation of UDIs within their system:** Various approaches towards UDI adoption in provider settings will require senior provider leadership to target specific strategies and personnel who will guide implementation. Having a "champion" for UDI implementation at the executive level in the organization will be critical towards advocating the importance of UDI, communicating its value to the system as a whole, and developing a cross-functional strategy for implementation. Provider systems should involve IT, supply chain, clinical, and external partner leadership, including vendors, GPOs, and manufacturers, early to develop a plan for the strategic rollout of implementation.
- 4. Provider systems should automate important safety reporting with UDIs:** EHR-based automated safety reporting should reduce the administrative burden on front-line clinical staff and increase the likelihood that important safety events are captured and communicated to FDA. The ASTER-D pilot, coordinated by Mercy

Hospitals and Outcome Sciences, demonstrated the ability to automate the adverse reporting process by transmitting safety information to the FDA after a triggering event. FDA continues to work with the ONC Structured Data Capture work group in their efforts to use to use EHR data as a source of patient and healthcare information, which may facilitate further progress towards automated safety reporting. FDA should communicate next steps for how provider systems and HIT vendors can build the requisite tools to transmit automatically generated safety reports.

5. Provider systems should deploy pilot studies to highlight specific use cases and the return on investment for implementing UDIs across the three major data systems (e.g. supply chain, clinical, and revenue management): While robust models for calculating the clinical impact and return on investment for UDI implementation remain undeveloped, provider systems should consider the deployment of pilots to enhance their future decision-making. Targeted pilot studies in specific care settings (for example, within the catheterization lab) could demonstrate the distinctive value of UDI to specific provider systems, while providing clear evidence on the prospect of expanding implementation across the organization.

6. Provider systems should integrate the flow of UDIs across supply chain, clinical, and revenue-cycle management systems to more efficiently realize the benefits of UDIs: UDIs have the capacity to help provider systems connect the purchase, acquisition, use and reimbursement of medical device across their systems. Provider systems should begin by integrating UDI into master data management plans as a core data element. MDMPs assist providers in creating a single data source that data systems across the provider system can use to ensure data consistency. By including UDI in MDMPs provider systems can develop the related governance, processes, and quality checks around its inclusion. Provider should also engage with their HIT vendors to push for the emergence of tools that connect the principal provider data systems, allowing UDI and medical device data to flow and synchronize across the organization.

7. The Office of the National Coordinator (ONC) and the Centers for Medicaid and Medicare Services (CMS) should support the incorporation of UDIs into EHR Certification Criteria and Stage 3 Meaningful Use (MU): Federal support of UDI implementation within EHRs would likely constitute a critical boost towards UDI adoption. Rather than being designated an optional standard for adoption, ONC should include UDI as a requirement in its associated certification criteria when CMS issues its proposed Stage 3 Meaningful Use objectives in 2017. By designating UDI capture within the EHR as a requirement, it will provide an increased incentive for provider systems to capture UDI in their EHR implementations. Such regulatory action should also increase the likelihood that future interoperability standards for EHRs will support UDI capture and transmittal.

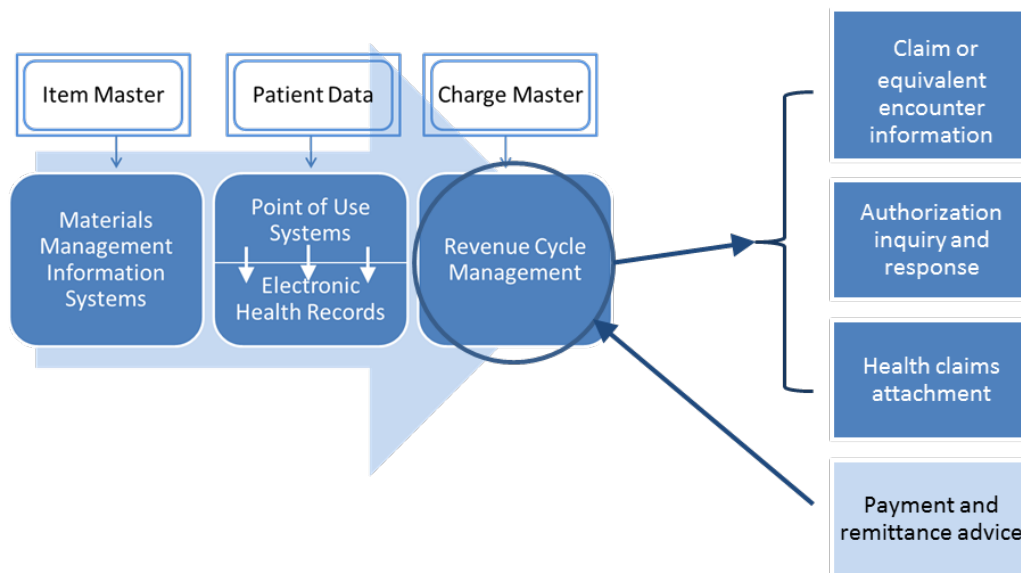
SECTION 4

Integrate UDIs into Administrative Transactions

Health care administrative transactions involve the transfer of health care encounter and payment-related information between payers and providers. These transactions include claim submissions, eligibility verification, claim status, claim payment, and remittance advice. They enable appropriate and accurate payment for health care services, procedures, and supplies by allowing payers and provider systems to exchange structured information in a timely manner. One of the most common forms of administrative transactions is the claim, which is a request for payment that a health care provider (or patient) submits to a payer for reimbursement. It provides a payer with a detailed, itemized record of health care services performed. The claim is derived from the provider's billing and revenue cycle management systems. As discussed in Section 3, the charge master is the repository within the provider system that lists of all the billable items that can be used over the course of a patient's care and designates a price for every procedure and item, based on a specific charge code. Data from the charge master, in conjunction with clinical data, feed the revenue management cycle which ultimately generates the final claim and patient bills. The generated claim is then submitted to facilitate payment back to the provider.

To assist the claim adjudication process for covered services, payers can request additional details in the form of a claims attachment. These are often paper-based and imaged transactions that supplement the information provided in the original electronic claim. Once a claim has been adjudicated, a payer will supply payment and remittance advice to explain the payment sent to a provider. Payment and remittance advice are derived from the initial claim information submitted by a provider. Alternatively, payment information can be routed through authorization requests. A number of devices or device related procedures (e.g., implantation) may require prior authorization by a payer. Currently, in order to receive a prior authorization for an implantable device, for example, a payer may require that providers fill out and transmit a form with information such as the name of procedure, procedural code, device manufacturer, and device model.⁷⁰ Through these authorization transactions, provider system revenue cycle management teams use their internal billing systems to prepare and send that information. Payers then send information back to providers regarding reimbursement of covered products and services (**Figure 9**).

Figure 9: Flow of reimbursement information through administrative transactions



The HIPAA Standards Development Process

The diversity of formats for administrative transactions is supported by the HIPAA standards development process. In the current environment created by the passage of HIPAA, provider systems are under pressure to demonstrate improved quality of care while keeping costs constrained. As such, several changes were made to simplify and standardize administrative transactions. These changes included a series of provisions which sought to standardize and streamline the flow of information between provider systems and payers. A critical component of this effort was the standardization of code sets for describing health care services, tests, procedures, and other activities.

Administrative transactions contain a number of codes that identify the procedures performed for a patient and any implanted device. The Accredited Standards Committee X12 is one of the six standards development organizations (SDOs) responsible for developing the technical details for HIPAA implementation of the existing standards around these administrative transactions. This responsibility entails determining the code sets used to identify various procedures. In the inpatient setting for diagnostic coding, the International Classification of Disease Ninth Revision, Clinical Modification (ICD-9-CM) and CPT codes are used by the physician to identify the type of procedures they performed; however, the specific device used is not identified. On October 1, 2015, providers and payers will be responsible for transitioning to version 10 of the ICD code set. ICD-10 will increase the specificity in which the patient's diagnosis and inpatient procedures are described on a claim.⁷¹ For medical devices, HIPAA established the HCPCS as primary code set for identifying device use in patient care. The code set aggregates devices into broad categories based on use and common physical characteristics (e.g. infusion pumps, non-programmable devices, implantables, etc.).⁷² In the outpatient setting, HCPCS-C codes can be used to identify the devices used in the patient's care but they do not capture the specific manufacturer and model. For example, a pacemaker, other than a single or dual chamber device, will have the HCPCS code C2621; however, there are many devices from various manufacturers, each with its own model number, classified within that code. As a result, the code set does not allow payers to identify specific devices with any level of granularity beyond the generic HCPCS-C code.

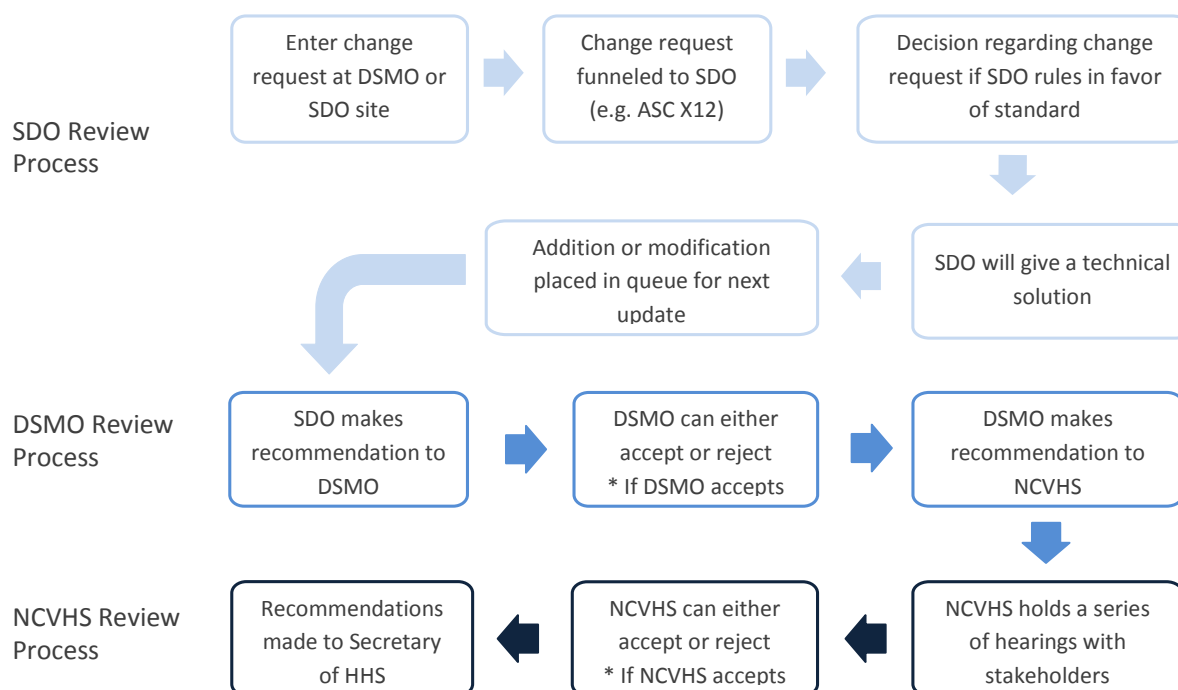
HIPAA provides for a standards development process that allows existing code sets within an administrative transaction to be altered. To do so, a change request must be submitted to the Designated Standard Maintenance Organizations (DSMO). A change request is submitted by payers or other interested parties who wish to alter the available code sets used in an administrative transaction. The purpose of these requests is to simplify the processes and costs behind these transactions. This change request should identify the type of request (e.g., eligibility, claim status), detail the business reason for the change request, and provide a way to implement the business reason for the change. If the change is related to the ASC X12 portions of administrative transactions, an additional set of questions related to implementation guides may be required. Once a change request has been submitted to DSMO, the three standards development organizations (SDOs) and three data content committees can opt in or out of handling the request. The change request can either involve changes to the standards or to the code sets (Figure 10). The six relevant organizations are: ASC X12, Dental Content Committee of the American Dental Association (DeCC), Health Level Seven (HL7), National Council for Prescription Drug Programs (NCPDP), National Uniform Billing Committee (NUBC) and National Uniform Claim Committee (NUCC).⁷³ These SDOs were designated by the secretary of Health and Human Services, per the HIPAA legislation and subsequent final rule, to develop and maintain administrative transactions standards and code sets. The SDOs cooperate with each other to update implementation guidelines and the HIPAA standards. Any change to the standards must go through them.

STAKEHOLDER EXPERIENCE ASCX12, NCPDP, and the Change Request Process

In June 2013, the Pew Charitable Trusts submitted a change request to ASC X12 in order to add UDI into administrative transactions via the claims form. In June 2014, NCVHS's Subcommittee on Standards held a hearing concerning the integration of UDI within administrative transactions and Pew's request to update the HIPAA transaction standards accordingly. Based on the testimony within that hearing, NCVHS, in a letter to the Secretary of Health and Human Services, recommended that HHS and industry cooperate further to investigate the costs and benefits of adding UDI into administrative transactions. ASC X12 is currently investigating the potential business cases of capturing UDI within claims and other administrative transactions. In addition, NCPDP has begun the process of reviewing its standards for UDI capture within its Retail Pharmacy Claims Transaction set, commissioning a UDI Task Group to develop recommendations for implementation.

For standards, the overall process for review of an addition or modification is shown in **Figure 10**. Once a change request is submitted and accepted, the addition or change will then be placed in the queue for next year's update to the standards. Once the change request has cleared the SDO process, it then begins the DSMO review process. The DSMO will take into account the recommendation made by the SDO, choose to accept or reject, and then issue its own recommendation to the National Committee on Vital Health Statistics (NCVHS). NCVHS then holds a series of meetings with stakeholders around the change request after which NCVHS can accept or reject the request and issue a recommendation to the Secretary of Health and Human Services.⁷⁴

Figure 10: SDO Process for Modification of Existing Standards and Adoption of New Standards



ASC X12 also develops a series of implementation guides that assist covered entities by defining specific activities for each transaction, listing non-medical standardized code sets, and providing directions for how data should be moved electronically. If the change request is related to the ASC X12 portions of the administrative transactions, the payer may need to submit an additional set of questions related to the implementation guides.

The change request process, if successful, can yield additions or modifications to the standards for administrative transactions.

For code sets, a similar process is involved. Currently, specific code sets for diagnoses and procedures are used in all transactions, including the Current Procedural Terminology (CPT), HCPCS, International Classification of Diseases - Ninth Revision (ICD-9), and the upcoming ICD-10. Any changes to the designated code sets (e.g., addition of a code set) can arise by way of congressional level changes in legislation or through regulation by way of a rulemaking process. With regards to regulation, once a change request is submitted by the owner and maintainer of the code set, all of the organizations in the DSMO would review the change request and vote on it. The code set change would need to be coordinated with the SDOs for incorporation into their adopted HIPAA guides.

I. Challenges to Administrative Transactions

Variations in Administrative Data Specificity and Format

There are a number of challenges that arise from the various formats through which administrative transactions are currently facilitated. Since HCPCS are unable to uniquely identify medical devices, valuable information concerning device quality is not reported to payers. As such, it is difficult for payers to track specific device utilization and performance patterns to inform more value-based reimbursement decisions. In addition, payer requests for supporting documentation, often provided through health claims attachments, is usually cumbersome and inefficient. A significant portion of health claims attachment transactions are paper-based and take the form of unstandardized, unstructured data (e.g., photocopy of the device label) which poses significant extract, transform, and load (ETL) challenges that encumber their integration into providers' electronic systems.⁷⁵ Authorization requests also have limited means towards identifying medical devices in administrative transactions since the specific device used on a patient is often unknown until the procedure is done.

Limits to Secondary Use Cases

In the absence of UDIs, payment information for medical devices at present is incapable of providing a level of granularity that can correlate specific devices to clinical outcomes, limiting the scope of secondary use cases for payers and providers. Additionally, due to the categorization of HCPCS and CPT codes into device types rather than by model and version, the code sets do not provide a level of detail that allows for routine and accurate cost effectiveness or patient outcome comparisons by specific device. The variability inherent to current administrative transactions codes are demonstrated below through the Unique Product Number (UPN) pilot led by the California Department of Health Care Services (DHCS).

STAKEHOLDER EXPERIENCE

UPN Pilot – Large Variability within HCPCS Codes

Through this pilot, the California Department of Health Care Services (DHCS) sought to test the feasibility and cost-effectiveness of UDI, formerly known as UPN, as an alternative to HCPCS codes, the current HIPAA coding standard for medical supplies. Examining a single HCPCS code, A7520, which refers to a Tracheostomy/Laryngectomy tube, the pilot found that this HCPCS code represented over 200 distinct products, including neonatal, pediatric, and adult tubes of different standards, sizes and materials. Moreover, the cost variability among this group ranged from \$21.62 and \$280.32 (Figure 11).

Figure 11: Products under HCPCS Code A7520 with maximum acquisition cost⁷⁶

	UDI CODE	MANUFACTURER	PRODUCT DESCRIPTION	MAXIMUM ACQUISITION COST
				COST
Extract of Corresponding UDIs to HCPCS A7520	35019315047675	Sims Portex	Blue Line trach tube uncuffed, 6.0mm Id	\$21.62
	10351688003782	Sims Portex	DIC trach tube uncuffed fenestrated, 7.0mm Id, 9.9mm Od	\$33.60
	10351688009586	Sims Portex	Uncuffed DIC tracheostomy tube, size 10	\$39.00
	05021312005557	Bivona	Adult trach tube, suffless, all silicone, 6.0mm Id	\$50.40
	20840029007840	Shiley	Neonatal 3.5 tracheostomy tube	\$57.60
	20840029008229	Shiley	Disposable cannula, cuffless size 4	\$63.41
	20840029008106	Shiley	Disposable cannula low pressure, cuffed trach tube, size 6	\$70.48
	20840029007741	Shiley	Trach tube, fenes, cuffless, size 4 FR	\$82.52
	20840029007802	Shiley	Laryngectomy tube, size 8	\$96.89
	04026704011957	Rusch	Tracheoflex trach set, Pediatric, no cuff adj flange, size 6.0mm	\$155.19
	05021312014733	Bivona	Flextend Plus neonatal trach tube, size 3.5	\$200.55
	35021312012570	Bivona	Neonatal Tracheostomy Tube 3.5 mm	\$280.32

Many payers are currently unable to make transparent the specific devices used in the care of individual members of their plan. This limits the ability of insured members to receive important follow-up information about medical device maintenance, safety, and performance. Non-specific reimbursement codes also obscure data on medical device payment utilization patterns for payers and providers. Devices that exhibit considerable variation in type and reimbursement are grouped together into general classes for reimbursement, with no evidence of their relative effectiveness. Without UDIs, it is more difficult for payers and providers to set effective reimbursement policies that are responsive to new data and evidence on specific medical devices.

Payers utilize administrative transactions data to maintain a broad perspective, taking advantage of their ability to track patients for relatively long time periods and across numerous encounters with different provider systems. Correspondingly, the extended use of many medical devices in patient care, such as implants, often necessitates the ability to track devices and associated patients over significant periods of time. While EHR data and other sources of clinical data can be a rich source of clinical detail, limitations in their ability to collect data as patients move from provider to provider renders them less useful for population level surveillance and performance tracking. Without the routine capture of UDIs in administrative transactions, payers are largely unable to conduct comprehensive and useful medical device postmarket surveillance. Providers are similarly limited in their ability to track patient outcomes, especially if their patients receive care from out-of-network physicians.⁷⁷ If the patient decides to switch providers, especially to a provider outside of an integrated network, the original provider will not necessarily have access to the patient's outcomes after that point. These challenges have been leading motivations for the inclusion of UDI into administrative transactions and mobilizing both payers and providers to play an active role in supervising the safety of medical devices affecting insured patients.

II. Value of Integrating UDIs into Administrative Transactions

The availability of UDIs should help mitigate the current challenges to transparency and efficiency in device reimbursement. By integrating UDIs into administrative transactions, patients, payers and provider systems will have an opportunity to build higher-levels of granularity into HIT systems to improve the understanding of medical device utilization, performance, and safety. Payers able to track the medical device's usage across the spectrum of care will have increased transparency concerning device costs and can access more granular reimbursement models. UDI implementation will also enhance fraud detection for payers, reducing the possibility of falsified billing submissions. For providers, UDI integration into administrative transactions would ultimately reduce their operational costs and facilitate improved clinical decision-making. By incorporating UDI

into billing systems and administrative transactions, provider systems can also gain deeper insight into the link between device use and cost and bill appropriately for medical device use. By establishing a clear link between the charge and item masters, provider systems would be able to attain a better accounting of their inventory, customize the level of granularity of reports, effectively manage revenue and billing, and reduce wasteful inefficiencies across systems. The improved communication between the provider's various systems would allow the provider, for example, to implant a device, appropriately charge for it, and automatically trigger the appropriate decrease in inventory.

Consequently, incorporating UDI into administrative transactions will be a tool that payers and providers can use to drive value-based health and improve their understanding of medical device use, providing a significant number of secondary benefits. Since claims data can provide a more general view of a device's use, especially compared to the more individualized information provided by an EHR, both payers and providers stand to gain significantly more secondary value by accessing the capabilities of the Sentinel System. The Sentinel System uses health care claims data to assess the safety of drugs and other medical products in large populations of patients in near-real time.⁷⁸ In addition, capturing the UDI within administrative transactions would supplement the information being provided to registries from the EHRs. By receiving unique device information from the claim, registries would be able to assess device performance on a longitudinal basis, bypassing the need to directly contact individual patients for outcomes.⁷⁹ Providers would be able to perform long-term analyses of device performance, audit the information that is sent to registries, and work with payers to identify safe and cost-effective medical devices. Providers would also be able to work with patients to ensure that the right devices are being chosen for their care. In addition, payers would be able to assist manufacturers and the FDA in managing recalls since they can most efficiently reach affected patients due to the personal information already present on the claims form and their ability to track patients even if they change providers.

There is an extensive range of benefits available to payers, providers, and the public from the inclusion of UDI in administrative transactions, listed below in Figure 12, ranging from quickly identifying beneficiaries affected by a recall to conducting cost and effectiveness studies. However, payers have not supported rapid UDI adoption in payment systems, particularly given that payer attention is currently focused on ICD-10 implementation and many other administrative changes. This will change over time; for now, if some payers were to begin asking for UDI to be included in administrative transactions, and began demonstrating value from its incorporation, this would help accelerate the collection of UDIs in administrative transactions.

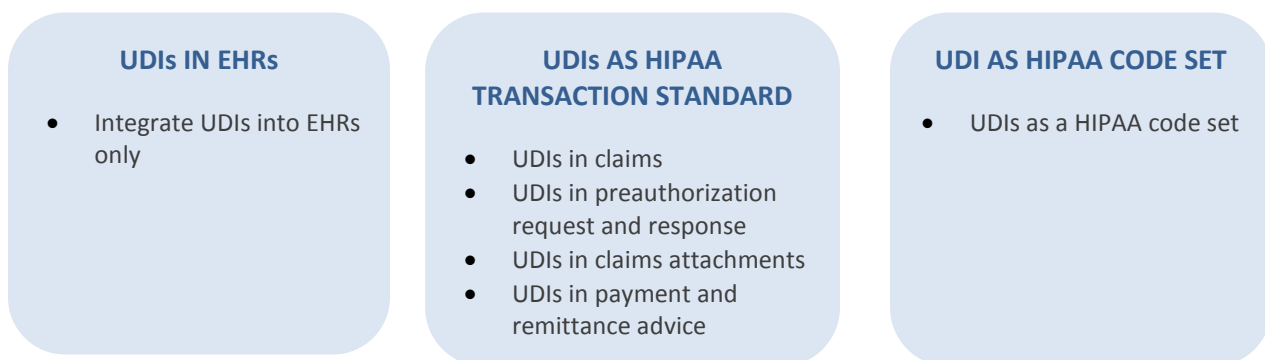
Figure 12. Value Use Cases of UDI Implementation into Administrative Transactions

DIRECT VALUE	INDIRECT VALUE	LIMITED VALUE
<ul style="list-style-type: none"> • Medical device safety surveillance • Comparative effectiveness and patient-centered outcomes research on medical devices • Tracking of medical device utilization patterns and analyses of appropriateness of care • Improved ability to support ongoing quality initiatives • Improved recall process • Efficient communication of safety information to patients and providers • Increased medical device reimbursement transparency • New opportunities for value-based purchasing and other support for enhanced value • Fraud detection 	<ul style="list-style-type: none"> • Provider access to critical device information • Patient access to device information and shared decision-making • Support for medical device innovation • Emergency preparedness and response • Anti-counterfeit detection 	<ul style="list-style-type: none"> • Identifying networked and telemetric medical devices • Improved supply chain integration and management

III. Strategies for Integrating UDI in Administrative Transactions

Promising strategies for integrating UDI into administrative transactions include the participation of many stakeholders including patients, payers, provider systems, and third-party HIT vendors. Significant effort will be needed on the part of these stakeholders to understand and articulate the ways in which UDI can support the above activities and how they can be integrated into existing systems. The strategies for integrating UDI into administrative transactions can be broken down into three broad categories as shown in Figure 13: incorporating UDI as a HIPAA transactions standard; as a HIPAA code set; and integrating the UDI into the EHR. While UDI integration into EHRs does not directly impact administrative transactions, they can be linked together to improve the visibility of patient outcomes and costs and are the starting point for UDI implementation.

Figure 13. Strategies for Integrating UDI into Administrative Transactions⁸⁰



Below, we explore the possibilities for each of the transactions that may allow various stakeholders to benefit from UDI inclusion, as well as the potential for UDIs to be included as a code set.

A. Integrating UDIs into EHRs Only

As covered in the “Implementing UDI in Provider Systems” section, UDIs captured via EHRs can be harnessed to accomplish many of the same valuable use cases of UDIs in administrative transactions and could be the starting point for UDI implementation. In this section, we explore the viability of an EHR-driven pathway that operates exclusively from having UDI in administrative transactions. This pathway would bypass storing UDI directly in administrative transactions but would rather pull UDIs and related medical device data from EHR systems. This mechanism could still enable transmission of UDIs and medical device transaction data to downstream stakeholders including payers. The following sections will then detail how UDI could be integrated within administrative transactions themselves.

EHR adoption is not yet at a level to sustain many of the use cases uniquely available to administrative transactions. While storing and extracting UDI-enriched EHR data will provide stakeholders access to rich clinical data on patients and medical devices, these systems lack interconnectivity, even within the same provider system. Patient mobility across health care provider systems presents barriers to aggregating disparate patient clinical data for research and analysis. As an example, a patient receiving an implant may find their data scattered amongst the implanting surgeon, primary care doctor, and emergency department HIT systems. Moreover, the Proposed Rule for EHR certification criteria includes UDI as a menu objective (i.e., can be one of a combination of functionalities selected) instead of a core objective (i.e., mandatory functionality), which allows stakeholders to opt in or out of incorporating UDI into their EHRs. Even though the Proposed Rule stipulated that UDI was optional, it was ultimately pulled from the Final Rule for 2015.

To achieve sustainability for UDI integration in EHR, EHR interoperability and functionality will need to expand to efficiently and routinely capture and export UDI data across stakeholder systems. In addition, payers, professional medical societies, public health agencies and others will need to make appropriate changes to their systems to be able to receive, aggregate, and parse EHR data. Important steps forward in this direction have

already been taken, particularly as part of ONC's Structured Data Capture Initiative to include incorporating EHR data into adverse event reports. As HIT efforts, such as EHR certification and Meaningful Use, move to include UDI in EHR systems, and software vendors and providers begin to make modifications to their supply chain and clinical systems to accommodate these changes, stakeholders may opt to begin directly sending EHR data containing UDI from providers to other providers, to payers or to registries, sidestepping inclusion of UDI in billing systems and administrative transactions. If full integration were to be achieved, linking EHR data that contains UDI with administrative transaction data would provide unprecedented visibility into patient outcomes and medical costs.

Despite the potential benefits of bypassing administrative transactions, they have a number of distinct advantages, including limits on the number stakeholders (i.e. payers) receiving patient data. Accordingly centralized collection of patient data and standardized data exchange is much more seamless for payers. Given the current incongruence of EHR systems and their inability to link with other EHR systems and administrative transaction data, UDI integration into EHRs may not support the various use cases on its own.

B. Integrating UDIs into Claims or Equivalent Encounter Information

At the provider site, the billing and revenue cycle management systems act as the aggregator for information important to report on the claims and codes appropriate reimbursement. If UDIs were required for reporting in claims, providers would need to pull information from the clinical data systems into the billing system or capture it at the point of payment to fulfill this requirement, generate a complete claim, and receive reimbursement. This would serve as a strong incentive for providers to incorporate UDI into their billing systems.

Though there are a number of configurations through which UDIs can be included in a claim, such as the level at which UDIs should be communicated (i.e. header, detail) and the level constraint, the optimal approach would integrate UDIs at the claim detail level as a situational rule.

There are two standard formats related to electronic exchange of claims data: ASC X12N 837 (837) and the NCPDP Retail Pharmacy Transactions.⁸¹ The primary format pertaining to medical devices in the provider setting, the 837, establishes the format and data contents of the Health Care Claim Transaction Set. Providers can use this standard to submit billing information and/or encounter information using this transaction set through intermediary billers or claims clearinghouses.⁸² Claims can then be submitted on the institutional or provider level. For high-risk implantable devices (e.g., pacemaker, hip), the institutional claims form will be the most pertinent. The UDI could be included on the 837 at the claim header, which identifies the start of a transaction set and its business purpose; and the claim detail, which is built on a hierarchical level structure based on the participants involved (e.g., payer to provider, patient to payer).⁸³ If the UDI were included in the claim header, it would apply to the entire claim; whereas, if the UDI were included at the detail level, it would apply only to that particular service or procedure.

Since devices are often associated with a particular service or procedure in a patient encounter, HCPCS and CPT codes are currently provided at the claim detail level. Similarly, providers and payers would benefit most from having UDIs included on the detail level. This would allow for a more focused understanding of device use in the context of the patient encounter, which in the case of implanted devices would be of particular importance because the UDI would be associated with the procedure code for implantation.

With the level at which the UDI is communicated determined, its level of constraint will need to be considered. A "required" designation would indicate that this item must be present in all data transactions because it is essential for this business use of the transaction set. A "situational" designation would indicate that this item's usage depends on an associated business rule which is specified in the ASC X12 implementation guide and which clearly and unambiguously states the requirement designation under each anticipated condition.⁸⁴ In this context, the UDI would be used for reporting when required by government regulation or a health plan, or as deemed by the provider to enhance claim reporting or adjudication processes. This will allow payers the flexibility to determine when and if they need the UDI, and work with providers to verify that their systems can support its capture.

For claims, UDIs may help support administrative processes by providing additional detail regarding devices used in a particular patient encounter even though UDIs may not be critical to these processes since current billing arrangements do not always require specific device information in order for claims to be adjudicated. However, UDI in claims can provide a link for patient outcomes and device use over the course of a patient's interaction with that device (e.g., the device is implanted by a surgeon and the primary physician conducts follow-up care), particularly as patients move from doctor to doctor. This link also provides the foundation for quality assessment and utilization review by payers and postmarket surveillance efforts on the part of public health agencies, as is the case for drugs in Mini-Sentinel.⁸⁵ In addition, registries could create a link to claims data, enhancing their ability to conduct long-term outcomes analyses.⁸⁶

STAKEHOLDER EXPERIENCE

Pew and WEDI Efforts to Capture UDI in Claims

The Pew Charitable Trusts (Pew) submitted a placeholder change request to ASC X12 to create a new field for UDIs of implanted devices in claims, pending the completion of business cases for the request. On April 7th, the Workgroup for Electronic Data Interchange (WEDI), in collaboration with Pew, released a white paper fleshing out the business cases for the capture and transmission of UDI. Through research and insight gained from convening stakeholders, WEDI discussed a number of business cases, including analyses by health plans, recall assistance by health plans, participation in FDA's Sentinel Initiative, and enhanced use of registries. WEDI also found that the optimal approach to achieving the stated value of UDI in claims would consist of a hybrid comprised of the following initiatives: include UDI as a situational rule, enable provider capture and transmittal of UDI across systems, expand registries to include UDI, conduct additional research into UDI in prior authorization, and deploy pilots with federal regulatory assistance to test and demonstrate UDI transmission and analysis.

C. Integrating UDIs into Authorization Request and Response

Though it would be advantageous for payers and providers to have the DI portion of the UDI on these forms, this option is ultimately limited in its scope of use. While payers would be able to more quickly and efficiently respond to the provider's authorization request, if implemented in isolation, it would limit the capture of UDI to medical device transactions requiring prior authorization and notification. More importantly, it would necessitate that the provider accurately anticipate which specific medical device will be used before a procedure is done, which for many surgical procedures, the exact model of implanted device may not be known in the days or weeks prior to the surgery. As a result, the UDIs may not be an accurate reflection of the devices actually used. Since prior authorization does not necessarily reflect actual device use, incorporating UDI into that transaction would, in itself, not effectively support quality assessments, utilization review, or postmarket surveillance efforts.

D. Integrating UDIs into Health Claims Attachments

As standards around health claims attachments are developed, there is an opportunity to incorporate UDIs as a structured data element, enabling quicker identification of devices via this process. However, major issues with this option include the low penetration of structured electronic health claims attachment forms in provider systems, the lack of a final rule regarding data standardization, and the limited range of using health claims attachments during routine care. While the claims attachment could serve as an alternative location for UDIs since they are often requested by payers to supplement information provided by HCPCS and CPT codes, they are ultimately not a viable strategy for UDI integration. The passage of HIPAA in 1996 directed the health care community to develop an electronic standard for health claims attachments. However, despite the passage of a proposed rule in 2005, a final rule was never published due to concerns around the maturity of standards and the ability to implement them. With the 2010 passage of the Patient Protection and Affordable Care Act, the Secretary of Health and Human Services was directed to issue final regulations around national standards, implementation specifications, and operating rules for health claims attachments; however, no standards have yet been published.⁸⁷ The goal of standardization is to streamline the process of submitting and adjudicating

claims by providing information in the form of structured electronic data, with the current standards under consideration developed by ASC X12 and HL7.

Requiring capture of UDIs on health claims attachments may also increase provider burden through the addition of an extra transaction that must be completed in conjunction with claim documentation. For these reasons, it is unlikely enough data would be routinely available or accessible for UDI in health claims attachment to support routine and useful postmarket surveillance of medical devices.

E. Integrating UDIs into Payment and Remittance Advice

Incorporation of UDIs into payment and remittance advice transactions would be beneficial as these transactions aggregate payer information and include adjudication for a succinct summary of the reimbursement for an episode of care; however, their usefulness depends on initial UDI integration into the claims form. Provider organizations would be able to utilize this summary information to conduct quality assessments and utilization reviews. However, unless the UDI is captured initially within the original claim forms, it would not flow downstream to the payment and remittance advice transactions. Standardizing UDI capture for payment and remittance would be ineffective unless UDI is already being captured at the claim level upstream.

Table 3: UDI ability to support different activity types in each administrative transaction

UDI Incorporated Into	Widespread Capture of Medical Device Types	Routinely and Accurately Captured During Care	Supports Quality Assessment and Utilization Review	Supports Electronic Standardization	Supports Postmarket Surveillance
Claims	Yes	Yes	Yes	Yes	Yes
HIPAA Code Set	Yes	Yes	Yes	Yes	Yes
Authorization Request and Response	Partially	Limited	Limited	Yes	Limited
Health Claims Attachment	Limited	Limited	Partially	Limited	Partially
Payment and Remittance Advice*	Yes	Yes	Yes	Yes	Yes

*Requires claim transactions to capture UDI upstream

F. UDI as a HIPAA code set

If UDIs were deemed critical to a wide range of administrative transactions, stakeholders might push for, and subsequently benefit from, including the DI portion of UDIs as a HIPAA code set. DIs applied across all relevant class I, II, and III medical device classes could function as a more accurate replacement or supplement for CPT codes and HCPCS. Through the change request process, the owner and maintainer of the code set would bring forward the code set for review. All of the organizations in the DSMO would review the change request and vote on it. The code set change would need to be coordinated with the SDOs for incorporation into their adopted HIPAA guides. Adapting the current fields used for CPT and HCPCS to capture UDI would mitigate burdensome additions to clinical workflows and HIT modifications, but this mechanism would also take the longest time to implement and require the most significant push from payers and other stakeholders to move forward.

STAKEHOLDER EXPERIENCE

The Universal Product Number (UPN) Pilot

The Universal Product Number (UPN) Pilot examined the potential for capturing UDIs in medical and pharmacy claims for diabetic supplies, enteral nutrition, incontinence, ostomy, tracheostomy, urologicals and wound care. Through this pilot, the California Department of Health Care Services (DHCS) sought to test the feasibility and cost-effectiveness of UDI, formerly known as UPN, as an alternative to the less specific HCPCS codes. Over the course of two years, UDIs were recorded in a segment of the claim form that serves as a general product identifier field and is currently only allowed for reporting NDCs for drug identification. The medical claim form includes a separate data element that allows for the reporting of HCPCS Level II codes. During the pilot, over seven million claims were processed with UDIs for a total of over \$600 million in provider reimbursements for devices from the following medical product categories: diabetic supplies, enteral nutrition, incontinence, ostomy, tracheostomy, urologicals, and wound care. The pilot found that UDI helped lower program costs, improve the quality of data collected, and improve patient safety along with demonstrating the potential to reduce fraud and abuse.

Despite these benefits, the UPN pilot also uncovered a series of challenges associated with capturing UDIs as part of claim transactions. These challenges include the lack of a single authority for UDI standardization and storage, complex and inconsistent labeling formats, lack of a federal mandate for standardized UDI use and labeling, and variable lengths and formats of existing unique identifiers. Participants indicated that many of these issues would likely be mitigated with the release of the final UDI regulation. At the close of the pilot, an evaluation was conducted to determine whether UDI met the federal criteria for adoption as a HIPAA coding standard. The evaluation found that UDI fully met eight out of 10 criteria and partially met the other two. As a result, California submitted a recommendation to the Secretary of the Department of Health and Human Services (HHS) to adopt UDI as a situational data element on institutional, professional and pharmacy claim forms to be directed for use in cases where UDI needed to be more specifically identified. HHS denied this request, indicating that UDIs lacked the maturity and widespread use necessary for consideration as a HIPAA standard. However, with the changing healthcare environment where transparency and accountability for the quality of care is becoming a vital, UDIs that can directly generate clinical evidence for a specific device may become more useful as a HIPAA standard.

Payers and provider systems would have to prepare for this significant changeover, which could require the difficult task of mapping current HCPCS to DIs. Since the final compliance deadline for UDI labeling on medical devices is 2020, UDI might not represent a complete code set until that time. Alternatively, recommending and mandating UDI as a HIPAA code set may speed up manufacturer compliance, since the UDI would begin to dictate reimbursement of manufacturer medical devices. However, the GUDID, which serves as the database for all UDIs with the FDA as a single authority, is being populated in phases based on device classification and may have limited ability to accommodate advanced data submission by manufacturers ahead of schedule. These factors make it difficult to assess the feasibility of pursuing the standardization of the DI as a HIPAA code set until the full rollout has been completed.

STAKEHOLDER EXPERIENCE

Physician Administered Drugs: Adding Capture of a HIPAA Code Set

The gradual reporting of NDCs for physician-administered drugs on medical claims may carry lessons for UDI implementation. Claim standards for inpatient, outpatient, and professional claims were developed to allow for the reporting of NDCs, a HIPAA code set for physician-administered drugs, as an optional reporting element. However, their use was not mandated. Initially, providers were required to submit the appropriate HCPCS codes, but no unique identifier for physician-administered drugs was required.

In implementing the NDC reporting requirement for physician-administered drugs, states, in coordination with CMS, allowed for a period of voluntary reporting, in which providers were encouraged to begin reporting NDCs for physician-administered drugs, but no claims were denied based upon lacking the code. In 2005, reporting NDCs for certain physician-administered drugs became mandatory as part of the federal Deficit Reduction Act (DRA) of 2005. The DRA expanded the Medicaid Drug Rebate Program to include physician-administered drugs. As such, Medicaid providers were required to report the NDC on outpatient and professional claims. State Medicaid programs use NDCs to reimburse claims, track utilization, and collect rebates from manufacturers; each of these activities was enhanced with the availability of NDCs in claims, contributing to significant cost savings. The initial voluntary use of NDCs on medical claims allowed providers who were ready to begin reporting NDCs for physician-administered drugs the opportunity to do so, while allowing providers who needed time to build the capabilities and workflows to report NDCs adequate flexibility. Such a phased strategy could also be successful for UDI reporting in claims.

IV. Recommendations

1. Include the device identifier portion of the UDI as a situational element at the claim detail level for high-risk, implantable medical devices: While payers could receive billing data by linking the EHR to administrative transaction data, integrating UDIs within administrative transactions will unlock a number of unique benefits, providing significant and unprecedented visibility into patient outcomes and medical costs, increasing reimbursement transparency, and enabling more comprehensive device surveillance. Existing systems that are routinely used for medical product safety surveillance, such as the Sentinel System, are already using claims as the primary data source. Incorporation of UDIs directly into the claims will enable devices to be included in Sentinel efforts. Integrating UDIs into claims can support administrative processes by providing additional detail regarding devices used in a particular patient encounter in a standardized format and complement the information provided by UDI integration within the EHR. UDIs should be integrated into the ASC X12 837 (837) and NCPDP Retail Pharmacy Transactions claims form as a situational rule on the claim detail level. Integrating the claim at the detail level allows for information collection concerning a particular procedure instead of applying to the entire claim. In addition, by integrating UDIs as a situational rule, payers will have the flexibility to determine individual requirements for capture of UDIs and can work with providers to make sure their systems can support its capture.

In order to add UDI as a field into the claims form, payers will need to follow the HIPAA standards development process covered in the “Introduction” and pursue the submission of a change request to the DSMO. Payers, provider organizations and trade groups, such as America’s Health Insurance Plans (AHIP), have begun the process of pushing UDI through the standards-making process. In addition, NCPDP commissioned its own UDI Task Group to review its standards and create guidelines for UDI implementation within the NCPDP claims transaction set.

2. Link medical device registries to claims data integrated with UDIs: The presence of UDIs within registries and the subsequent link to claims data that capture patient information (for example, a patient with an implanted cardiac stent identified with a UDI would be captured within the billing information) presents a number of valuable benefits to payers, providers, and manufacturers. These benefits include enhanced capacity for long-

term outcomes analyses and more robust evaluations of device safety and effectiveness. Registries would no longer be restricted by the short-term limitations of the patient data they already collect since they would be able to more accurately match patients to the data present within the claim. Registries linked to claims data would enable multiple stakeholders to access long-term evaluations of patient outcomes that would otherwise not be possible.

3. Commission a payer-led pilot project to demonstrate the primary and secondary benefits of UDIs within claims: To demonstrate the primary and secondary value of UDI in claims, payers and CMS should pursue the deployment of pilot studies. While there are significant barriers to conducting a pilot study since the comprehensive benefits of UDI implementation in administrative transactions might only become apparent with universal adoption by payers and providers, a focused study that examined specific use cases, particularly for fields of high interest or cost to payers, between one payer and one provider could provide evidentiary support and highlight potential business uses to both stakeholders.

4. Include the DI portion of the UDI in payment and remittance advice: To supplement the information provided by UDI integration into the 837, UDIs should also be implemented within the ASC X12 835 payment and remittance advice transaction set. While UDI integration into payment and remittance advice is not a viable strategy on its own since the information provided by this advice is drawn from the claim in the first place, its integration in conjunction with the 837 would help payers more efficiently communicate claims and assist providers with their own assessments of quality and utilization.

Similar to Recommendation 1, payers and other interested parties will need to engage the HIPAA standards development process, through ASC X12 and NCPDP, to add UDIs into payment remittance advice as they would with the claim. Since HIPAA requires that all electronic transactions follow a standard format, payers and provider systems will need to update their electronic systems to capture the claim and subsequent payment advice.

5. Pursue the compliance and development of the DI portion of the UDI as a Health Insurance Portability and Accountability Act (HIPAA) code set to replace Common Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System (HCPCS) for medical devices: In the long term, payers should pursue the adoption of the DI portion of the UDI as a HIPAA code set to replace or work in conjunction with HCPCS. While inclusion of both the DI and PI portions of the UDI may be important, starting with only the DI could be the best option due to potential technical challenges and standards requirements. FDA's maintenance of the Global Unique Device Identification Database (GUDID), which will house and maintain all DIs published by labelers and made available to the public, will bolster the use of the DI in claims. Such a single authority should allow the DI to represent a consistent source of information for maintaining a rigorous standard of medical device identification. However, the GUDID is still in the beginning stages of development and will need to be able to incorporate additional entries from labelers. Providers and payers would need to update their systems to allow them to map DIs to the current CPT codes and HCPCS within their systems in order to accommodate individual UDI entries. While this transition would be gradual and take considerable amount of time to implement, it would bring a considerable number of benefits to payers and providers. DI integration would mitigate the current challenges posed by CPT codes and HCPCS by allowing devices to be identified beyond broad categories, allowing payers and providers to better track device performance and reimburse for specific devices. UDI integration as a code set could help improve the quality of data collection efforts, lower costs, reduce incidences of fraud and abuse, and ultimately, improve patient safety.

SECTION 5

Integrate UDIs into Patient-Directed Tools

Advances in medical devices are enabling patients to live longer, more functional lives while providing physicians with new treatment options to address complex health issues. To manage their healthcare efficiently, patients with medical devices and those who anticipate using a device, need to receive accurate information related to the proper operation, safety, and overall performance for their particular medical device. Currently, there is a gap in providing patients with important and timely information about their medical devices. It is vital that patients have easy access to information regarding the devices they use and have reliable mechanisms to support bidirectional communication of device operation and performance. Efforts to monitor and improve the performance of medical devices must increasingly capture the patient perspective, in part, due to the difficulty of separating technical or mechanical device function from improper usage of the device.

Presently, patients that undergo an implant receive information regarding the implanted device from their provider usually via a paper-based implant card. Patients are then supposed to record this important medical information along with their medications, allergies and other critical information. With the current advances in information technology, device information can be more effectively delivered electronically to patients through a set of tools developed to engage patients and empower them to manage their health. Patient-directed tools can therefore be defined as use tools that engage directly with patients as the end user. Patients can drive this effort by demanding information regarding the devices they are implanted with or use from providers. With the availability of UDIs, it is vital that patients request for their UDIs from the physician. Although this information is primarily important to patients and providers, other stakeholders (i.e. manufacturers, public health agencies, and payers) will also benefit from an expanded set of tools by improving the communication of medical device safety information, patient engagement and patient satisfaction. This section will cover strategies for integrating UDIs into patient-directed tools to effectively communicate device specific information to patients and receive important feedback.

Improving Outcomes with Patient Engagement

Patients who are more engaged and involved in a shared decision making process with their provider may be more satisfied with the quality of care they receive.⁸⁸ Improving patient engagement and access to information can help patients understand the importance of monitoring the performance of their medical devices, improve communication with their providers to learn how their particular device works, and understand what potential problems might arise and how they should report these problems to their providers. Developing patient-directed tools that engage patients to capture medical device information and track their devices through alternative and consumer channels can help facilitate earlier safety responses and improve dissemination of safety information.

Diversity of Patient-Directed Tools Available

There exists a range of novel and useful patient-directed tools targeted towards engaging and informing patients about their health care and more specifically about their medical devices. Broadly, these tools include educational and instructive material such as patient checklists and questionnaires, to more sophisticated and electronic tools such as personal health records (PHR), and consumer medical applications. Each tool offers a separate set of modalities for patient interaction and particular advantages. UDIs can be easily integrated into these tools and allow the patients and providers to exchange information regarding the use, effectiveness and safety. For example, the checklist and questionnaire sent to each patient can contain the UDI which will be used as the primary identifier for communication of information regarding the device. In addition, patients could record or register their UDI into the PHR and consumer medical application respectively and receive device specific information or provide feedback to providers or other relevant parties.

Checklists and Questionnaires

Patient and provider checklists and questionnaires comprise some of the most effective and least costly patient-directed tools. Checklists are systematized steps in a list that are used during the course of care to mitigate errors and to help better inform both patients and providers to improve quality of care.⁸⁹ Patient access to

checklists usually occurs through interactions with provider systems, internet resources, or health literature. Though checklists can have a limited range of utility as they can restrict communication between the provider and patient to a one way interaction, they render health system encounters more transparent, reduce error, and open up channels of informational exchange between patients and providers.

Examples include pre-appointment checklists that clearly inform what patients should bring to their appointment, typically including relevant medical records, insurance information, health logs and personal identification. Providers may also utilize checklists to ensure patients are asked critical information such as whether the patient has any implantable medical devices. These checklists may change in content depending on the practice area and the reason for their appointment. AHRQ maintains a webpage that publishes reports on medical checklists, including the top ten questions that patients should consider asking their provider.⁹⁰ FDA has also published a patient checklist for home healthcare medical devices such as ventilators and blood glucose monitors as well as recommended actions for providers to discuss metal allergies with patients before medical device implantation.^{91,92}

Personal Health Records

The growth of digital patient communities, patient connectivity and the release of electronic health information to patients present additional opportunities and challenges for stakeholders seeking to better engage with patients and provide accurate information about medical devices to their end users. Personal health records (PHRs) allow patient to access, manage, modify and share their health information at their own discretion. It has been estimated that PHR adoption by health care consumers will increase by 221 percent from 2012 to 2017.^{93,94}

Although PHRs are similar in technical structure and informational content to EHRs, PHRs are intended to be used differently, by allowing patients to independently view, download, and modify, their electronic health information. PHRs can be web-based, electronic stand-alone, paper-based or have some intermediate level of connectivity and digitization. PHRs have been developed by several sponsors including payers, consumer HIT vendors, provider systems, and other third-parties. For example, a payer-run PHR platform may enable patients to input patient health information over the internet by themselves into a standardized electronic form that can retrieve and disperse patient health information across diverse provider systems. Additional functionality of PHRs includes appointment requests, health and wellness management and many others. There is increasing promise that PHRs will be able to serve as a comprehensive platform to capture longitudinal patient health records, encourage patients to become more active in their care, lower administrative duplication of information, and capture disparate sources of patient data.

Linking PHRs with EHRs

Linking EHRs with PHRs has proven to be a powerful combination for increasing the fidelity and relevancy of data used not only by patients, but also provider systems, payers, and researchers. By linking EHRs through an integrated PHR platform, provider systems can more seamlessly develop asynchronous and bidirectional interaction with patients. By allowing patients access to their health information on their own time, PHRs empower patients and provide them with the opportunity to supplement EHR information and flag or correct any errors. This linkage also opens up the possibility for greater collaborative efforts to improve patient engagement with clinicians, in contrast to the current interactions of providers and patients that are primarily discrete episodes of provider-centric communication and care.^{95,96}

Unlike EHRs that originate and remain mostly within the custody of provider systems and payers, PHRs can be built and managed across a range of entities. Where PHRs originate from and who pays for them are important considerations for addressing privacy and sustainability concerns. PHRs originating from HIPAA-regulated entities generally must be HIPAA-compliant, as well as any patient health information that is inbound to PHRs.⁹⁷ PHRs originating from non HIPAA-regulated entities, and that do not contain HIPAA-protected information, have far wider latitude in their privacy agreements. These differences in laws and regulations surrounding privacy issues between EHRs and PHRs means that patients and developers of PHRs must be increasingly vigilant about their collection, transfer and use of patient health information.

Federal PHR Implementations

There have been several federal efforts to build PHR solutions and enhance their use. Most notable have been the Department of Veterans Affairs' (VA) My HealtheVet program, a number of Centers for Medicare & Medicaid Services (CMS) pilots, and the Blue Button program. Over 2.2 million users are registered for My HealtheVet.⁹⁸ Through My HealtheVet, patients can log and modify personal and health-related information, such as addresses, emergency contacts, blood pressure and weight.⁹⁹ While more research may be required to understand the true advantages of PHRs such as the My HealtheVet program, there is evidence that the program has assisted in helping patients to become more active in their care, and patients report higher levels of care satisfaction.¹⁰⁰

CMS conducted a number of successful PHR pilots among their fee-for-service, Medicare Advantage, and Medicare Part D beneficiaries.¹⁰¹ An important finding from these pilots was the need for patients to have a simplified user interface that is able to pre-populate a PHR with comprehensive patient health information.¹⁰² A key advantage of Federal implementations of PHRs could be the closer integration or cooperation of provider networks and government payers. PHR platforms that have greater access to important patient health information, including medical device data, may prove more helpful to providers and patients.

Blue Button and Blue Button+

The Blue Button program was launched in 2010 by the Department of Veteran Affairs, but has since expanded in use to CMS, the Department of Defense, and a number of private payers.¹⁰³ Blue Button allows patients to download their health information in human-readable format. Downloaded patient health information can then be viewed in isolation or used across different personal health record platforms. ONC is working on an effort to improve the current functionality of the Blue Button program named Blue Button+. Blue Button+ seeks to standardize and structure Blue Button data for improved machine-readability and application development.¹⁰⁴ By improving the automation and application-building aspects of electronic patient health information, patients can leverage that information across a wide variety of PHR platforms and patient health information services.

Industry PHR Implementations

PHR platforms have also been built by private industry stakeholders, with a wide variation in features, technical architectures and business models. High profile efforts include web-based implementations of PHRs managed by large third-party developers such as Google Health, Microsoft HealthVault and WebMD Health Manager.¹⁰⁵ A key advantage to Google Health and Microsoft HealthVault technical architecture was their open application programming interface (API) that allowed third-parties to develop additional applications for improved functionality.¹⁰⁶ While a number of industry PHR initiatives have survived, they often struggle with gaining access to relevant patient health information and developing sustainable business models. Google Health most notably ceased operations in 2011.¹⁰⁷

Some of the most sustainable PHR initiatives have been led by health plans and employers who often have prior relationships established with provider networks to access relevant patient health information and can use PHRs to differentiate their market offerings from competitors. Efforts by the America's Health Insurance Plans (AHIP) and Blue Cross Blue Shield Association have led to standards development by HL7 and ASC X12 to standardize a common PHR data set and exchange standards.^{108,109,110,111} However, there is no standardized format across PHRs as of yet. The lack of standardization and interoperability between various PHR systems and patient engagement tools may pose barriers to patient engagement.¹¹²

Consumer Medical Applications (CMAs)

Checklists, questionnaires and PHRs most often exist within the context of direct interactions between provider systems and patients. However, patients and health care consumers are increasingly shifting their focus to patient-directed tools and platforms that distribute important and comprehensive medical information that is delivered outside the confines of provider systems. A growing medium for patients to receive medical information has been through consumer technology such as mobile phones and internet applications. Ninety percent of Americans own a cell phone and two-thirds use their phones to connect to the internet.¹¹³ A 2013 report found that 10 percent of U.S. health care consumers have used a mobile application to track their health

and 33 percent of consumers use their phone to look for health information.^{114 115} Decision makers have recognized this as an important trend as more Americans increase their adoption of consumer medical technology.

CMAs lack a widely agreed upon definition. They can be generally defined as electronic programs or hardware that allow health care consumers to actively participate in their own health care and wellness.^{116,117} An increasing number of CMAs are web-based and mobile, following trends in health care consumer technology adoption.^{118,119} CMAs also include online patient registries that aggregate patient and clinical information to support evidence development and dissemination for disease and outcomes. CMAs can fulfill a variety of functions, including informing health care consumers about relevant medical information, improving health outcomes, and facilitating provider-patient interactions.¹²⁰

Websites such as PatientsLikeMe and mobile applications such as MedWatcher, are examples of CMAs that are improving the ability of health care consumers to receive and report medical device safety information. PatientsLikeMe is an internet community where patients can directly share information about their conditions and treatment with each other. PatientsLikeMe is particularly effective in capturing patient reported outcomes (PROs) and providing an interactive, easy-to-use forum where patients can support each other and investigate their own research questions. Studies of patient participation in these kinds of communities have found that they empower patients and improve patient knowledge and sense of agency in their own care.¹²¹

MedWatcher was developed by Boston Children's Hospital and Harvard Medical School in collaboration with FDA.¹²² The mobile application allows its users to receive news alerts, develop a personal watch list, conduct FDA-approved medical product library searches, and report adverse events for drugs, vaccines, and medical devices.¹²³ MedWatcher also supports the ability to take photographs of medical devices that are exhibiting visible damage or malfunction. FDA believes that CMA such as MedWatcher could be an effective alternative to traditional slower methods of adverse event reporting such as mail or phone.

CMAs and Patient Generated Health Data (PGHD)

A critical function of CMAs is their ability to collect and exchange patient-generated health data (PGHD). PGHD are health-related data created, recorded, or gathered by or from patients (or on behalf of them) with a particular disease condition, and can be used to supplement existing clinical data to provide a comprehensive view of the patients living with that particular disease.¹²⁴ PGHD can help elucidate understanding of the disease condition, improve quality of care, and increase patient satisfaction.

There is, however, some trepidation on the part of both providers and patients regarding the input of data from patients outside the clinical setting. Patients remain concerned about the privacy of communications and whether their messages are successfully received and reviewed by their physician, while providers are concerned with issues surrounding data overload and identifying messages that require an immediate response from a physician. In addition, technical challenges related to integrity, validity, and transmission of PGHD remain ongoing. Nevertheless, the evolving health IT infrastructure, along with well-established rules of engagement between providers, and patients could provide a secure means of communication and mitigate some of these challenges, thereby facilitating the use of PGHD.

CMAs stand at the intersection of consumer and medical technology, and many opportunities exist to expand patient access to medical device information. For example, in April of 2014, the NIH announced \$500,000 in grant awards for research into mobile health applications.¹²⁵ The funding is focused on improving research into patient-provider communication through mobile health applications that can assist in patient disease management, shared decision-making, telehealth, and remote monitoring of biomedical data. Continued public and private support for consumer medical applications should markedly improve the quality and quantity of available tools to engage patients.

I. Challenges to Integrating Medical Devices into Patient-Directed Tools

The challenges to developing effective tools that provide patients with medical device information in the current environment include the inability to uniquely identify devices, the absence of standardized medical device information for capture and exchange, and the low penetration of such tools into patient populations. Though UDI integration into patient-directed tools alone may not speed adoption, it should provide these tools with much richer data that could benefit patients. Furthermore, developing easily adoptable mechanism such as recording UDIs in implant cards, checklists, questionnaires, and PHRs should provide great value for all the stakeholders in the healthcare ecosystem at very low cost.

Limited Medical Device Information Available for Patients

Patients that seek to utilize their medical device information via patient-direct tools require easy and convenient ways to identify their device. Currently, patients retain and transmit medical device information primarily through implant cards provided by the hospital at discharge after an implantation. Most implant cards lack a digital equivalent for automated electronic capture and only cover a small subset of the total medical devices patients encounter, thus missing important devices such as radiological imaging machines and diagnostic equipment.

Fragmented Data Standards Hinder Developer Incentives to Integrate Device Data

In an idealized scenario, patients would not be required to actively collect their medical device data, but instead would be able to benefit from automated data capture and storage. A single identifier captured into their medical records should be able to flow down and across the various touch points of patient-provider interactions. Because few developers are willing to develop tools that capture disparate and fragmented information, the lack of a single identifier and the prevalence of unstandardized medical device data have impeded the technical development of patient-directed tools that can successfully integrate medical device information.

Device Identification Standards for PGHD

Similarly, health information originating from patients can be limited in usefulness if a patient-associated medical device cannot be rapidly and consistently identified. PGHD exchange of medical devices is largely nonexistent, limited or unstructured. If this trend persists, medical devices will be largely isolated from the advances made in capturing the patient experience to improve health care. Websites and blogs are major resources for patients seeking information regarding medical devices. These internet platforms are supported by patients who input information about their own health care. Because there is no standard way to uniquely identify and share information regarding a particular device, there is no readily available information about specific device safety, performance, and lifestyle effects. These internet-based platforms must then contend with sourcing and sorting free-text and unstandardized medical device identification data or, alternatively, settling for broad medical device classifications.

Device Identification Standards for Machine-Generated Data and Networking

Data generated from medical devices are increasingly facing outward, following trends in networking and IoT technology. Novel communication features built into medical devices enable them to securely connect and transmit data to other devices and networks. This networked ecosystem of devices has the capacity to aggregate and provide data directly to patients and providers, which in turn can be used to monitor and actively manage a disease condition. In addition, as manufacturers and patient-directed tool developers learn from these interactions, opportunities exist for continuous product improvement through direct engagement with patients. Critical to this function, however, is the need to uniquely identify the devices and their associated attributes within digital ecosystems. A single identifier that can pre-populate critical data fields and that can ensure uniform classification would be a large step forward.

II. Value of Integrating UDIs into Patient-Directed Tools

Patient-directed tools comprise a wide variety of methods and products to enhance patient engagement and quality of care. Likewise, the number of valuable use cases of including UDIs into patient-directed tools is highly variable and contingent on the type of tools being used.

If UDIs are implemented across the health care environment, namely thorough FDA databases and provider networks, patients will find more opportunities to access device-specific information or demand that this information is automatically available for them to view, direct, and transmit as they see fit. These tools can be used by patients to report any incidents or performance concerns regarding the devices they use. Successful continuity of care is especially important for implantable and high-risk medical devices that stay with patients over long periods. Therefore, implementing UDIs into patient-directed tools would allow patients greater access to information regarding their medical devices during the course of care as well as reporting any adverse events through the specific device identifier.

Although integrating UDIs into patient-directed tools focuses directly on providing patient access to device-specific information and targeting patient empowerment, there is substantial secondary value to the broader healthcare system. Early detection of safety issues can prevent re-hospitalization and allow effective corrective actions. PGHD linked with UDIs can furnish providers and other stakeholders' with invaluable information regarding the performance of medical devices across different patient cohorts. Overall, the integration of UDIs into patient-directed tools will not only present patients the opportunity to manage their health better, but will also enable providers and payers to provide better value and quality of care. **Figure 14** lists a number of valuable use cases that could be achieved by integrating UDIs into patient and consumer-directed tools.

Figure 14: Valuable Use Cases to Using UDIs to Develop Patient-Directed Tools

DIRECT VALUE	INDIRECT VALUE	LIMITED VALUE
<ul style="list-style-type: none"> Improved ability to support ongoing quality initiatives Improved recall process Efficient communication of safety information to patients and providers Patient access to device information and shared decision-making Provider access to critical device information Emergency preparedness and response Identifying networked and telemetric medical devices 	<ul style="list-style-type: none"> Comparative effectiveness and patient-centered outcomes Tracking of medical device utilization patterns and analyses of appropriateness of care Medical device safety surveillance Support for medical device innovation 	<ul style="list-style-type: none"> Improved supply chain integration and management Increased medical device reimbursement transparency Improved fraud detection Improved anti-counterfeit detection New opportunities for value-based purchasing and other support for enhanced value

In an ideal scenario, patients would have access to a single platform or a set of CMAs that offer on-demand information about medical devices and meet many of the direct value use cases found in Table 1. Using consumer medical applications enriched with UDIs could empower patients to think more critically about the specific devices they use, rather than assuming each medical device is interchangeable with the next. The ubiquitous nature of consumer technology also gives patients more opportunities to interact with information about their devices outside the context of provider and payer systems. Continuous patient engagement will be critical to gathering more data on how medical devices perform and function for patients once they leave the doctor's office.

III. Strategies for Integrating UDIs Into Patient-Directed Tools

Enhancing Patient Awareness: “Know Your UDI”

To manage their health better, patients should be encouraged to request important information regarding their implanted device or devices they use. Therefore, patients should be first educated to request for information regarding their specific device. Patient advocacy groups can take a leadership role in educating and empowering patients. A national “Know Your UDI” campaign to make patients aware of their role in engaging and requesting for their UDI should be developed. Providers, consumer groups, and manufacturers in collaboration with FDA, should develop such an initiative that conveys to patients the importance of recording their UDIs along with other important personal medical information.

Capture UDIs in Patient and Provider Checklists and Questionnaires for Implantable Devices

An important tactic for enabling patients to use UDIs is to engage them early. A simple strategy is to ensure that UDI is relayed to patients at the POC, especially for high-risk implantable medical devices. Patients are typically given medical device ID cards after a medical device is implanted. Including UDIs into these ID cards should prove an inexpensive but highly effective strategy to inform patients how to uniquely identify their device. In addition, patient checklists and questionnaires can be used to drive patient participation as well as to encourage providers to supply patients with important device information before and after surgery. In the case of devices, communication between the patient and provider, be it a checklist or questionnaire, should use UDIs as a key identifier to exchange information. In pre-surgery consultations, providing the patient with the Device Identifier (DI) should enable the patient to get the relevant information regarding the device via the GUDID or manufacturer. Post-surgery, the UDI should be the key element used to communicate any information regarding the implanted device.

A complementary strategy involves primary care providers and relevant specialty providers asking patients for their implanted device UDIs when they inquire about a patient’s surgical or procedure history and ensuring that information is available in the patient’s record. This would demonstrate to patients the importance of UDIs as an identifier 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. Clinically validated questionnaires can be valuable to providers not only by giving them important information that can help physicians provide a better quality of care but also enhance data capture and aggregation for meta-analysis to generate evidence regarding the performance of the devices that patients were treated with. Developing provider checklists that incorporate questions asking for UDIs could also boost the capture of UDIs across HIT systems.

Integrate UDIs into Personal Health Records

PHRs could function as an important platform for providers and payers to build UDIs into patient-directed tools. A preliminary and easily viable method for integrating UDIs into PHRs would be for providers or patients to enter UDIs directly into PHRs. This might serve to fill gaps in EHR capture of UDIs across provider systems, and devices not captured by a provider during a patient encounter. Another more long-term method for incorporating UDIs into PHRs is to automatically tether EHR data that captures UDI information. This method would require that UDIs be routinely captured in a standardized method across EHR systems.

PHRs that include UDIs could serve as the focal point for patients communicating information regarding their specific device bi-directionally with providers and manufacturers, providing these stakeholders an additional channel of communication with patients. PHRs that incorporate UDIs can couple this information with supplementary patient and device information that can easily be understood by patients, and enable patients to make well-informed decisions regarding their health. For example, PHRs that could deliver electronic education materials for UDI-labeled devices might improve use and comprehension through an actual visual demonstration that paper-based materials cannot achieve. Additionally, customizing the information that patients receive could motivate patients to participate more in their own care. A patient who receives customized medical device information may be more likely to update their contact information to receive important safety communications.

PHR platforms using UDIs as the key identifier across various data sources will require APIs and electronic data interchanges (EDI) to link the relevant information together for patient use. The ability to connect various FDA medical device databases (e.g., GUDID, recall database, adverse event reporting) with PHRs could be an important functionality.

STAKEHOLDER EXPERIENCE

The openFDA Initiative

The openFDA Initiative by the FDA has been a landmark development in response for calls to increase medical product information transparency. Through openFDA, there is now broader access to FDA raw datasets, open APIs, and relevant documentation to inform the HIT developer community. Recently FDA announced the addition of its Recall Enterprise System (RES) to the openFDA Initiative through the release of a publicly available API. This API will allow developers to access numerous recall reports on drugs, medical devices and food. Recall reports detail the reason for voluntary and FDA-directed recalls and relevant product information. By publishing this API, there exists a powerful opportunity for developers of patient tools to link recall data with PHR information.

The FDA expects to be able to pull UDIs from the GUDID into the RES system to minimize duplication of resources and transcription errors. Having the UDIs available in the RES API will be beneficial for developers looking to inform patients about pertinent recall information and could possibly speed recall response times. As the FDA continues to release more data and publish additional tools, there will be more opportunities to link UDIs with PHR data. In particular, while openFDA API support for adverse event reporting is available for drugs, there is no analogous API for medical devices. Releasing adverse event reporting data through an API could be another useful tool for researchers and developers looking to better inform and engage with patients.

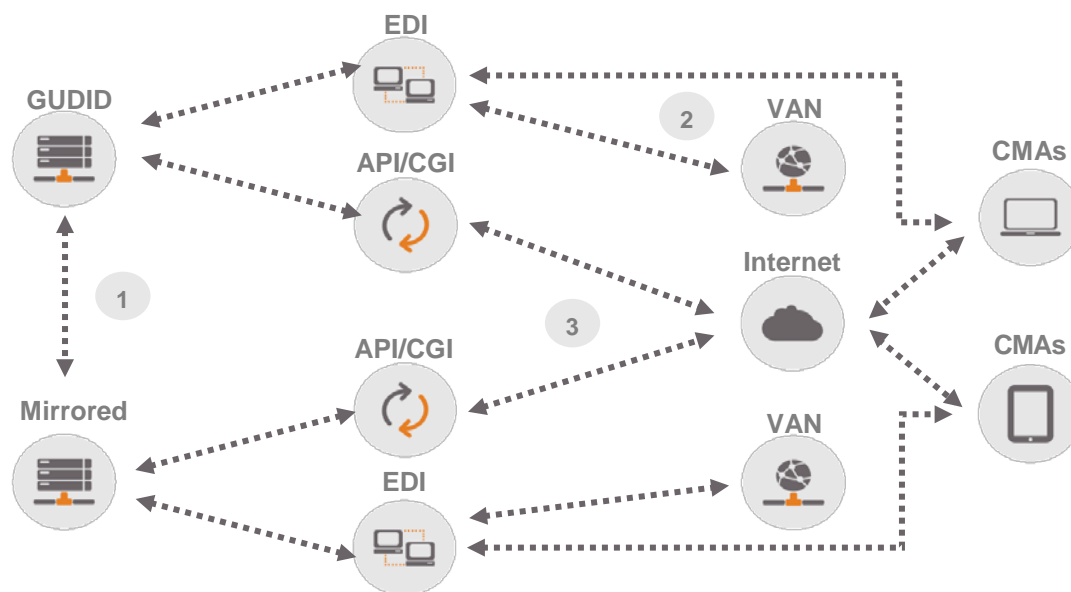
Incorporating UDIs into PHRs could also assist in efforts to locate and notify patients about important medical device information. The goal of matching a medical device and its UDI with an at-risk patient poses significant barriers. Patient mobility hampers efforts to locate patients and previously recorded patient contact numbers may be out of date. Electronic PHRs could mitigate these problems by providing a central platform where patients could receive current safety information about their devices and update their contact information at their convenience. Having a UDI incorporated into PHR platforms will be critical for identifying which patient should be notified and what course of action they should take. Correspondingly, PHR implementations might be a viable tool in ensuring that, once a patient is identified, their contact information is up-to-date and accurate.

Integrate UDIs into Consumer Medical Applications

Integrating UDIs into CMAs will be a pivotal step towards increasing the availability of medical device safety information for health care consumers and expanding the number of channels for patient adverse event reporting. This integration will require the development of technical and legal infrastructure that gives CMA developer's access to UDIs and relevant medical device safety databases. FDA databases such as the GUDID, RES, and Manufacturer and User Facility Device Experience (MAUDE) are major repositories of UDIs and medical device safety data. Depending on trends in UDI implementation, third-party data pools, EHRs, and administrative transactions may be additional UDI repositories.

In order for CMAs to access these UDIs and medical device safety data, FDA, provider systems and payers could pursue the development of tools such as common gateway interfaces (CGIs), APIs, EDIs and databases mirroring solutions. A simplified depiction of the roles each of these tools could play is shown in Figure 15 below. To deploy some of these tools, database proprietors that have device-specific safety information (via UDIs) with no internet data exchange capabilities would have to update their respective systems to enhance these capabilities.

Figure 15. Integrating UDIs into Consumer Medical Applications



1. The original databases that contain UDIs and relevant medical device safety data can be copied into duplicate or mirrored databases. These mirrored databases reduce the strain of data transmission on the original databases by accepting data traffic that would otherwise flow toward the original database. This can have the effect of increasing the reliability and speed of connections between consumer medical applications and target databases.

2. Electronic data interchanges provide specific standards for transmitting data between partners. This standardized data can then be transferred via peer-to-peer connections or through value-added networks (VANs). VANs act as intermediaries that can authenticate and sort inbound and outbound data.

3. Common gateway interfaces (CGI) give databases that are connected to the internet the ability to generate customized responses for inbound requests from web-based consumer medical applications. This is especially helpful for web servers receiving user-specific data and issuing dynamic responses to consumer medical applications. APIs are proprietary programs that can process inbound requests from external programs or devices and send back information from a database. This information is structured data that is detailed in additional API documentation. APIs can be advantageous to develop when the amount of data being exchanged is voluminous, however, because they are proprietary solutions they have limited portability across web servers.

As discussed previously in the section, patient registries, such as PatientsLikeMe and the MedWatcher application maintained by FDA, are promising channels for relaying important medical device information to patients. As PatientsLikeMe has shown, patient registries can play a critically important role in educating patients and granting them access to information on device safety and effectiveness. Registry data should be made transparent to patients, with summary reports on device effectiveness made public on an annual basis.¹²⁶ By granting patients direct access to population level data, they can be empowered to understand their conditions, the role their devices are playing in their care, and engage with other patients. Integrating UDI support into applications similar to MedWatcher by asking users for their UDI, and providing UDIs during safety alerts could be a successful strategy to implement UDIs across a mature CMA. Such an implementation could serve as an influential case study to demonstrate the value of UDIs for CMAs. In addition, manufacturers may also find it beneficial to provide device information to providers and patients, and receive and collect feedback regarding the performance of their device via UDIs. In the current system, manufacturers are not usually privy to clinical information regarding the performance of their device and must conduct costly post-approval studies to collect this information. Alternatively, using patient/provider-directed tools, manufacturers can obtain information on devices via UDIs which will not only help in identifying when a device malfunctions, but also provides evidentiary data subsequent device development.

UDIs in Meaningful Use Stage III and IV

The American Recovery and Reinvestment Act of 2009 (ARRA) contains provisions for reimbursement for provider systems who adopt healthcare information technology (HIT) that meets the appropriate level of MU criteria. One of the goals of MU is to encourage providers to use HIT to communicate and engage with their patients. CMS's MU Stage II requirements for payment incentives to payers include at least three patient

engagement-related deliverables of providers. To meet Stage II, provider systems must provide clinical summaries to patients after each visit. They must use electronic secure messaging to communicate with patients on relevant health information with a minimum of 5 percent of their patients during the review period. Finally, the providers must provide patients with the ability to view online, download and transmit information about a hospital admission, and give them access to any health information about that patient which the provider receives (the relevant UDI information could be provided at this point) within four days of receiving it.

While Stages I and II of MU are primarily concerned with EHR adoption and clinical processes, the proposed measures for Stage III focus primarily on improved outcomes and patient engagement. Stage III goals include that 10 percent of a provider's patients to have the ability to submit patient-generated health information to improve performance on high priority health conditions, and/or to improve patient engagement through shared decision making by empowering patients to more actively manage their own health.¹²⁷ MU Stages III and IV could incentivize UDI integration into patient-directed tools. A recent recommendation made by the Meaningful Use Working Group outlined a MU Stage III objective that UDIs should be recorded by provider systems when patients have medical devices implanted. The objective measure would be to capture UDIs in 80 percent of these encounters over the EHR reporting period.¹²⁸ Such a clear incentive for provider systems to capture UDIs would increase the likelihood that patients have access to this data, either through retrieval of their medical records or linkages between a patient's EHR and PHR.

IV. Recommendations

1. Patient advocacy groups, FDA, and other strategic partners should develop awareness among patients to request the UDIs of their medical devices from providers (i.e., “Know Your UDI” campaign); efforts could be led by patient advocacy organizations: Patient advocacy groups, patient rights organizations, and other patient-facing health care stakeholders should seize the leadership opportunity to educate and empower patients to routinely request the UDI of their medical devices. While patients remain the ultimate arbiters of how they request and consume medical information, these organizations have key leadership roles to play in shaping the normative conversations surrounding patient care. Patient demand will be a critical driver of how effectively UDIs are used in the health care system. Simple and direct campaigns that encourage patients to “Know Your UDI” will signal to stakeholders upstream how important it will be to provide UDIs to patients.

2. Patient and provider checklists and questionnaires should include the capture of UDIs for high-risk implantable medical devices: Checklists and questionnaires that include UDI capture of high-risk implantable medical devices can be given to patients before surgery, with their discharge summaries, and incorporated with implant cards. The questionnaires and checklists should be interactive, providing a mechanism for patients to make their providers aware of updates in their health status, especially in the instance that the patient has changed locations or providers. This could be particularly useful given where electronic information might be inaccessible across provider systems or between different locations due to interoperable systems. Key items and questions for patient checklists and questionnaires could include: requesting providers for their UDI post-implantation surgery; informing primary care physicians of their implantable UDIs; a reminder to input/register UDIs into any PHRs currently used by the patient; and a reminder to register their UDIs on patient recall alert applications.

3. PHR developers should integrate UDIs into PHR implementations: Future PHR implementation should be capable of receiving UDIs from multiple sources, including from patients, individual providers, and through tethered EHRs. Linking EHRs with PHRs will be of the greatest value to patients and the most advantageous pathway for capturing UDIs in PHRs. Current EHR implementations could be modified to capture UDIs and automatically populate that information into patient PHRs. This optimal scenario will require larger up-front costs for updating existing EHR implementations and incorporating UDIs into a standardized template such as the Consolidated Clinical Document Architecture (C-CDA). A less effective, but easier alternative would specify that PHR implementations begin incorporating fields for UDIs that must be manually filled in by patients. CMS, DoD, and the VA have either developed or piloted PHRs for their members and beneficiaries. These PHRs reach millions of patients who could immediately benefit from having the UDI of their medical devices logged and

accessible, especially for high-risk implantable devices. Federal implementations of UDIs into PHRs could serve as an informative business case for private industry, possibly spurring adoption. CMS, DoD, and the VA should begin an exploratory analysis of the costs and benefits associated with building a field for UDI capture in their PHR implementation.

4. Consumer medical application developers should work in collaboration with patients, patient advocacy groups, and FDA to integrate UDIs into their web resources and applications: CMAs represent a valuable opportunity to build highly effective tools that can provide customized and easily accessible information to patients on-demand. FDA should work to integrate UDI support into the Medwatcher mobile application to facilitate increased efficiency and specificity in adverse event reporting and ensure that patients remain fully informed on the status of their medical devices. Medwatcher may serve as a pilot study for understanding the impact of UDIs on the larger landscape of consumer medical applications. Web resources and patient communities, such as PatientsLikeMe should also pursue UDI-support as a way to encourage patients to document and track their own medical devices.

5. Patient advocacy groups, the National Library of Medicine (NLM), and the FDA should work in collaboration to develop tools that increase the accessibility and openness of federal databases containing UDIs and medical device information: Patient advocacy organizations, third party data pools, NLM, and FDA should collaborate with patients, CMA developers and consortia to develop the necessary tools to lower the barrier for developers, and health care consumers to access UDIs and relevant medical device safety information stored in federal and private databases. Strategies should center on the development of open architecture tools that allow a diversity of developers to build patient-directed tools that can be tested in the market. Key considerations should include how to prioritize health care consumer data security and privacy and how to build tools that are scalable and open to an array of application platforms. The FDA collaboration with NLM on the development of the GUDID should explore solutions to make the GUDID open and accessible to developers. Such solutions could include working with data pools to mirror the GUDID, building open APIs, and exploring EDI implementations. These tools could assist in automating the exchange of medical device information between patients, FDA, providers, manufacturers, and even registries to improve product safety, patient engagement, and quality improvement.

SECTION 6

Conclusion

The previous sections have extensively focused on the value of UDI implementation across the different stakeholders in the healthcare ecosystem. While complete UDI integration into seamless workflows and an interoperable health IT infrastructure across the healthcare ecosystem are needed to fully optimize the many benefits of UDIs, including higher value health care, relatively straightforward steps can be taken by key participants in the health care system to begin using and benefiting from UDIs right away. Having patients demand UDIs from their providers and enabling providers to scan UDIs at the POC and store them into the EHRs will be foundational elements of effective implementation. Many of the strategies for integrating UDIs across all the stakeholders are not specific to UDI implementation; rather, they are central to any healthcare intervention that requires building the health IT infrastructure and are complementary to ongoing strategies for EHRs implementation and health information exchange (HIE). Such strategies include:

- Stakeholder buy-in
- Demonstrate the ROI and articulate the benefits for each stakeholder
- Interoperability of the health IT infrastructure across the healthcare ecosystem
- Standardization of data formats and specifications
- Build a universal source of truth for UDIs and a supplementary system for device attributes with linkages to patient information and clinical attributes
- Develop a governance structure for UDIs data repository, mandate rules of engagement for different stakeholders, and establish strong codes of ethical conduct centered on patients

In the “Introduction”, we postulated clinical scenarios for two patients with medical devices: Woody Smith and Linda Hayes. These scenarios illustrate how UDI implementation will flow across the health care ecosystem, affect patient care, and provide a broad overview of how providers and patients can use the information unlocked by UDIs to inform their medical decision-making (see pages 70 and 71).

BOX A: CLINICAL SCENARIO #1

Woody Smith



Woody Smith needs a knee replacement but wants to understand his options before he goes to the hospital. He can receive information about his potential knee implant inclusive of the DI from his orthopedic surgeon prior to surgery.



Woody can perform research regarding his specific device since information would be available via CMAs for potential patients such as Woody, the GUDID or patient internet communities where the public can log into and find information regarding medical devices input by the patients who have them.



Having performed this initial research and consulted with the operating surgeon, Woody goes to the hospital. During the surgery, the UDI of the implant components is scanned, which electronically records them in Woody's clinical record. The UDI is also electronically transmitted to the supply chain system, the billing system, and subsequently included on the claims form to the payer.



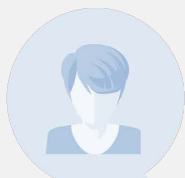
At discharge, Woody can register the UDI into his PHR via the Blue Button+ program available through his provider and also through his mobile application to enable bidirectional communication with his provider on his implant. He can also receive alerts regarding his implant as well as report any potential adverse event to the provider, the FDA or the manufacturer. The UDI, as the information key, will allow Woody to access the GUDID, clarify any questions he may have for his providers, or share in social media with other joint replacement patients.



Importantly, Woody will be able to quickly ascertain, by using his UDI, if his implant is involved in a recall or safety alert, avoiding unnecessary anxiety or the need to contact his orthopedic surgeon. The UDI from Woody's surgery is also available to be transmitted to clinical registries for further research.

BOX B: CLINICAL SCENARIO #2

Linda Hayes



Linda Hayes, who lives in Boston, already has a pacemaker. When it was implanted, the device's UDI was recorded in her EHR. She believes that she needs a revision surgery of the pacemaker wires, but wants to be sure.



Since her device has a UDI that was recorded in her EHR, Linda has previously recorded her UDI into her PHR and CMA before she goes for a revision surgery. She can use this information to discuss any concerns regarding the device with her physician. She could also query the DI portion of her device in the FDA recall database, or get the manufacturer information from the GUDID and see if there has been any status update on the safety of the device model that was implanted in her. If it was determined that her implanted device was malfunctioning, she now has the ability via CMAs or the FDA's MedWatcher application to reach the manufacturer and FDA to alert them. She could also join a patient forum and, using her DI, identify other patients who use a similar device and exchange informal information regarding their experience with the device. After performing her research, she goes to the provider, who confirms that the pacemaker wires need to be replaced. The procedure is completed and the new pacemaker is noted in her EHR.



Two months after her revision procedure, Linda is in an accident driving home after grocery shopping and is rushed to a nearby hospital. The doctors determine that she might need surgery unrelated to the pacemaker she had implanted several years ago. The hospital has access to her EHR records and as a result, the physicians treating her are aware of the implanted device and take necessary precautions when prescribing an MRI or other test or procedure that could be impacted by the implant.



A few years later, Linda travels to Florida on vacation and experiences severe chest pain. She goes to the emergency room (ER) but, in contrast to the provider she saw after her car accident, it lacks access to her EHR. Due to the lack of interoperability between provider sites, the physicians do not have access to her EHR records, forcing them to rely on alternative options for obtaining Linda's medical records. One method is to request the patient data from the payer. Although Linda has been to several provider sites, she may have only one health insurer. If UDIs are captured through claims data this information will be accessible through the payment information.



Alternatively, Linda may have a PHR or patient application containing her medical information along with the UDI of her cardiac implant. The physicians can then quickly access Linda's medical records and UDI via her own mobile application containing her PHR and use it to obtain critical device information to guide her care. In the case of pacemakers, the UDI would give immediate access to performance characteristics of the device that would be helpful to the physician during emergency procedures. In addition, her payer will have her UDI and will be able to provide that information even though the hospital does not have access to her EHR.



Linda is a responsible adult who actively manages her health and wellbeing. Linda's personal health information is updated regularly on a mobile application that stores this information on her PHR. She has given power of attorney to her daughter (her emergency contact) to provide that information in the case of an emergency. Therefore, Linda's PHR that contained her UDI was available to the provider in Tampa, Florida.

The above clinical scenarios present idealized versions of the role UDIs can play in both interoperable and non-interoperable environments. As discussed previously, there are straightforward, achievable steps that all stakeholders can take to realize these aspirational situations and make UDIs a critical and helpful component of patient care. To realize these scenarios, we identify the following strategies to be top priorities for the integration of UDIs across all stakeholders.

- A general consensus among stakeholders to use UDIs as the key element for any activities or transactions pertaining to medical devices;
- a field to capture UDI information in patient electronic health records (EHRs);
- the ability for provider systems to scan, enter and store UDIs in patient EHR at the POC;
- provider ability to internally transmit UDI information to supply chain and billing systems once a device has been used at the POC;
- provider ability to transmit UDI information from EHRs to patients, registries and payers; and
- capability of patients, registries and payers to access UDI information through the provider system.

Mercy, through the UDI demonstration project, has demonstrated successful implementation of UDI into their patient health records (see appendix C). Similarly, we recommend that provider systems be incentivized to capture UDIs at the POC such that it can subsequently be disseminated to patients, registries and payers. Tools should be developed using UDIs as the key element to depict medical devices so that patients can bi-directionally communicate concerns regarding their devices with providers. Payers should be encouraged to use device UDIs for transactions regarding payment and billing. Finally, all device registries should have a field to capture UDIs as the key source for identifying a specific device.

Lastly, a health sector-wide pilot to evaluate the value of UDIs to involved stakeholders is recommended to explore the challenges of UDI implementation as well as the cost and return on investment for each group. CMS, working with the FDA, could sponsor such a pilot, with the ONC setting the required standards for data specifications and interoperability between stakeholders. These efforts to include UDIs in a seamless flow across different stakeholders should be integrated into the current efforts by CMS and ONC to build a health IT infrastructure pertaining to the use of EHRs.

APPENDIX A

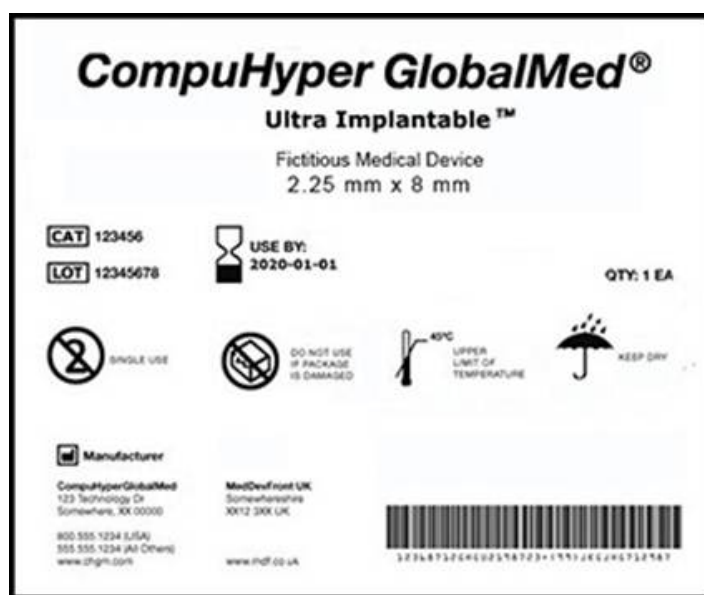
Unique Device Identifier (UDI) Basics

UDI is an alphanumeric code that is composed of two parts: the mandatory fixed Device Identifier (DI) which indicates the device's labeler and version/model number and the conditional variable Production Identifier (PI) that identifies one or more of the following when included on the label of a device:

- lot or batch number within which a device was manufactured;
- serial number of a specific device;
- expiration date of a specific device; and
- date a specific device was manufactured and the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product regulated as a device.¹²⁹

A fictitious example of what the UDI could look like on a medical device label is in Figure 16 below.¹³⁰

Figure 16. UDI appearance on a medical device label



UDIs are required to be in both plain text and a form that allows its capture through automatic identification and data capture (AIDC) technology in provider systems. Device labelers are required to submit the DI portion to the GUDID, the FDA's repository of UDI information (See Appendix B). A new DI is required by the FDA when a change results in a new version or model, as determined by the labeler. In addition, any changes by the labeler to the attributes of a UDI that are immutable attributes in the GUDID would warrant a new DI.

APPENDIX B

Global Unique Device Identification Database (GUDID)

The Global Unique Device Identification Database (GUDID) is the FDA-managed database that will serve as a reference catalog for every device with a unique device identifier. The UDI final rule requires device labelers to submit the DI portion of the UDI and other relevant device attributes to the GUDID for every device required to bear a UDI. The PIs are not submitted to the GUDID, though the DI record can indicate which PI attributes are on the label of the device. Labelers can submit the DIs to the GUDID in two ways: GUDID web interface where labelers can enter their data as one DI record at a time or HL7 Structured Product Labeling where labelers submit device information via xml files.

The GUDID will be populated with data about devices according to the compliance timeline in the Final Rule. The DI information stored in the GUDID will be publicly accessible;; plans are to enable search function to via secure web interface, download capability and “system to system search and retrieval via web service.” At this time, the ability to search the GUDID is disabled since there are not a sufficient number of entries present within the GUDID.¹ The GUDID will also not contain any personally identifiable information.

¹ U.S. Food and Drug Administration. *Global Unique Device Identification Database (GUDID): Guidance for Industry and Food and Drug Administration Staff*. Guidance. Silver Spring: U.S. Department of Health and Human Services, 2014.
<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf>>.

APPENDIX C

Mercy Health Case Study

The Mercy Unique Device Identifier Demonstration Project: A Case Study of UDI Implementation in the Electronic Information Systems of a Large Health System

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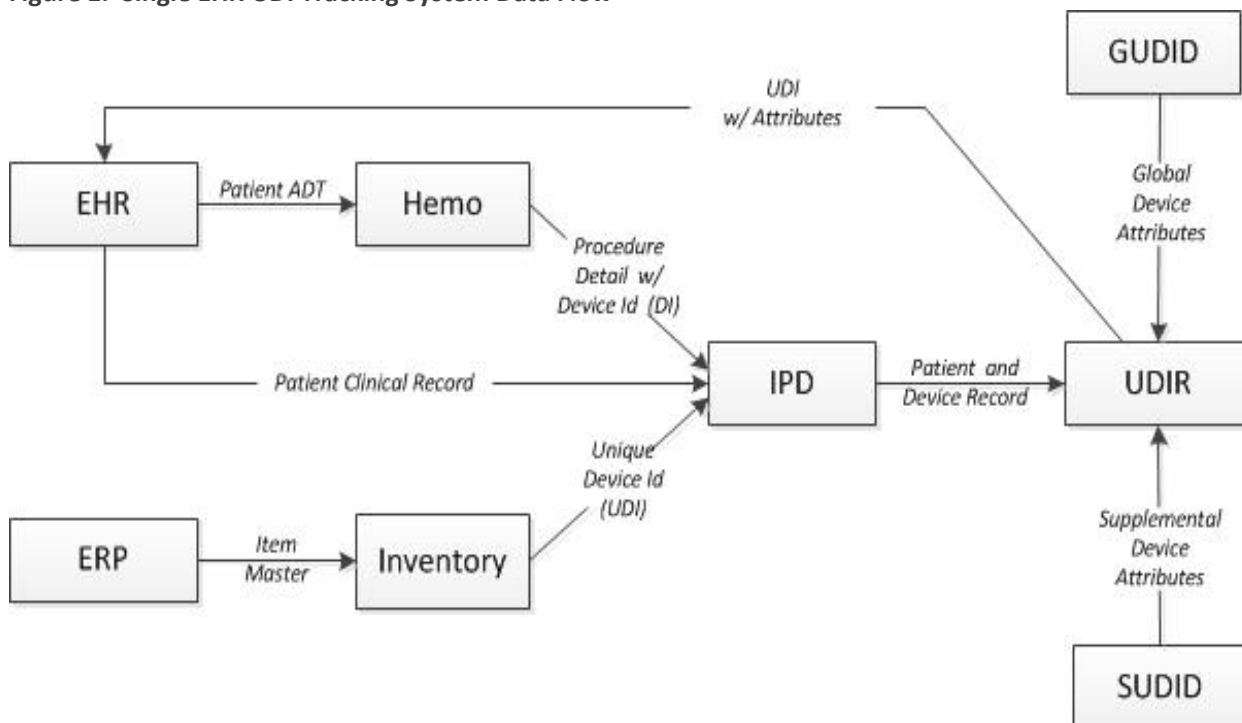
From May, 2012, through December, 2013, Mercy performed a Demonstration Project under the U.S. Food and Drug Administration's (FDA's) Medical Device Epidemiology Network (MDEpiNet) initiative whereby prototype unique device identifiers (UDIs) were implemented in Mercy's electronic information systems.¹³¹ Mercy is a 4 state integrated delivery system headquartered in St. Louis, Missouri, that is comprised of 34 hospitals with a total of 4,396 licensed beds ranging from small, critical access rural facilities to large, tertiary care urban medical centers. Five of Mercy's 34 hospitals have cardiac catheterization laboratories (Cath Labs) that collectively implant over 5,000 coronary stents annually.

Mercy's Demonstration Project is described in detail elsewhere.¹³² Briefly, the Project had 3 principal aims:

- To implement a prototype UDI solution for coronary stents in the information systems of a multi-hospital system
- To identify obstacles to implementation of the prototype UDI solution and to characterize the effectiveness of interventions to overcome them; and
- To assess the validity and utility of data obtained from an electronic health record (EHR) system in post-market surveillance using the UDI.

The ultimate goal of the Demonstration, then, was the creation of a database containing both patient information from clinical records (the EHR and hemodynamic software) and UDI-associated device attributes obtained from the FDA's Global UDI Database (GUDID) and from a second source containing other clinically significant coronary stent attributes (the Supplemental UDI Database or SUDID). The resultant database, termed the UDI Research database or UDIR, was created through the Mercy Integrated Patient Datamart (IPD), which is the Mercy enterprise data warehouse that includes clinical, administrative, and operational data derived from multiple data sources across Mercy Health system. The UDIR can be refreshed with new clinical data on a regular basis enabling longitudinal safety surveillance and research. Data flow into the UDIR is illustrated in Figure 1. Pivotal to the function of the UDIR is capturing coronary stent UDIs in an automated fashion and joining them with the clinical records of the patients in which they are implanted. Automated UDI capture was enabled by a point of use (POU) barcode scanning and inventory management system.

Figure 1. Single EHR UDI Tracking System Data Flow

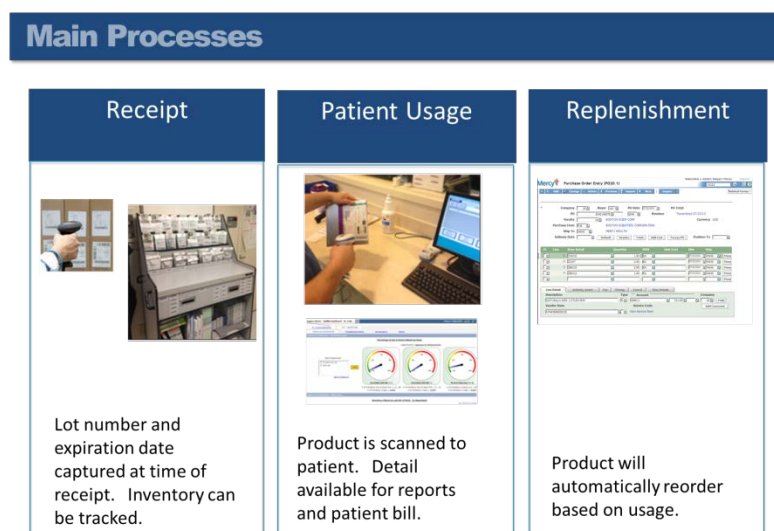


Data from the EHR, Cath Lab Hemo, ERP (including the UDI) and Inventory systems flow into the IPD. Integrated clinical and device data flow from the IPD into the UDIR. UDI-associated coronary stent attributes flow from the FDA's GUDID and the SUDID into the UDIR where they are joined with the patient-device record. UDI and attribute data flow back to the EHR from the UDIR. ADT = Admission/Discharge/Transfer HL7 messages; EHR = Electronic Health Record; ERP = Enterprise Resource Processing; GUDID = Global Unique Device Identification Database; Hemo (Hemodynamic Software); IPD = Integrated Patient Datamart; SUDID = Supplemental Unique Device Identification Database; UDI = Unique Device Identifier; UDIR = Unique Device Identification Research

I. The Point-of-Use System

Prior to the UDI Demonstration Project Mercy Cath Labs did not have an automated system to manage shelf level inventory quantities. Inventory replenishment was performed by clinical personnel who would walk through the department and physically inspect each item to determine if replenishment was needed. The OptiFlex™ CL system (Omniceil, Mountain View, CA) was implemented to improve inventory management and track Cath Lab supplies and procedures in support of the UDI Demonstration Project. The basic processes involved with this point of use system are illustrated in Figure 1. The system was felt to have many putative benefits for supply management including time savings, prevention of procedure delays, lower costs, and increased revenue. The system captures a product's identification number and expiration date (components of the UDI) at time of receipt so that inventory can be tracked. When the product is scanned for patient usage the detail is available for the clinical record, operational reports, and billing. Additionally the system automatically reorders products based on usage.

Figure 1. OptiFlex™ CL Point of Use System



II. Lessons Learned

Technology Integration

During the initial gap analysis of the systems and processes in the Cath Labs, it was discovered that the hemodynamic software (Merge Hemo™, Merge, Chicago IL) was unable to receive barcode product information from OptiFlex™ CL. Due to this lack of integration of OptiFlex™ CL and Merge Hemo™, “double scanning” was required: First, a stent’s Mercy-generated barcode was scanned into OptiFlex™ CL. Second, the stent’s manufacturer assigned barcode was scanned into Merge Hemo™. This was the only workable solution during the timeframe of the Demonstration Project but a functioning interface between the two systems would be the best workflow solution for clinical staff.

Discussions with Merge and Omnicell regarding the integration of their systems uncovered significant obstacles related to the companies’ commercial interests. Merge, for instance, values the closed architecture of their software as a competitive advantage. As a result of these concerns, the discussions with both vendors have been escalated to the senior leadership level for issue resolution. Optimizing the inventory management system as well as developing a system for moving data between OptiFlex™ CL and Merge Hemo™ have consumed more time and resources than initially anticipated.

Capturing Information

In the initial stages of implementation, three problems were discovered: First, the Merge software drops a key digit from the GTIN. Secondly, the item master in Mercy’s Enterprise Resource Planning (ERP) software (Infor Lawson, New York, NY) cannot handle GTIN lineage. The FDA’s UDI rule requires that, if a product undergoes significant modification, it be assigned a new UDI (GTIN in the Mercy Demonstration Project). GTIN lineage refers to the association of the resultant GTIN with the GTINs of previous product versions such that device history is not lost. Because the ERP system is not able to store GTIN/UDI lineage, each new UDI requires a new product number in the item master. When the FDA’s UDI requirements actually go into effect, product ordering will be more complex, and downstream analysis will require the creation of product lineages by manufacturer in order to group like items for purposes of safety surveillance and research. Finally, none of Mercy’s systems were able to store the UDI-associated device attributes from the GUDID and SUDID. This functionality would be quite useful in that it would make the attributes immediately available to clinicians and other system users, thus obviating the need for obtaining them from the reference databases every time they are needed.

The team faced some challenges related to the barcodes themselves. Two barcode standards are commonly used in health care: GTIN and HIBC (Health Industry Business Communications Council, Phoenix, AZ). Mercy had to capture item GTINs or HIBCs in the ERP system to enable the automated scanning of the product bar codes. Unfortunately, not all products had assigned GTINs or HIBCs. In those cases scanning of those items and downstream analyses related to them were not possible. Secondly, many manufacturers are transitioning from HIBCs to GTINs necessitating the development of HIBC-GTIN crosswalks. An analysis of Mercy’s experience with the various identifier standards during a 3 month period as documented by OptiFlex™ CL is illustrated in Tables 1 and 2. Although 41% of cataloged items have barcodes using the GTIN standard and 33% have barcodes using HIBC, 56% of items actually used have GTIN barcodes and only 7% are labeled with HIBC standards.

Table 1. Count of Barcode Types

Identifier Standard	Total	
GTIN	3,897	41%
HIBC	3,202	33%
Other	2,509	26%
Grand Total	9,608	

Table 2. Three Month Barcode Utilization Comparison

Identifier Standard	Total	
GTIN	1,943,116	56%
HIBC	233,892	7%
Other	1,296,860	37%
Grand Total	3,473,868	

During the time of the Demonstration Project 1 of 3 coronary stent manufacturers utilized HIBCs for some of their products while the others used only GTINs. However, Mercy’s ERP system can capture only one identifier standard per item with GTIN being the standard chosen for coronary stents because it is more widely used than HIBC by stent manufacturers. Because of the decision to employ only GTIN standards, it was originally thought there was a need for a HIBC to GTIN crosswalk for products not having GTINs. But it was later discovered that we could link the products from our ERP system to our POU system using our vendor item number obviating the need for the crosswalk. Further, OptiFlex™ CL was able to accept both versions of the device identifier greatly enhancing our ability to manage through the Demonstration Project.

Application and Data Limitations

The automated inventory system implemented was not without flaws. Several application-related issues arose during system implementation that limited the success of the Demonstration Project. First, it was discovered that OptiFlex™ CL requires a serial number to track inventory at the shelf level but manufacturers employ lot numbers and not serial numbers for coronary stents. This required Mercy to create custom labels with “dummy” serial numbers and barcodes for coronary stents. When stents are received at the Cath Lab, the manufacturers’ product GTINs or HIBCs are manually linked in OptiFlex™ CL with the Mercy-generated “dummy” serial numbers. This approach is not sustainable; however, this flaw in the OptiFlex™ CL system can only be resolved by Omnicell. A product upgrade due after completion of the Demonstration Project was expected to eliminate the need for “dummy” serial numbers. Secondly, each Mercy Cath Lab operates on a separate instance of Merge Hemo™. This made it necessary to create multiple versions of each interface between Merge Hemo™ and the UDIR to support consistent implementation across all Cath Labs.

In addition to these software limitations, there were some differences between Mercy and FDA requirements that necessitated additional adjustments. One such difference was that Mercy, similar to many other health systems, uses GS1’s Global Location Numbers (GLNs) for uniquely identifying facilities, while the FDA utilizes the D-U-N-S® number (Dun and Bradstreet, Milburn, NJ) for this purpose. To ensure data consistency and

interoperability between Mercy and the federal government, a "GLN to D-U-N-S" cross-reference database was constructed.

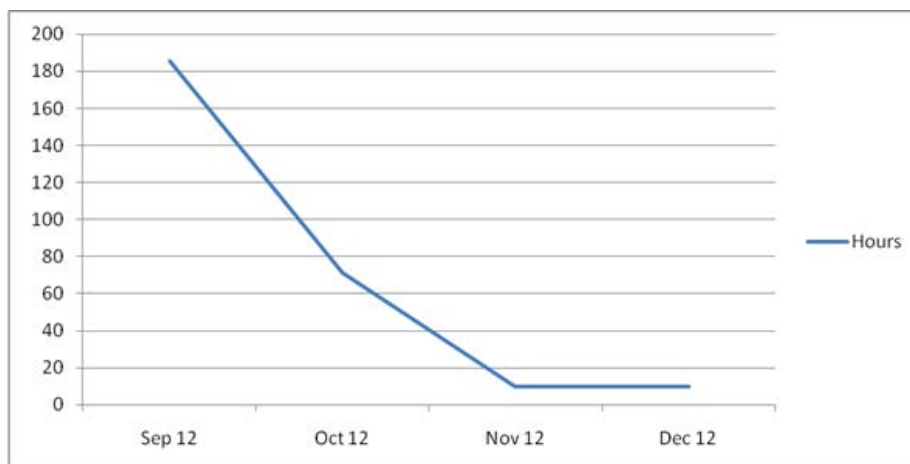
Finally, even though FDA draft requirements for UDIs standardize the device identifier number, device descriptions are not standardized so Mercy continues to employ multiple item descriptions with each UDI in our systems. In the future these descriptions need to be standardized—perhaps through the use of the GUDID.

Implementation Effort

The Mercy operational consultant members of the implementation team were quite experienced in systems implementation. They each had over 10 years of such experience prior to this project, including the implementation of other POU systems at Mercy in nursing, electrophysiology laboratories, interventional radiology, computed tomographic imaging, and emergency departments. It is, therefore remarkable that they found the amount of effort required of the team to implement the Cath Lab POU system surprising. This included much more assistance for Cath Lab team members than had been anticipated. Cath Lab Directors were required to put in a significant amount of effort for the first 3 months of the implementation. Additionally, one other person on the Cath Lab team was given the assignments of leading the effort to develop new work streams and of incorporating new activities which were not part of the department's prior labor plans or productivity standards. Examples include item master maintenance, establishing and maintaining reorder points, and regular physical inventory counts.

Figure 2 shows the operational consultant work effort that was required over the 3 months immediately following initiation of the POU system at the Mercy Hospital St. Louis Cath Lab. There was a steady decrease in required consultant support hours over initial 3 months of the project that remained constant thereafter.

Figure 2. Operational Consultant Support Hours for the St. Louis Cath Lab Point of Use System Implementation



Training Methods

Training programs in the OptiFlex™ CL system were developed and customized to specific user roles. Additionally inventory management training was provided to designated Cath Lab staff. Training included initial in-person classroom sessions and 2 types of online e-learning sessions: the first for content to supplement the classroom sessions and the second for on-demand refresher courses. The classroom training was most effective for inventory management training due to the complexity of the material. The e-learning system was convenient and effective for teaching other new material and for reinforcing what was taught in the classroom. The e-learning system proved to be the most effective method for training in OptiFlex™ CL scanning because it allowed Cath Lab personnel to balance training time with patient care time in their busy schedules.

Charging/Billing

Implementation of the POU system has improved both our charge reconciliation and accuracy. Uniquely identifying items by utilizing the barcode at the time of use and tracking inventory have enabled us to improve our overall charging process. Further, barcode scanning at the point of care has also enabled automation of the charging process. Prior to the implementation, charges were compiled manually on a piece of paper and handed to a unit secretary for entry after the procedure. Now charges are collected at the time of care in the scanning process resulting in “real time” and more accurate documentation.

This new process has presented some challenges as well. For instance, prior to POU system implementation the revenue team in the Mercy Finance Department and Cath Labs believed that each item was uniquely identified in our billing system with its own charge code. In the course of implementation, this was found not to be the case. Many items were discovered not to have unique charge codes and codes of similar items were being used instead. This failure to identify each item uniquely was due to differing perspectives with respect to the meaning of uniqueness held by clinical and operational personnel. Clinicians look on “uniqueness” in terms of function while operational staff define uniqueness in terms of specific catalog items. For instance, in the clinician’s mind all 2.3 mm stents would have a unique charge code. From an operational perspective, on the other hand, each vendor’s 2.3 mm stent (catalog item) should have its own unique charge code. This misunderstanding was rendered moot by implementation of the automated inventory system, which allowed product scanning at the point of care in the Cath Lab and eliminated problems with erroneous product data resulting from incorrect charge codes being entered by clinical personnel.

Product Barcodes

The approach chosen for establishing a barcode scanning system to capture coronary stent prototype UDIs was to implement a comprehensive inventory system that included scanning all items used in the Cath Lab, not just the implantables, since it would have been quite difficult for Cath Lab personnel to operate 2 distinct inventory management systems. In so doing we discovered that many products have multiple barcodes located on them and some items have no barcodes at all. To eliminate the possibility of barcode confusion in the instance of coronary stents, a Mercy-generated “dummy” barcode was scanned as the “UDI.” For other items with multiple codes, the correct “UDI” (e.g., GTIN) codes had to be identified and pointed out to the clinicians as the codes to be scanned. Additionally, a specific GS1 bar code format was used whenever possible because it is easily recognized by staff, further decreasing the possibility of incorrect scanning. Some confusion regarding multiple barcodes remains but is decreasing over time as clinicians gain scanning experience. Internally generated barcodes were also used for items that had no manufacturer assigned barcode at all.

Inventory Value

Prior to the implementation of the system annual physical inventories were performed to obtain a value of all supplies for the General Ledger. In one of the Cath Labs the last annual value prior to the introduction of the automated system was approximately \$800,000. After the POU system was put in place and each item on every shelf was scanned and uniquely identified, the actual inventory value was determined to be over \$1.9 million. During the first 6 months of system implementation the inventory value was managed down to \$1.56 million resulting in significant cost savings related to excess inventory.

Expired Inventory

The automated inventory system permits tracking of products not only to the patient but also to “the shelf” in the Cath Lab creating ready visibility of the expiration dates of products in inventory. This has allowed either the timely transfer of products about to expire to another facility where they can be used prior to expiration or their return to the vendor. Since many of these products are on consignment from the manufacturer, the benefit of more efficient inventory management with decreased waste accrues directly to the vendor. This has led to negotiations resulting in lower per unit product costs to Mercy. One vendor lost \$300,000 of expired product in the 6 months prior to initiation of the POU system and is now negotiating a shared savings arrangement with Mercy related to decreased product wastage.

Overall Complexity

Prior to OptiFlex™ CL implementation Cath Lab personnel required very little knowledge of information systems in order to perform supply management activities. After implementation, in addition to becoming familiar with the new POU system, clinical staff had to learn how to navigate and operate other support systems. An example is Mercy's business intelligence (BI) reporting tool. Once supply information was stored electronically, it was easily accessible and reports could be generated through the BI tool. Clinical staff, however, were not able to use the tool and required training on it in addition to the POU system. We initially failed to recognize the full extent of training needs related to the BI software and other 3rd party support systems, but have since worked with staff to ensure their familiarity with these valuable tools for improving both patient care and achieving operational efficiencies.

Perspectives of Mercy Cath Lab Directors

From the viewpoint of Mercy Cath Lab leaders, the new automated inventory management system has offered a number of advantages. OptiFlex™ CL has improved efficiency in the Cath Lab by expediting the process of counting and reordering supplies, allowing clinical personnel to better track product expiration, charge for items used, and easily double check charges. OptiFlex™ CL has also enabled the scheduling of necessary departmental reports and creation of custom reports by vendor and product group. Additionally, the system has created visibility of inventory by location within the department and allowed for the automated replenishment of supplies while giving Cath Lab personnel the information needed to determine the appropriate inventory levels within the department.

It was initially difficult for Cath Lab staff to learn a new system and to change the familiar workflow. Figure 3 and Table 3 illustrate the number of clinical staff hours and their distribution among various functions related to inventory management before and after OptiFlex™ CL implementation. Prior to implementation Cath Lab personnel had been scanning manufacturer barcodes into Merge at the time items were used but the data were not shared with any other system. As mentioned above, OptiFlex™ CL requires a second scan to capture data in the inventory management system in order to obtain the charging, reporting, and reorder advantages. This has led to a doubling of the amount of time spent scanning items at the point of use. However, the primary benefit of automated reorder resulting from the new process was the virtual elimination of the last minute supply acquisition that previously decreased staff efficiency and often delayed procedures. On the downside, scanning has significantly increased the time spent in receiving inventory but it has also decreased the time required for item set-up prior to procedures and for inventory maintenance. Additionally, scanning has greatly expedited order review, which, prior to implementation of the new inventory management system, required manual entry of supply orders—a process that OptiFlex™ CL automated.

Figure 3. Cardiac Cath Lab Inventory Process

*Includes all inventory processes as well as charging and documentation of items

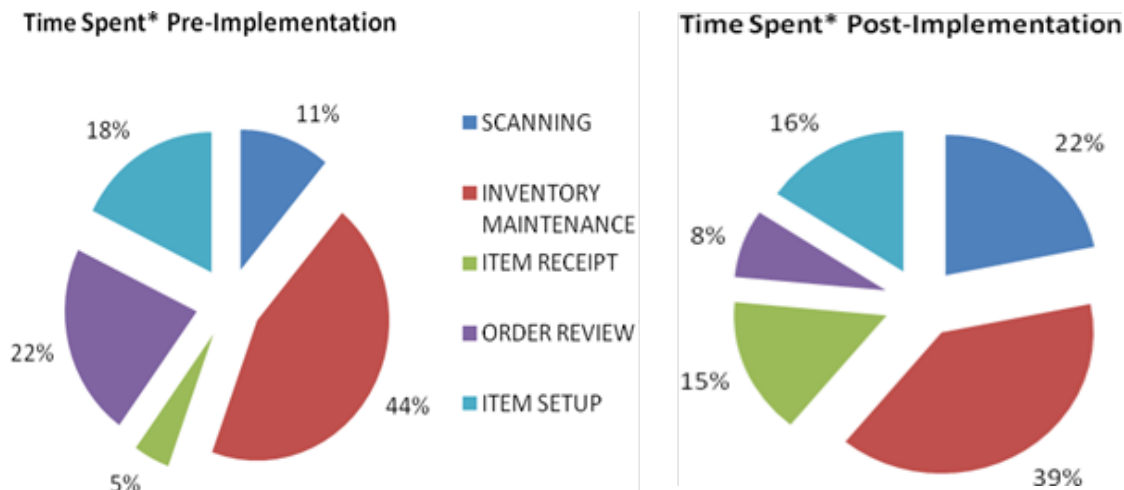


Table 3. Breakdown by Hours

PRE- OPTIFLEX™CL	Hours
POINT OF USE SCANNING	260
INVENTORY MAINTENANCE	1040
ITEM RECEIPT	104
ORDER REVIEW	520
ITEM SETUP	416
TOTAL	2340

POST-OPTIFLEX™CL	Hours
POINT OF USE SCANNING	520
INVENTORY MAINTENANCE	936
ITEM RECEIPT	374.4
ORDER REVIEW	187.2
ITEM SETUP	374.4
TOTAL	2392

Overall the new inventory management system has added significant operational and data procurement functionality without increasing staff workload or significantly disrupting workflow. As a matter of fact, staff feel that it has improved workflow with the exception of double scanning, which is seen as a temporary problem. Once the need for this step can be eliminated, we estimate that Cath Lab personnel will see an actual reduction in inventory management workload of approximately 200 hours per year compared to the situation prior to implementation of the POU system. Finally, a remaining issue that requires resolution is the presence on some products of multiple barcodes, which are major obstacles to workflow efficiency.

APPENDIX D

Glossary of Terms

510(k) pathway: Pre-market submission of a medical device to show that it is substantially equivalent to another legally marketed medical device in both safety and effectiveness.

Accountable care organization (ACO): Collaborative group of health systems, doctors, and hospitals that coordinate the care of Medicare beneficiaries.

Accredited Standards Committee (ASC) X12: One of the six Designated Standards Organizations under the HIPAA, responsible for developing the technical business processes for HIPAA implementation of existing standards for administrative transactions.

Active surveillance: Continuous, systematic collection, analysis, and interpretation of health data in near-real time.

Administrative transactions: The transfer of health care encounter and payment-related information between payers and provider systems.

Adverse event: An undesirable event associated with the use of a medical product on a patient.

Agency for Health Research and Quality (AHRQ): Agency of the U.S. Department of Health and Human Services that conducts research to improve safety, accessibility, quality, and affordability of American health care.

Adverse Spontaneous Triggered Events Reporting (ASTER): Pilot project for a new model of gathering and reporting spontaneous adverse drug events (ADEs), by using data contained in the EHR and submitting reports electronically. ASTER-D is the pilot project built on the same principles, but specific to medical devices.

Application programming interface (API): Proprietary programs that can process inbound requests from external programs or devices and send back information from a database.

Automatic identification and data capture (AIDC): Any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or other computer system via an automated process.

Centers for Medicare & Medicaid Services (CMS): An agency of the United States Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and health insurance portability standards.

Change request: A request submitted by payers or other interested parties who wish to alter the available administrative transactions and code sets.

Charge master: Repository within the provider system that lists all of the billable items that can be used over the course of a patient's care and designates a price for every procedure and item, based on a specific charge code.

Checklist: Systematized steps in a list used during the course of care to mitigate errors and better inform patients and providers.

Claim: The primary format for administrative transaction; a request for payment, submitted by a health care provider or patient to a payer for reimbursement; contains a detailed, itemized record of performed health care services.

Claims attachment: An administrative transaction that supplements information provided in the original electronic claim.

Clinical data warehouse: Repositories within the provider system that collect information pulled from the EHR and other administrative databases.

Comparative Effectiveness Research (CER): Research that informs health care decision-making by comparing the outcomes and quality of different treatment options.

Consumer medical application (CMA): Electronic program or hardware that allows health care consumers to actively participate in their own health care and wellness.

Counterfeit devices: Devices that either mimic an approved device or make fraudulent claims towards their effectiveness or condition.

Current Procedure Terminology (CPT) codes: Code set maintained by the American Medical Association used for reporting medical procedures and services.

Data pools: central database that contains information necessary for conducting standardized business transactions.

Designated Standards Maintenance Organization (DSMO): Organizations established by HIPAA focused on managing change requests to HIPAA's electronic transaction standards.

Device identifier (DI): A mandatory, fixed portion of the UDI that identifies the labeler and the specific version or model of a device.

Durable medical equipment (DME): Any long-lasting medical equipment used in the patient's home setting to improve his or her quality of life.

Electronic data interchange (EDI): Communication system that establishes standards for the electronic exchange of data.

Electronic health record (EHR): Electronic platforms that contain patient medical history and clinical information including prescriptions, lab tests, diagnoses, medical device use, and procedures.

Enterprise resource planning (ERP): Management software that allow firms to collect, store, and analyze data from business activities.

Food and Drug Administration (FDA): An agency of the United States Department of Health and Human Services responsible for protecting public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics, and products that emit radiation.

Food and Drug Administration Amendments Act of 2007 (FDAAA): Signed into law in 2007, established the Sentinel Initiative, a long-term surveillance program for monitoring the safety of FDA-approved drugs and other medical products using electronic data from routine care

Food and Drug Administration Safety and Innovation Act (FDASIA): Signed into law in 2012, required FDA to establish a program for routinely and systematically assessing information concerning device recalls and to issue a proposed rule for establishing a unique identification system.

Global Unique Device Identification Database (GUDID): An FDA-administered database that includes a standard set of basic identifying elements for each device with a UDI (See Appendix B).

Group purchasing organization (GPO): Entity that assists a group of providers in saving costs by purchasing inventory in bulk, reducing per-unit expenditures.

Healthcare Common Procedure Coding System (HCPCS): Primary code set, as designated by HIPAA, for identifying medical device use in patient care.

Health Information Exchange: Transmission of vital patient information across a provider site to improve the speed and quality of patient care.

Health information technology (HIT): Electronic systems that facilitate the management of patient health information and its exchange between providers, payers, and government agencies.

Health Level 7 International (HL7): An American National Standards Institute accredited organization and standards development organization recognized by HIPAA, focused on the exchange, integration, sharing, and retrieval of electronic health information.

HIPAA: Health Insurance Portability and Accountability Act, designates standards for facilitating and simplifying administrative transactions.

Humanitarian device exemption: Regulatory pathway that exempts medical devices that benefit patients by treating or diagnosing a condition that affects less than 4,000 Americans per year, that have no comparable equivalents, and could not be brought to market without the exemption, from undergoing clinical investigations demonstrating device effectiveness.

Item Master: Data repository within the provider's supply chain system that serves as the primary source of information for items and materials regularly used throughout the provider site.

Internet of Things (IoT): Technology that enables physical objects to respond to dynamic environments and provide feedback to monitoring systems in real-time by connecting them to a synonymous virtual object that can be tracked, modified, and analyzed across networks.

Labeler: any person who causes a label to be applied to a device, or who causes the label of a device to be modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label. In most instances, the labeler would be the device manufacturer, but the labeler may be a specification developer, a single-use device reprocessor, a convenience kit assembler, a repackager, or a relabeler.

Manufacturer: A firm that creates medical devices for public use.

Materials management information system (MMIS): IT platform within the provider system for supply chain management that draws medical product information from the item master.

Manufacturer and User Facility Device Experience (MAUDE): Database that houses medical device reports of adverse events and product problems from mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporter (health care professionals, patients and consumers).

Meaningful use: Initiative launched by CMS under the Medicare and Medicaid EHR Incentive Program to give providers financial incentives for implementing and meaningfully using certified EHR technology that improves patient care.

Medical device: Defined by the U.S. Food and Drug Administration as an “instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.”

Medical Project Safety Network (MedSun): Adverse event reporting program launched by the Center for Devices and Radiological Health (CDRH) as partnership between approximately 250 clinical sites and FDA.

National Drug Code (NDC): A unique product identifier for drugs intended for human use.

Office of the National Coordinator for Health Information Technology (ONC): An agency of the U.S. Department of Health and Human Services responsible for supporting health information technology adoption and promoting health information exchange.

Passive surveillance: Safety surveillance that emphasizes the passive collection of adverse event data for analysis and action.

Patient-Center Outcomes Research (PCOR): Facilitates communication between patients and providers to assess the benefits and harms of preventive and therapeutic care and improve decision-making.

Patient-Generated Health Data (PGHD): Health-related data created, recorded, or gathered by or from patients (or on behalf of them) with a particular disease condition that can be used to supplement existing clinical data.

Payer: Entity which provides coverage and reimbursement to providers for medical products and services used in a patient's care.

Payment and remittance advice: Information derived from the initial claim that payers use to explain the payment sent to a provider.

Personal health record (PHR): Web-based, electronic stand-alone, or paper-based platform that allows patients to access, manage, modify, and share their health information at their own discretion.

Postmarket surveillance: The systematic collection, analysis, interpretation, and dissemination of health-related data to improve public health and reduce morbidity and mortality.

Preauthorization request and response: An administrative transaction where a payer provides prior authorization for the use of a device or device-related procedure in a patient's care to facilitate reimbursement to providers.

Pre-market approval: Scientific and regulatory process through which FDA reviews a Class III medical device for public use.

Production identifier (PI): A conditional, variable portion of a UDI that identifies one of more of the following when included on the label of a device: the lot or batch number, serial number, expiration date, manufacture date, distinct identification codes of a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

Provider: An individual health care worker who provides clinical care to patients.

Provider system: A setting (health system, hospital, doctor's office, etc.) in which medical care is given to patients

Recall: A firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.

Registry: A system that collects and maintains structured records on a specific disease, condition, procedure, or medical product for a specified time period and population.

Revenue-cycle management: An administrative IT system within a provider site responsible for generating claims for submission to payers.

Radio Frequency Identification: Wireless system that uses electromagnetic fields to transfer data and automatically identify objects with attached tags.

Section 522 study: FDA-ordered postmarket surveillance study requiring device manufacturers to conduct studies of Class III and II medical devices under conditions specified under Section 522 of the Federal Food, Drug, and Cosmetic Act.

Sentinel Initiative: FDA's national postmarket surveillance system for prescription drugs which uses health care claims data to assess the safety of drugs and other medical products in large patient populations in near-real time.

Total product life cycle (TPLC): Framework for following a medical device from its design, submission through pre-market approval to its use in the post-market setting.

Situational rule: An ASC X12 rule that depends on an associated business rule which is specified in the implementation guide and which clearly and unambiguously states the requirement designation.

Unique device identifier (UDI): A unique numeric or alphanumeric code that consists of a device identifier and a production identifier (See Appendix A).

Universal product number (UPN): Product identifier, often encapsulated within a barcode, that can be automatically captured within computerized systems.

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