Unique Device Identifiers:
Facilitating the Capture and Transmission of UDI

April 7, 2014

Prepared by:

NOTICE: The project that is the subject of this report was approved by the Workgroup for Electronic Data Interchange Foundation (The WEDI Foundation). The WEDI Foundation, formed in 2004, is a multi-stakeholder charitable non-profit dedicated to scientific research and education in order to foster the improvement of administrative and clinical healthcare information exchange.

Additional copies of this report are available from Leanne Cardwell at lcardwell@wedi.org.

For more information about the Workgroup for Electronic Data Interchange Foundation, visit the WEDI home page at: www.wedi.org

Acknowledgments

This study was made possible through the support of The Pew Charitable Trusts. The WEDI Foundation thanks everyone who presented and participated in panel discussions during the public workshops, informing the WEDI Foundation and assisting in developing its approach and thought process on the statement task. These individuals are listed in Appendix A of this document.

Contents

Executive Summary

Medical technology and devices deliver remarkable advances in the health and care of individuals; however, the full risks and effectiveness of medical devices are not completely known because of the lack of a robust postmarket surveillance system in the United States. Without an effective system to gather and share the unique identification of devices, conducting recalls or understanding device performance is difficult.

To address this problem, the U.S. Food and Drug Administration (FDA) is establishing the new unique device identifier (UDI) system, which will provide each device with a unique number corresponding to its make, model, and other clinically relevant information, such as lot number and expiration date. Manufacturers of high-risk implantable devices will begin including the UDI on product packaging in September 2014. In a phased approach over the next several years, labels on virtually all devices will be required to contain the UDI. The true benefits will be realized with the capture and transmission of UDI throughout healthcare to evaluate device performance and conduct device recalls.

The medical device postmarket surveillance system should 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 (FDA, 2012). Unfortunately, the current system does not accomplish any of these objectives.

CHALLENGE

Determine the best option for transmitting the UDI for non-dental high-risk implants among stakeholders to achieve the full benefits of a quality medical device postmarket surveillance system without adding significant cost and complexity

To address this challenge, WEDI conducted a series of meetings involving multiple stakeholders from the healthcare industry to discuss the many facets of postmarket surveillance with particular focus on the transmission of UDI from providers to payers. The focus of these discussions was high-risk implanted devices only[1]. UDI transmission is not cost-effective, nor necessary, for all devices. Only those devices that are prone to failure and would cause substantial harm to patients should have the UDI transmitted. High-risk, implanted medical devices fit that definition.

The outcome of the discussions was recognition that a hybrid approach would be the optimum solution to enable the UDI to become an integral component of the postmarket surveillance system in the United States.

[1] Refers to non-dental devices

This hybrid approach would include:

- Developing provider system capabilities to capture and electronically integrate the UDI into their internal systems so the UDI is available within their clinical systems, supply chains, and administrative systems

- Implementing reporting registries to consolidate device information, including UDI, from facilities

- Adding UDI as an optional field, via a situational rule to the ASC X12N standards, to enable providers and payers to transmit and use the UDI of high risk implants on a voluntary basis

- Deploying pilots with support of the Food & Drug Administration (FDA) that test and demonstrate UDI being transmitted between the critical entities (e.g., provider to payer, provider to registry, etc.) to evaluate the transmission methods.

Background

Legislative and Regulatory History

In 2007, Congress passed legislation that directed the FDA to issue regulations establishing a UDI system for medical devices to provide early detection of defective devices and facilitate device recalls to enhance patient safety and reduce medical errors. In 2013, the FDA issued regulations establishing this UDI system. The stated purpose of the regulations was to initiate improvements in the postmarket surveillance program for medical devices by assigning a unique identifier to each medical device. The UDI legislation required the publication and storage of UDI medical device information in a single FDA database accessible to the public. The Global UDI Database (GUDID) administered by the FDA will be used to meet this requirement. The labeler of the device, which in most cases is the device manufacturer, is required to submit data on the device to the GUDID to serve as a reference catalog for every product with an identifier. GUDID will not contain any information on patients or providers. The FDA intends for the GUDID to operate in a manner similar to the National Drug Code (NDC) database and to provide many of the same benefits.

Components of UDI

The UDI is a code on each device label, package, and/or device itself that is comprised of two parts. The first part is the device identifier (DI). The DI is static and identifies the version or model of the device, and will be included in the GUDID. The second part is the production identifier (PI). The PI is dynamic and distinguishes the device by listing the lot or batch number, serial number, manufacturing date, and expiration date.

UDI numbers will be assigned by issuing agencies accredited by the FDA (e.g., GS1, Health Industry Business Communications Council (HIBCC), and the International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA)) and created and maintained by the manufacturer of the device.

The UDI will be both human readable and encoded in automatic identification and data capture (AIDC) technology. To ensure maximum efficiency and to reduce errors associated with manual recording of the lengthy field, the UDI should be scanned and transmitted electronically.

Overview of FDA's Sentinel Program

The FDA developed the Sentinel Initiative to comply with the Food and Drug Administration Amendments Act of 2007, which required the FDA to collaborate with public, academic, and private entities to develop methods for obtaining access to disparate healthcare data sources and to analyze healthcare safety data. In 2012, Congress directed the FDA to expand Sentinel to include devices.

Sentinel is built upon a secure network portal that enables the FDA to issue requests to participating health plans and aggregate the data—primarily from claims—that are returned. The source data gives access to 382 million person-years of observation time, 3.7 billion dispensings, 4.1 billion unique encounters, 46 million acute inpatient stays, and 24 million people with one or more laboratory test result.

By working with the participating payers, Sentinel was used to successfully investigate safety concerns with drugs. For example, FDA used Sentinel to assess reports and risks of serious bleeding events regarding the anticoagulant Pradaxa (dabigatran) (FDA, 2012). Through the Sentinel analysis of insurance claims, the FDA was able to issue a safety announcement on this drug. Similarly, using Sentinel, the FDA conducted an analysis of the rotavirus vaccine that resulted in approval of revisions to

the prescribing information and patient information for RotaTeq (FDA, 2013). Because Sentinel relies on claims data from payers, including the UDI in the claim could enable the FDA to utilize Sentinel to conduct assessments and analyses on medical devices and outcomes in a manner similar to the analyses conducted on Pradaxa and RotaTeq.

Existing UDI Pilot Projects

Pilot projects attempting to utilize existing device data are underway in several payer and provider organizations, including a payer that is conducting a pilot specifically focused on device recalls where information on the device implanted is sent from the provider to the payer. As the payer will be publishing the results of the pilot, the company has chosen not to be named at this time.

In addition to the payer pilot focused on device recalls, two other pilot projects that have results regarding the technical feasibility, business value, and cost effectiveness of capturing and transmitting UDI are:

- Mercy Health System UDI demonstration project
- California Medicaid UDI pilot project

Mercy Health System UDI Demonstration Project

In 2012, Mercy Health System began a demonstration project to implement a coronary artery stent UDI-based surveillance system using the electronic health records (EHRs) in a multi-hospital system. Mercy initially created its own internal UDI using the manufacturer and device code numbers, since manufacturers are not required to implement UDI until September 2014.

Mercy found the following benefits by capturing UDI in their EHR, billing, and supply chain systems (Drozda, 2013):

- The ability to determine the most effective stents in different patient situations
- Operational efficiencies in the various departments that use device data in the integrated technology systems by using scanning devices to reduce manual entry and by having the device data readily available within each department for use and analysis by the medical staff
- Cost savings through the reduction of the medical devices inventory and the use of automated re-ordering

California Medicaid (Medi-Cal) UDI Pilot Project

In June 2009, the California Medicaid Program (Medi-Cal) commenced a two-year pilot that required participating providers to submit the universal product number (UPN), a unique number that a manufacturer assigns to its products, as part of the claim for reimbursements. The UPN was used for the Medi-Cal project because the UDI did not yet exist. For this project, Medi-Cal used the HCPCS code field in the ASC X12 claim transaction with a situational provision to transmit the UPN. The HCPCS field cannot be used to transmit the UDI in the future, because the field is not large enough to hold the UDI, and the situational provision was only approved for this Medi-Cal pilot.

During the pilot, Medi-Cal processed seven million claims and $600 million in provider reimbursements that resulted in the following (DHCS, 2011) (Watson and Rivera, 2012):

- $30 million savings in supply contracting

- Lower operational costs for Medi-Cal and providers because of faster, more accurate adjudication and elimination of the need to request additional information on claim attachments
- Enhanced identification of claims data by specific product attributes, such as manufacturer name and product functionality
- Better control in the determination of medical necessity, rate setting, establishment of utilization controls, preparation of fiscal reports, and monitoring of healthcare outcomes
- Greater accountability with the providers and manufacturers
- Improved identification and removal of defective products from Medi-Cal's list of covered benefits

Acknowledging that costs would be incurred with changing processes and systems to include UDI, the experiences from pilot projects indicate that the potential benefits for providers and payers outweigh the costs.

Surveillance Challenge

The full risks and effectiveness of medical devices are not completely known because of the lack of a robust postmarket surveillance system in the United States. Without an effective system to gather and share the unique identification of devices, conducting recalls or understanding device performance is difficult.

The medical device postmarket surveillance system should (FDA, 2012):

- Quickly identify poorly performing devices
- Accurately characterize and disseminate information about real-world device performance, including the clinical benefits and risks of marketed devices
- Efficiently generate data to support premarket clearance or approval of new devices and new uses of currently marketed devices

The current postmarket surveillance system is flawed, but UDI will provide a new tool for strengthening existing data sources that are or could be used to assess device safety and to recall products. In some cases, additional actions are needed to integrate UDI into these data sources.

Given the deficiencies in device postmarket surveillance and the new opportunity afforded by the new UDI regulations to generate improvements, the WEDI Foundation assessed the current strengths and weaknesses of various data sources and analyzed how to effectively integrate UDI through its capture and transmission.

Postmarket Surveillance

There are four primary data sources that are or could be used to conduct device postmarket surveillance:

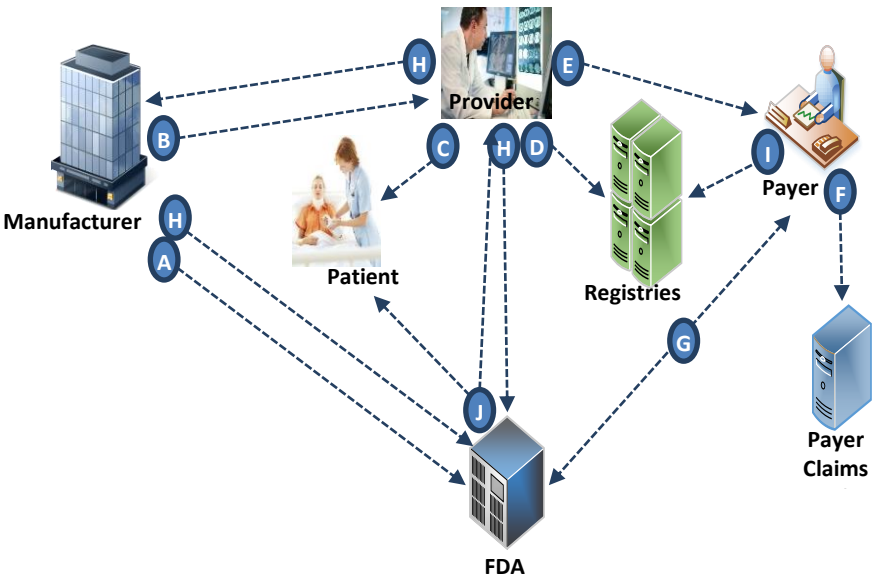
- Adverse Event Reporting System (AERS) is a combination of voluntary reporting of health event issues and the mandatory reporting of possible device-associated serious injuries, deaths, and malfunctions.

- EHRs contain patient data at the individual provider level. Most EHRs currently lack information on devices used in patient care, though there are early-stage efforts to include UDIs in patient records to support recall resolution and care coordination.
- National and international device registries are created and maintained on specific devices of interest by private organizations. An example of such a registry is the National Cardiovascular Data Registry operated by the American College of Cardiology.
- Claims and administrative transactions transmitted from provider to payer may be accessed and aggregated through the FDA Sentinel System (for drugs and biologics) and for analysis by each payer individually. Today, claims lack information on the device used and therefore cannot be utilized for postmarket surveillance. An existing example of using claims is the work currently done assessing drug safety.

Each of these potential sources serves a specific role within the postmarket surveillance system and has its own strengths and weaknesses, which are identified in the following table.

SOURCE	AERS	EHRs	REGISTRIES	CLAIMS
ROLE in POSTMARKET SURVEILLANCE	Identifies some safety concerns for FDA	Identifies patients with recalled devices; could be used in other analyses, but significant interoperability challenges exist	Assesses questions associated with specific procedures involving medical devices	Tracks patient longitudinal records and analysis of large data sets to identify safety signals
STRENGTHS	A process currently exists FDA receives a large number of reports Patients and providers can submit reports	Most large medical centers currently use EHRs Detailed clinical information on patients is maintained No time lag exists for providers to access this data	Contents include very focused and detailed information on the product, procedure, and patient Each registry addresses a very specific focus Registries consolidate data from individual reporting institutions	A transmission process currently exists for providers to send data to payers, payers to store data in claims database, and payers to send data to the FDA Sentinel system There is a process to aggregate data across very large numbers of patients There is a successful history in using claims data for postmarket surveillance of pharmaceuticals
WEAKNESSES	Often reports are not submitted in a timely manner Reports only identify problems, not total number of devices in use Not all problems are reported Many reports do not readily identify the problem or device for the FDA	Not all EHRs have added fields for tracking UDI data It is difficult to share and aggregate data across providers, which poses significant issues when the patient is being treated by a provider who did not implant the device Large data sets and longitudinal records are not readily available Currently not included in any certification program	Registries do not exist for every high-risk medical device, and are currently not conducting device surveillance Registries are expensive to develop and maintain No standardized exports exist from EHRs Recording of data into registries is manual There are no existing standards or regulations regarding the data, formats, protocols, procedures, and governance across registries	Claims information is not as detailed as other data sources, specifically EHRs and registries Often there is a time lag between the completion of the procedure and the submission of the claim The standard claim transaction has to be changed to include the UDI Provider systems need to be modified to capture the UDI using AIDC technologies and make it available to the claim process Claims and administrative transactions maintained by health insurance payers are accessed and aggregated through the FDA Sentinel System for drugs and biologics, but not currently for devices

The following exhibit depicts a macro-level view of how the elements of UDI could potentially interact.



UDI Process Flow Events

A. Manufacturer sends UDI information to FDA database
B. Manufacturer ships device to provider and provider captures device UDI information
C. Provider issues medical information with UDI to patient
D. Provider submits UDI information to registries
E. Provider files claim with payer
F. Payer stores UDI in claims database
G. FDA Sentinel gathers claim data from payers
H. Provider and manufacturer report adverse events
I. Registries utilize claims data from payers
J. FDA alerts provider and patient of recall

Discussion on UDI Transport and Storage

The goal of UDI transport and storage is to better understand and evaluate device performance and assist with device recalls. There are systems that could contain UDI data and other systems that could analyze this information to assess device performance or locate patients with recalled devices.

Data sets that contain or could contain UDI data include EHRs (housed by providers) and claims (housed by payers), if they contain a specific field to document the UDI. Systems that could analyze these data include FDA's Sentinel Initiative, registries run by third-party organizations, internal systems used by health plans to assess the quality of care of their beneficiaries, and all-payer claims databases.

The challenge is to establish the most efficient and cost-effective method to transmit UDI data from a system that contains UDI to one that can analyze UDI. The two potential methods for transmitting the UDI utilize EHRs and claims.

UDI Transmission via EHRs

An option to achieve the goal of improved data for postmarket surveillance and recalls is to transmit UDI via EHRs. However, there are limitations that prevent the EHR from being the primary source of reporting UDI. These limitations include limited interoperability and data sharing capabilities between EHR systems, and an inability for EHRs to export UDI data to external systems. It will not be possible in the foreseeable future for EHRs and related registries to be used in such a way for postmarket surveillance.

UDI Transmission via Claims

The stakeholder working group convened by WEDI explored another source of UDI data—claims databases (submitted data from providers via claim transactions). Since it will not be efficient in the

near future for EHRs and device registries to be utilized for postmarket surveillance, an advantage of transmitting UDI in claims is that the existing infrastructure can be leveraged, with some modifications.

Expanding existing transactions to accommodate UDI in the claim via a situational rule[2] for reporting purposes would create opportunities for providers to voluntarily extract UDI data from institutions and consolidate data within payers. UDI could potentially be accessible for postmarket surveillance sooner than what could occur via EHR transmissions and registries.

Options for the Transmission of UDI

Based on these sources of data, the stakeholder working group identified the following options regarding the capture and transmission of UDI:

1. Maintain the status quo and do not enable providers and payers to transmit UDI
2. Enhance EHR functionality to enable UDI to be transmitted directly from EHRs to registries, payers and other data systems
3. Modify the claim to allow for reporting of UDI to payers

Option 1: Maintain the status quo and do not enable providers and payers to transmit UDI

Currently, the means of evaluating device performance are inadequate. There are no standardized exports between providers and payers. The FDA Adverse Event Reporting System (AERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. AERS currently is the only system for reporting adverse events, but this channel of communication is not consistent among all providers and manufacturers.

The current adverse event reporting system requires manufacturers to report problems to the FDA; however, once the provider receives the device, the manufacturer rarely receives information regarding the patient or device to report problems. Providers submit the required mandatory reports on device use to the FDA. These reports may not be useful, if the patient receives treatment from a provider other than the one who performed the implant procedure. Since the manufacturer and often the treating physician do not have specific, reliable information regarding the performance of all of their devices, relying on the AERS for postmarket surveillance will not enable the intended UDI benefits to be achieved.

Benefits to Option 1 include:

- No additional burdens would be placed on providers or payers

Shortcomings to Option 1 include:

- Quality and outcomes data of medical devices would neither be tracked nor analyzed
- Identification of patients affected by medical device problems or recalls would only be possible by individual providers on a case-by-case basis
- Cost effectiveness of devices and associated procedures would not be determinable
- The ability to conduct postmarket surveillance would improve only marginally beyond the capabilities that currently exist

[2] According to ASC X12, "*Required means the item must be present in all data transactions. Situational means the usage depends on an associated business rule which is specified in the implementation guide and which clearly and unambiguously states the requirement designation…*"

Option 2: Enhance EHR functionality to enable UDI to be transmitted directly from EHRs to registries, payers and other data systems

The second option would be to transmit the UDI directly from the EHRs to other stakeholders, including registries, FDA, and payers. Within providers, EHRs contain large amounts of data for clinical purposes (e.g., patient recovery observations, complications, and follow-ups) and will require the addition of UDI functionality. To be used for postmarket surveillance, systems would need to be established to receive the UDI directly from EHRs. In addition, the EHRs would need to be modified to include functionalities and capabilities to transmit the UDI directly to new systems, such as registries.

Benefits to Option 2 include:

- Specific characteristics and metrics could be determined and tracked for each device type
- Registry owners or payers could have detailed medical device databases
- Entities within healthcare focused on specific fields of medicine, such as orthopedics or cardiology, could include UDI into existing registries, each of which would have its own purpose, criteria and guidelines
- Only providers who practice in the specific fields of medicine pertaining to the registry would participate
- Providers could develop a single transmission mechanism from their EHRs to send UDI to multiple recipients and force the receiving systems to agree to receive the data via the same mechanism and in the same format

Shortcomings to Option 2 include:

- Providers would have to make changes to their EHRs to capture and transmit UDI data to the appropriate registries and/or payers
- Payers would have to develop new medical device databases and establish new systems and processes within their quality and outcomes divisions
- The current Sentinel system could not be utilized to evaluate device safety, as Sentinel relies predominantly on claims data
- Registries would have to be developed, if they do not exist, or existing registries would have to be modified for each type of medical device
- The infrastructure for each registry would have to be developed with each provider
- The expense of developing and managing registries is significant, therefore adding new types of medical devices would be cost prohibitive; however, as data become more easily accessible, these types of registries may be more viable in the future
- Providing data to registries is usually burdensome on providers, because duplicative work can be required
- Governance of state-level registries would have to be established to conduct postmarket surveillance of medical devices (there are models for performing this governance, such as the Physician Quality Reporting System (PQRS) program administered by CMS, but there would be significant regulatory changes required to address such a framework in the future)

Option 3: Modify the claim to allow for reporting of UDI to payers

The third option would involve modifying the Accredited Standard Committee (ASC X12) claim transaction to carry structured UDI data for specific non-dental, high-risk implants such as hips, knees, and coronary artery stents. This option would incorporate UDI data into electronic transactions between providers and payers. Each provider and hospital would agree to transmit the UDI for a limited and

defined set of devices. The UDI will be used for reporting the unique device identifier when a health plan and hospital mutually agree to transmit this information or as deemed by the provider to enhance claim reporting. This approach would be completely voluntary for providers, and not require providers that are not capable of transmitting the UDI to include it in claims data. Essentially, this approach would enable providers and payers to establish pilot projects for capturing and transmitting the UDI.

To accomplish this option, providers would need to evaluate their EHR or inventory management systems and ensure that appropriate linkages are in place with their billing systems. This integration would include modification of existing hospital charge master systems in order to accommodate the finite lists of high-risk, implantable devices for which each hospital has agreed to transmit the UDI. The charge master systems typically have a single entry to contain the device type and the amount the hospital charges for that device. Incorporating UDI would require a separate entry in the charge master system for every UDI. For example, a hospital that performs stent implants today may have one entry in the charge master system for a stent. With UDI, there would be an entry for every stent type from every manufacturer, which would significantly increase the number of the entries in a hospital charge master system.

This option could provide expanded insight into medical device performance for patients, providers, payers, and manufacturers. Outcomes and associative data would greatly improve the holistic view of a patient, since performance of a medical device would be considered. A holistic view is particularly desirable considering the span of use of some devices and the potential for patients to move geographically and to have multiple providers. Additionally, Sentinel—which has access to a critical mass of patient data from major payers—has successfully assessed drug performance and could be similarly utilized for devices.

While the current claims infrastructure would be sufficient to assess device outcomes with the addition of UDI, to improve on this option, industry could develop an all-payer claims database in which to store UDI data. With this all-payer claims database, the patient information would also be tracked, if the patient did not remain with the same payer. Should the patient switch to a different payer, the information in the patient's former payer claims database would be available. This all-payer claims database would also allow private payers to share data with other payers and back to submitting institutions to enhance their own quality efforts.

Benefits of Option 3 include:

- Many of the postmarket surveillance goals for medical devices would be achieved
- Payers could conduct their own quality analyses on devices and assist with locating patients implanted with recalled devices
- Registries could link with claims to enhance longitudinal analyses of devices
- The FDA's Sentinel system, which relies predominantly on claims data, could be utilized to assess device performance as is currently done with drugs
- Pilot programs could transmit UDI for interested providers and health plans
- Collaborating providers and payers would decide which implants would involve transmission of the UDI
- Costs are anticipated to be less than Option 2 while significant benefits could be achieved
- If developed, all-payer claims databases would be able to incorporate UDI for analysis and evaluation across multiple payer datasets

Shortcomings to Option 3 include:

- Participating providers would have to make changes to their respective systems to:
  - capture and transmit UDI data as part of the claim
  - receive and process UDI data as part of the claim
  - analyze UDI data and provide the data for postmarket surveillance
- Patients that change payers would not be tracked longitudinally, unless those payers participated in Sentinel or participated in all-payer claims databases; however, the magnitude of data available from claims would lessen the impact
- A situational rule could become a requirement for payment by a payer
- Clinical and administrative data capture typically occurs in two different systems and would require integration
- Adding UDI to the claim will add a level of burden and cost to providers who will have to modify their systems to move the UDI from their EHR/clinical systems to billing systems

Business Case for the Transmission of UDI to Payers as Part of a Hybrid Approach

Through our research, it was determined that a blended solution (hybrid approach) could serve as an effective strategy to build a repository of UDI data to enhance postmarket surveillance.

In this approach, it is recommended that EHRs should both collect UDI data and develop exports to payers, public registries, and billing systems in order to address “short-term” and “long-term” goals in collecting UDI. Since EHRs will not be capable of this type of export in the foreseeable future and due to the associated challenges with creating device registries, it is suggested that ASC X12 modify the claim transactions to accommodate the transmission of UDI.

Many benefits could result from the transmission of UDI to payers as part of a hybrid approach:

- Payers could assist with recalls by using UDI data to more quickly and efficiently reach the patient than the healthcare facility in which the procedure was performed, which in many cases could have been several years prior. Currently, many of the highest risk recalls end without all devices accounted for and identified, partially because hospitals and manufacturers lack up-to-date contact information. Health plans, on the other hand, are another stakeholder that can contact the patient and often will have more recent contact information.

- FDA's Sentinel system has successfully evaluated drug safety. Sentinel, though, lacks access to data on device quality and the specific devices used in care. UDI transmission to the health plan would enable Sentinel evaluations of device quality. Richard Platt, MD, MSc, Professor and Chair of the Harvard Medical School Department of Population Medicine at the Harvard Pilgrim Health Care Institute and the Sentinel Program Lead, stated that transmitting the UDI in the claim is the least burdensome method for using Sentinel with devices (Platt, 2013).

- Payers would have access to detailed device information to conduct their own analyses on device quality and performance. As payers currently lack any information on the specific devices used, this information would provide them with previously unattained data to assess the care of beneficiaries. This information would support longitudinal analyses when patients see multiple providers or obtain follow-up care from a physician that did not conduct the initial procedure. As stated in the comments from the America’s Health Insurance Plans (Bocchino, 2012) and Kaiser Permanente (Ferguson, 2012) submitted in response to the FDA UDI Rule, the presence of

the UDI in the claim would enable patients, procedures, costs, and devices to be related, analyzed, and evaluated based on outcomes.

- Both existing and new registries could link with claims data to provide longitudinal analyses on medical devices. As registries often only house short-term outcomes data, this capability would ensure long-term data collection linked to detailed patient information.

- As proven successful in the Medi-Cal pilot project, providing a mechanism for providers to transmit the UDI to payers could result in many operational and financial benefits. The transaction and situational provision used for Medi-Cal cannot be used with UDI because:
  - The HCPCS field is not large enough to hold the UDI
  - The situational provision was only approved for the Medi-Cal pilot

To achieve these goals, a situational rule such as the following could be appropriate:

SITUATIONAL RULE

The suggested language for a proposed situational rule for providers and payers to include UDI in the claim as optional for reporting purposes is the following:

The UDI will be used for reporting the unique device identifier when a health plan and hospital mutually agree to transmit this information or as deemed by the provider to enhance claim reporting.

Including the UDI in the claim with the proposed situational rule makes the inclusion of UDI voluntary, meaning providers would not be required to report it and payers would not be required to collect it, unless they have both agreed to do so. Providers would need to make changes to their charge master and billing systems to include UDI (both DI and PI). The UDI pilot projects have made these changes, or are in the process of making these changes, because their evaluations indicated that the potential benefits and costs savings outweigh the costs of the changes.

Ultimately, through this situational rule, providers, payers, registries, and the FDA could compare the efficacy of similar devices to:

- Determine quality based on actual results in large patient populations
- Identify poorly performing devices and safety risks
- Assess differences in the performance of devices to improve competition among manufacturers and ensure that patients use the highest quality and most appropriate technologies for their conditions
- Assist with device recalls to ensure that all patients affected by failing technology receive appropriate follow-up care

Payers and providers would be able to work together to identify the best-performing and cost-effective medical devices. Patients and providers would be able to make decisions regarding specific medical

devices and procedures based on historical, factual data. Providers and patients would be able to make informed selections of medical devices best suited for each patient's situation.

ASC X12 Elements for Including UDI in the Claim with a Situational Rule

To be clear, the situational rule would apply to the institutional claim transaction and would not be mandatory. Through the proposed rule, UDI transmission would be voluntary for both providers and payers, who would need to mutually agree to collect and transmit the UDI for certain products that they identify. This approach would support pilot projects that any health plan (including Medicare) or providers would like to conduct and would ensure that providers without the capability to transmit UDI would not be required to send device data. Recent health IT initiatives, such as Meaningful Use, also create opportunities to enhance the capture and usage of UDI. Currently, UDI is being discussed for inclusion in the draft standards for Meaningful Use Stage 3, which will drive adoption by EHR vendors.

The WEDI Foundation's stakeholder group assessed the option to develop the elements for including UDI in the claim with a situational rule. The suggested language for a proposed situational rule is:

- The UDI will be used for reporting the unique device identifier when a health plan and hospital mutually agree to transmit this information, a pilot project developed by a hospital and health plan requires the transmission of this data, or as deemed by the provider to enhance claim reporting.
- Since the UDI will be included for reporting purposes, a HIPAA code set is not required at this time.

Structure of UDI Data and Fields

Devices

The claim transaction would be used to transmit the UDI for high risk implants such as knees, hips, and cardio stents. It is not the intent of the healthcare industry to transmit UDI for the very large volume, low risk medical devices such as wound dressings.

When a medical device is implanted, the UDI for that medical device should be reported. The ability to transmit multiple UDIs is necessary for procedures that utilize multiple high-risk components per procedure. For example, if a hip transplant is performed on a patient that uses the bundled hip package as it was manufactured and labeled by the manufacturer, then the one UDI for that hip implant is transmitted. If pieces of one hip from one manufacturer/ type (e.g., titanium) and pieces from another manufacturer/type (e.g., ceramic) are used to construct a complete hip, then the UDIs for the high-risk, implanted components are transmitted. Similarly, in a procedure involving many small implants (such as screws), the high risk implanted components could be transmitted or not at all if the screws were not deemed high risk and worthy of transmission by the payer and provider. Conversely, if those screws could represent significant risk to the patient and the payer and provider agree to transmit their UDIs, then that information would be included in the claim.

UDI

The entire UDI comprised of the device identifier (DI) and production identifier (PI) is to be transmitted in the claim transaction.

Field Type

A single medical procedure can involve multiple UDIs to comprise the entire implanted medical device; therefore, the claim transaction should have the ability to include the UDI as a structured field at the claim line level.

Embedding the UDI within an attachment would place it inside of an unstructured document (such as large PDF documents) that would not provide the format and standardization necessary for extraction, reporting, and analysis. Additionally, attachments are large documents that would occupy much more hard drive space than structured fields.

Furthermore, the lack of consistency and uniformity in the use and handling of attachments between providers and payers would not readily enable the UDI to be available for postmarket surveillance.

Additional Area for Further Consideration

The ASC X12 278 transaction set is called the Health Care Services Review Information. A healthcare provider will send a 278 transaction to request an authorization from a payer. The transaction may also be used by the payer to respond to this request for an authorization. Thus, the 278 can be used either as a one-way transaction, or as a two-way "request/response" type of transaction. The ASC X12N Subcommittee developed three unique implementation guides based on the 278 transaction set. Of these, the Health Care Services Review and Response guide was mandated by HIPAA as the standard format for EDI transmissions of authorizations and referrals.[3]

In 2012, the CR8 segment of the 278 transaction was modified to accommodate the reporting of all implant types from its previous usage of just a pacemaker. The CR8 segment only captures the type of implant, make, model, series number, and warranty but it does not include the UDI. The WEDI TAC did not discuss using the 278 Notification (278N) transaction as a means to report the UDI. The TAC did discuss prior authorization and the 278 (HIPAA mandated transaction) but decided not to include it at this time. The 278N is a different business purpose of the 278 transaction than the 278 Prior Authorization Request and Response. Very few entities have implemented the 278N to date and this transaction requires further research as another possible avenue for transmitting UDI.

[3] http://www.1edisource.com/learn-about-edi/transaction-sets/tset/278#axzz2y2ERTz7E

Conclusion

There is general consensus among healthcare stakeholders that having UDI available for postmarket surveillance has enormous potential for improving public health and device safety. Each of the pilot projects involving providers and payers that has been completed or is underway has yielded positive financial and efficiency results.

The hybrid approach is optimum to enable UDI to be accessible for postmarket surveillance and is comprised of the following combination of initiatives:

- The UDI should be added to the claim with a situational rule to enable interested providers and payers, on a voluntary basis, to transmit and use the UDI for high-risk implants
- Providers should work to capture and electronically integrate the UDI into their internal systems so the UDI is available within their clinical systems, supply chains, and administrative systems
- Registries should be modified to add UDI and work to consolidate data from facilities
- All-payer claims databases should be modified to add UDI and work to consolidate data from multiple all-payer claim databases
- Further research should be done to evaluate if UDI should be included in the preauthorization transaction to enable interested payers and providers, on a voluntary basis, to transmit and use the UDI for high-risk implants
- With support of the FDA, pilot projects should be developed that demonstrate UDI being transmitted between entities (e.g., provider to payer, provider to registry, etc.)

This approach uses existing infrastructure and minimizes the burden on any individual stakeholder and enables each stakeholder to utilize UDI along its own timeline.

EHRs should eventually be able to transmit the UDI from providers to registries, payers, and other stakeholders; however, that capability will not be realized until well into the future. Achieving the benefits of UDI in the foreseeable future requires the inclusion of UDI in claims. The proposed situational rule establishes a voluntary approach to achieve the goals of postmarket surveillance to improve device safety and public health with minimal additional costs, complexities, and burdens.

Appendix A: Stakeholder Meeting Participants

The participants in the UDI project were:

Organization	First Name	Last Name
AAHAM - Chennai Chapter	Maya	Mohan
Abbott	John	Terwilliger
Aetna	Michele	Lanzetta
Aetna	Phillip	Lerner
Aetna	Sally	McDonald
Akin Gump	Emily	Strunk
Allscripts	Eric	Grindstaff
Allscripts	Danielle	Jones
Altarum Institute	Tim	Borchert
American Dental Association	Jean	Narcisi
American Health Information Management Association	Meryl	Bloomrosen
American Health Insurance Plans	Tom	Meyers
American Hospital Association	George	Arges
American Hospital Association	Chantal	Worzala
American Medical Association	Bob	Poiesz
American Medical Association	Nancy	Spector
Applied Policy	Jim	Scott
Applied Policy	Melissa	Andel
Arizona Medicaid	Melanie	Lopez
Azuba	Bart	Carlson
Blue Cross Blue Shield Alabama	Tony	Benson
Blue Cross Blue Shield Arizona	Cindy	Bell
Blue Cross Blue Shield Arizona	Jennifer	DiChiara
Blue Cross Blue Shield Arizona	Sheri	Jackson
Blue Cross Blue Shield Association	Gail	Kocher

Organization	First Name	Last Name
Blue Cross Blue Shield Florida	Tab	Harris
Blue Cross Blue Shield South Carolina	Jim	Daley
Blue Cross Blue Shield South Carolina	Tonya	Dorsey
Brookings Institution	Greg	Daniel
CareFirst	Marilyn	Collins
CareFirst	Nurzetty	Rahim
CareFirst	Tamara	Tromblay
Cerner	Patricia	Chism
Cerner	R	Lantz
Centers for Medicare and Medicaid Services	Matthew	Albright
Centers for Medicare and Medicaid Services	Jason	Jackson
Centers for Medicare and Medicaid Services	Marc	Wynne
Clinical Trials Transformation Initiative	Bray	Patrick-Lake
Cognosante	Susan	Ackley
Community Health Systems	Laurie	Holtsford
Consumers Union	Lisa	McGiffert
Deloitte	Renu	Pandit-Pant
Delta Dental of New Jersey, Inc.	Joe	Stanton
Dignity Health	Nancy	Cahill
Dignity Health	Channin	DeHaan
Dignity Health	Joseph	Dysko
Dignity Health	Tran	Le
Dignity Health	Kelley	Moore
Dignity Health	Penny	Thurman
Dignity Health	Nataiya	Waller
Dignity Health, St. Bernardine Medical Center	Daryl	Cannon
Edifecs	Basil	Pais
Edifecs	Prasad	Pavuluri

Organization	First Name	Last Name
Edifecs	Gregg	Prothero
Edifecs	Ruby	Raley
Emblem Health	Frank	Bacchus
Emdeon	Kelly	Butler
Enclarity, a LexisNexis Company	Michele	Cleary
Epic	Mukesh	Allu
Epic	Kenny	Jackelen
Express Scripts	Ashley	Maples
Faulkton Area Medical Center	Heather	Bode
Federation of American Hospitals	Samantha	Burch
Federation of American Hospitals	Jayne	Chambers
Food and Drug Administration	Jay	Crowley
Food and Drug Administration	Thomas	Gross
Food and Drug Administration	Behnaz	Minaei
Food and Drug Administration	Terrie	Reed
GE Healthcare	Michael	Dahlweid
Geisinger Center for Health Research	Jove	Graham
Geisinger Health System	Kevin	Capatch
Geisinger Health System	Sam Anson	Herbert
Geisinger Health System	Don	Masser
Geisinger Health System	Deb	Templeton
GNYHA	Stewart	Presser
Harvard Pilgrim	Joanne	Cochran
Harvard Pilgrim	Richard	Platt
Health and Human Services	Scott	Douglas
Health and Human Services	Erin	Rubens
Health Care Services Corporation	Durwin	Day
Health Transactions, Inc.	Sue	Miller

Organization	First Name	Last Name
Healthcare Supply Chain Association	Frank	Moore
HealthNautica	Shailesh	Bhobe
Highmark	Suzann	Bottaro
Highmark	Doug	Renshaw
Highmark	Karen	Shutt
Highmark	Robert	Twining
Hoag Memorial Hospital Presbyterian	Quality	Reps
Independent Consultant	James	Kaneski
Indian Health Service (HIS), HHS	Charolett	Melcher
Intermountain Healthcare	Erin	Selin
John Hopkins Health System	Bonnie	Aumann
John Hopkins Health System	Shenean	Lee
Kaiser Permanente	Michael	Innes
Kaiser Permanente	Anthony	Rizzi
Kaiser Permanente	Jim	Whicker
Kaiser Permanente	Megan	Zimmermann
Knapp Consulting (President)	Paul	Knapp
Legacy Health	Denyce	Campo
Mayo Clinic	Laurie	Darst
McKesson	Kathy	Hayden
McKesson Technology Solutions	Mike	Marchlik
Medical Group Management Association	Robert	Tennant
Medical Mutual	Randy	Cloesmeyer
Medicity, a Healthagen Business	Saurabh	Mathur
MedImpact Healthcare Solutions, Inc.	Carol	Germain
Mercy	Joseph	Drozda
Mercy	Curtis	Dudley
MN Dept Labor & Industry, Workers Comp Division	Lisa	Wichterman

Organization	First Name	Last Name
Moda Health	Patricia	Van Dyke
NALC Health Benefit Plan	Anita	Lutrario
National Research Center for Women & Families Cancer Prevention and Treatment Fund	Paul	Brown
National Council for Prescription Drug Programs	Lynn	Gilbertson
National Council for Prescription Drug Programs	Kay	Morgan
National Council for Prescription Drug Programs	Sue	Thompson
NextGen	Gloria	Davis
National Institutes of Health	John	Kilbourne
National Women's Health Network	Kate	Ryan
Office of E-Health Standards and Services, CMS	Gladys	Wheeler
Office of E-Health Standards and Services, CMS	Kamahanahokulani	Farrar
Office of the National Coordinator	Nayan	Jain
Office of the National Coordinator	Behnaz	Minaei
Office of the National Coordinator	Sandra	Rausch
Optum	Tammy	Banks
Optum	Patrick	Sauer
OTB Solutions	Chris	Gilbert
OTB Solutions	Shelly	McDermot
PracticeFusion	Richard	Loomis, MD
Premier Healthcare Alliance	Lauren	Choi
Premier Healthcare Alliance	Cheryl	Fahlman
Presbyterian Healthcare Services	Andrea	Kinsley
Public Employees Health Program	Lance	Toms
PwC	Ginger	Parker
QuadraMed, Inc.	Elizabeth	Cramer
RelayHealth	Denise	Oviatt
RelayHealth	Trebba	Putnam
Sentry	William	Kirsh

Organization	First Name	Last Name
Sentry	Lisa	Tonkinson
Siemens Healthcare	Valdez	Ladd
Siemens Healthcare	Kathleen	Ochal
Southcoast	Manny	Mello
St. Joseph Health	Cathy	Mesnik
State of Utah	P	Buck
Systems Made Simple	Andrew	Underhill
TM Floyd & Company	David	Arnold
TM Floyd & Company	Terry	Floyd
TM Floyd & Company	John	Starmack
The Pew Charitable Trusts	Ben	Moscovitch
The Pew Charitable Trusts	Josh	Rising
The Rybar Group, Inc.	Claudia	Garabelli
The Weiker Group	Margaret	Weiker
UnitedHealthcare	Nancy	Berger
University of Utah Hospitals and Clinics	Amy	Mitchell
University of Washington	Sarah	Lucas
WEDI	Leanne	Cardwell
WEDI	Samantha	Holvey
WEDI	Devin	Jopp
WellPoint	Christol	Green
WPS Insurance	Laurie	Burckhardt
Xerox State Healthcare, LLC	Maggie	Ramey
Zirmed	Juliana	Sorbo

References

Rice, S. (March 21, 2014). *Medical Device Recalls Nearly Doubled Since 2003, FDA Says*. Modern Healthcare.

U.S. Food and Drug Administration (FDA). (2012). *Strengthening our National System for Medical Device Postmarket Surveillance*. FDA Center for Devices and Radiological Health.

Gross, T., Crowley, J. (October 25, 2012). *Unique Device Identification in the Service of Public Health.* New England Journal of Medicine.

Platt, R. (2013). FDA's Mini-Sentinel Program: Monitoring Device Safety with and without the UDI. (Presentation at the UDI Stakeholder meeting on December 10, 2013 – copyrighted all rights reserved and comments following the presentation). Harvard Pilgrim Health Care Institute Harvard Medical School.

U.S. Food and Drug Administration (FDA). (November 2, 2012). *Update on the risk for serious bleeding events with the anticoagulant Pradaxa (dabigatran)*. FDA Drug Safety Communication.

U.S. Food and Drug Administration (FDA). (June 13, 2013). *FDA Releases Final Study Results of a Mini-Sentinel Postlicensure Observational Study of Rotavirus Vaccines and Intussusception*. FDA Safety Communication.

Drozda, J. (2013). *FDA UDI Demonstration*. (Presented at UDI Stakeholder meeting on December 10, 2013 – copyrighted all rights reserved). Mercy Health.

California Department of Health Care Services (DHCS) (2011). *Universal Product Number Pilot Project Evaluation Outcome Report.* California Department of Health Care Services.

Watson, P., Rivera, S. (2012). *Unique Device Identifiers in Health Care Administrative Transactions, California UDI Pilot Overview, Lessons Learned and Recommendations.* California Department of Health Care Services.

Wilson, N., Drozda, J. (May 22/29, 2013). *Value of Unique Device Identification in the Digital Health Infrastructure*. Journal of the American Medical Association.

Bocchino, C. (2012). *Comments to Docket No. FDA-2011-N-0090 Unique Device Identification System.* America's Health Insurance Plans.

Ferguson, J., Potter, L. (2012). *Comments to Docket No. FDA-2011-N-0090 Unique Device Identification System.* Kaiser Permanente.

Glossary

278 – Electronic data interchange standard transaction for requesting authorization and services review

278N – Electronic data interchange standard transaction to exchange notification data

Adverse Event Reporting System (AERS) – A database containing information on adverse events and medication error reports submitted to the FDA

Automatic identification and data capture (AIDC) – The process for identifying objects, collecting data about them, and entering those data into a data store without human intervention

All-payer claims databases – Databases designed to contain de-identified health insurance eligibility and claims information from all healthcare payers within a state

Accredited Standards Committee (ASC) X12 – Standards organization for electronic data interchange

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

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

Electronic Health Record (EHR) – Computer software used to maintain health information and demographics about patients

Food and Drug Administration (FDA) – An agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, and veterinary products

Global UDI Database (GUDID) – An FDA database that includes a standard set of basic identifying elements for each device with a UDI

HIPAA – Health Insurance Portability and Accountability Act

Medi-Cal – California’s Medicaid healthcare program

National Drug Code (NDC) – A unique product identifier used in the United States for drugs intended for human use

Production identifier (PI) – A conditional, variable portion of a UDI that can identify the lot or batch number, serial number, expiration date, manufacture date, and distinct identifying codes of a medical device

Postmarket surveillance – The practice of monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market

Registry – A repository for a predefined purpose that contains a defined set of health, demographic, and medical device data for patients with specific health characteristics

Sentinel Initiative – The FDA's national electronic system that aims to develop and implement a proactive system that will complement existing systems that are in place to track reports of adverse events linked to the use of its regulated products

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

Universal product number (UPN) – Identifier for medical/surgical products assigned by the manufacturer/labeler and represented in both human readable and bar code formats on the product