

# UDI2CLAIMS

A HARVARD MEDICAL SCHOOL/BRIGHAM AND WOMEN'S HOSPITAL/GEISINGER HEALTH SYSTEM  
PILOT STUDY

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## Transmitting the UDI from the Point of Use to Insurance Claims: Changes in Workflows and Information Systems May 2017

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## Introduction and Purpose of the White Paper

Recent recalls of medical devices and our changing health care system have highlighted the inadequacies of current methods for monitoring the performance, use, and safety of implanted devices. The United States Food and Drug Administration (FDA) has required manufacturers to include a Unique Device Identifier (UDI) on all devices. Many Electronic Health Records (EHRs) have a field to record the UDI. These data could be used to monitor the safety of medical devices, facilitate comparative effectiveness research, and increase patient awareness of the devices they are living with. However, there has been minimal use of these fields in the EHR and limited data sharing beyond current voluntary and passive reporting. One solution under discussion has been to include the UDI on insurance claims. Here we describe the planning phase of one institution's efforts to record the UDI at the clinical point of use (POU) and transmit it to an insurance company on the insurance claim.

## Background

Patients, clinicians, payers, manufacturers and the FDA all need reliable and timely data and information on the performance and safety of implanted medical devices such as stents and artificial joints. Based on the experience of post-market adverse events with drugs,<sup>1</sup> it may be particularly important to capture data after approval by the FDA and when devices reach the market. Patients and their clinicians want to make informed decisions regarding their choice of implants using the best available research or surveillance data; payers are interested in identifying devices associated with superior outcomes; manufacturers and hospitals need to collaborate to alert patients when and if a recall occurs; manufacturers seek feedback on the performance of their products not only to assess their safety but also to help them to refine current models or design new ones; and the FDA has the public health responsibility to ensure safety and effectiveness of medical devices. Obtaining this information requires the establishment of a system that reliably captures data from multiple sources, links and synthesizes the data, and makes it available to stakeholders as well as researchers. Ideally, such a system has access to the results of all procedures involving implanted devices so that valid comparisons can be drawn among competing alternatives and a timely warning can be raised in case of a device defect or failure. Key to such a system is a standard for documentation and linking of medical device identification information to the patient experience with the device.

Such a system exists for medications -- The Sentinel Initiative -- which is a national electronic system for the active monitoring of the safety of products under the regulation of the FDA,<sup>2</sup> and was enabled by establishment of national drug codes (NDC) for pharmaceuticals. Sentinel is a distributed data network in which the data, largely claims along with clinical data from registries, are maintained in local repositories under the control of the data's owners. Sentinel, following an extensive pilot, Mini-Sentinel,<sup>3</sup> is now operational but is restricted to medications. The basis for a similar system for tracking and identifying devices did not exist until the FDA Amendments Act of 2007 (FDAAA) instructed the FDA to create a Unique Device Identifier (UDI) system. A 2012 report entitled "Strengthening our National System for Medical Device Post-Market Surveillance"<sup>4</sup> highlighted the surveillance gap for devices. The Food and Drug Administration Safety and Innovation Act Of 2012 expressed the intent to extend the Sentinel Initiative to devices.<sup>5</sup> However, full implementation is not possible today because insurance claims lack data on the specific device used.

The FDA subsequently published a final rule in 2013 requiring manufacturers to label medical devices with the UDI.<sup>6</sup> The UDI consists of a device identifier (DI), which specifies the manufacturer and the model, and a production identifier (PI), which includes information such as the expiration date, the batch or lot number, and/or serial number. Deadlines for manufacturers to implement UDIs were set by the FDA,<sup>7</sup> beginning in September 2014. The FDA, in collaboration with the National Library of Medicine, also established a publicly accessible database, the Access Global Unique Device Identifier Database (AccessGUDID), to serve as a

downloadable and searchable reference catalog containing the DI and key safety, regulatory, and supply chain information for every FDA-regulated device.<sup>8 9</sup>

Although the FDA's authority encompasses device labeling requirements and establishment and stewardship of the only comprehensive manufacturer-based device identification catalog, it does not extend to requiring hospitals to capture UDIs in a patient's EHR, download data from AccessGUDID, or to take any action with the data such as transmitting it to registries or to payers by including it in claims. The functionality of a certified EHR falls under the purview of the Office of the National Coordinator (ONC) for Health Information Technology. Its most recent certification criteria for EHR vendors, set to take effect in 2018, requires that the Common Clinical Data Set (CCDS), which is a summary of a patient's most important health information, include the UDI (if known or available), a list of all devices implanted in a patient, and a link to the GUDID.<sup>10, 11</sup> Almost concurrently, on October 16, 2015, CMS issued a final rule regarding the incentive payments for Stage 3 EHR meaningful use, that requires eligible providers and hospitals to include a "summary of care record" containing the UDI as part of their Health Information Exchange requirement beginning in 2018.<sup>12</sup> No comparable ruling has been issued with respect to including UDIs in claims, but there has been considerable support by the Accredited Standards Committee X12 (hereinafter referred as X12), a private standards organization with membership from government and industry, to include the DI for implantable devices in insurance claim forms (<http://forums.x12.org/>).

Claims data offer the benefit of covering all procedures, allowing patients, with identity appropriately protected, to be tracked longitudinally and geographically over multiple providers, and allowing their doctors to identify clinically relevant information about the implants. Thus, if claims data were to include DIs, they would permit tracking of outcomes associated with all high-risk implanted devices. In addition, claims data on a very large number of patients would allow clinicians, manufacturers, payers and researchers to make informed decisions regarding a given product. The potential benefits suggest that projects that demonstrate the feasibility of transmitting UDI data in claims should be given high priority.

In testimony before a Congressional committee in 2016, the Acting Administrator of the Centers for Medicare and Medicaid (CMS) stated that including UDI in claims "has merit, particularly from a research perspective,"<sup>13</sup> and subsequently endorsed the idea in a joint letter with the head of the FDA to the X12 (<http://www.modernhealthcare.com/assets/pdf/CH106132714.PDF>). The issue has received bipartisan support from Congress,<sup>14</sup> and the Inspector General of the Department of Health and Human Services alerted the Acting Administrator that "the lack of medical device-specific information in the claims data impedes the ability of the CMS to readily identify and effectively track Medicare's total costs related to the replacement of recalled or defective devices."<sup>15</sup>

Class III devices, which are used to sustain or support life, are the highest risk devices and are now being shipped with UDI labels conforming to regulations. A demonstration project on how to record the UDI of a device upon arrival at the facility, capture it at the POU, and transmit it to a registry for research purposes has been described in the literature.<sup>16, 17</sup> The work is currently being extended under the MDEpiNET initiative, "Building UDI into Longitudinal Data for Medical Device Evaluation" (BUILD) (<http://mdepinet.org/build/>). The participants plan to capture the UDIs in their cardiac catheterization laboratories via barcode scanners, store the data in their EHRs and then transmit it via their individual information hubs to a national registry. Within the first twelve months of monitoring, the participants were able to detect significant safety issues with a vascular closure device compared to others devices.<sup>18</sup>

There is an emerging and robust community of learning groups (<http://www.ahrmm.org/resources/learning-udi-community/index.shtml>) and demonstration projects (<http://mdepinet.org/build/>) focused on UDIs, as well as collaborative efforts in building foundational elements for UDI implementation and use.<sup>9, 19, 20</sup> Descriptions of the incorporation of the UDI in hospital processes and lessons learned, albeit limited, are appearing in the published literature.<sup>18</sup> Despite facing significant regulatory changes, and uncertainties regarding EHR requirements, and pressures about resource availability, overall, a growing number of U.S.

hospitals have been moving forward to capture UDIs in their systems. The initiatives typically involve multiple areas of the hospital system including supply chain management, clinical services at the POU, and EHRs.

Here, we describe the plans at the Brigham and Women's Hospital in Boston, Massachusetts (BWH), a member of Partners HealthCare, to extend these efforts by transmitting the UDI from the POU through the billing system and then to a payer. This process will have three steps: 1) scanning the UDI barcodes for devices implanted in its cardiac catheterization laboratory (Cath Lab) and storing it in the Cath Lab's EHR; 2) transmitting the UDI from the clinical record to the hospital billing system; and 3) transmitting the UDI from the hospital billing system to the payer, Blue Cross Blue Shield of Massachusetts (BCBSMA), via an electronic claim form. Step 1 had already been implemented in the Cath Lab before the start of this project. Thus, this white paper focuses on the process currently followed in the Cath Lab to capture the UDI and enter it into the patient's EHR. BWH is also planning to pilot UDI entry in the two vascular surgery operating rooms (ORs). The remainder of the paper describes plans for implementing steps 2 and 3. It is important to note that the processes described below will run in parallel with the standard process of claims transactions without substantively affecting it.

## Methods/Description of the UDI2Claims Pilot Project

The UDI2Claims project was partially funded by a contract from the Patient-Centered Outcomes Research Institute (PCORI) to demonstrate the feasibility of transmitting UDIs from a clinical EHR system to insurance claims. Given the ongoing debate regarding the value of the UDI in the claim and the feasibility of transmitting the UDI from the EHR to the claim, this project will identify issues associated with the documentation and transmission of the UDI for the hospital system, payer, and the patient.

The UDI2Claims project was launched in November 2016. To accomplish our aims, we formed working groups with multiple departments, including but not limited to: Partners eCare; the BWH Cath Lab clinical staff; the BWH vascular operating room clinical staff; nursing and health IT; Epic technical support; BCBSMA Performance Measurement Program Strategy and Quality Oversight; the BWH Center for Patients and Families; Revenue Operations/Systems; and Materials Management. Geisinger Health System, a healthcare provider and health plan, is also participating under the auspices of our contract, but their experience is not reported here. This paper, with support from The Pew Charitable Trusts, focuses on the changes in workflows and information systems of the UDI2Claims project.

### Step 1. UDI Capture and Documentation at the Point of Use: How the UDI is captured with a barcode scanner, and how the EHR system stores the UDI as part of a patient and procedure record into the EHR

The elements necessary for electronic capture and documentation of UDI at the POU include: a hospital reference database that contains the DI portion of the UDIs of devices routinely used at the POU; barcode scanners programmed to scan and parse the UDI; a method for matching the DIs in the reference database and the DIs of scanned device UDIs; and an implant record in the EHR.

The three sub-steps followed in a majority of cases are described below. What happens when the match is unsuccessful because the reference database does not contain data on the device is also described.

#### **Step 1a – Populate the reference database**

Data on the type of device, e.g. a cardiac or vascular stent, currently resides in the Supply Record of Epic, the EHR used at BWH. The following data are routinely uploaded into the Supply Record from PeopleSoft, the hospital's materials management system:<sup>i</sup>

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<sup>i</sup> In the future, much of this information ultimately may come directly from AccessGUDID. Epic and other vendors should be able to capture this information. Processes for resolving

- A description of the item
- Inventory location, in this case, the Cath Lab
- Type of supply, e.g., stent
- Manufacturer
- Supplier
- Name of the implant
- Model or catalog number

At this time, the DI is not available in PeopleSoft for use in the pilot. The desired – and future – goal is for the DI to be documented in PeopleSoft and available for routine upload into the Supply Record of Epic. Since comparison of the hospital reference database and the scanned DI is critical for the matching process, temporary solutions are being used as described below. Their details reflect the complication introduced by the different UDI formats employed by the three UDI issuing agencies approved by the FDA.<sup>21</sup>

- Global Standards One (GS1) – The DI of the device, its manufacturer or labeler and the device model, is currently being manually entered by Partners eCare staff into an available field in the Supply Record. The GS1 format appears to be the most frequently seen on cardiac devices implanted at BWH.
- Health Industry Business Communications Council (HIBCC) – Because the DI of devices encoded in accordance with the HIBCC protocol includes the model number, one of the fields of the Supply Record contains the model number which is currently used for matching.<sup>ii</sup>
- International Council for Commonality in Blood Banking Automation (ICCBBA) – No devices currently used in the Cath Lab use the protocol of this issuing agency, and no process has been developed to support the matching.

### **Step 1b – Scan and parse the UDI of the implanted device at the Point of use**

Using a scanner and an Automatic Identification and Data Capture (AIDC) system with the capability of interpreting multiple bar code formats, a Cath Lab technician scans the UDI barcode on the package of the device after it has been successfully implanted in a patient. The data is parsed into three components by Cupid, Epic’s module specialized for Cath Labs, and stored in the implant record (OpTime is the module to be used by the ORs for the same purpose, and will not require any significant re-programming). Cupid includes separate fields for the following three components of the UDI:

1. The DI, specifying the manufacturer and the model number
2. The lot or batch number
3. The expiration date (for devices such as drug eluting stents, which must be implanted before their expiration date, or when the packaging can no longer guarantee the sterility of its contents)

Whereas the lot or batch number and expiration date are stored in the implant record, the entire PI is not. In addition, under newer versions of Epic, selected information from the GUDID such as the name of the device and the name of the manufacturer, is subsequently downloaded and stored along with the DI in the implant record.

### **Step 1c – Match reference and scanned data**

The matching process depends on the UDI format:

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mismatches between local system databases and AccessGUDID have not been developed, to our knowledge.

<sup>ii</sup> GS1 has been more traditionally used on cardiac devices. HIBCC has been more traditionally used in orthopedics although many manufacturers are switching over.

- GS1 – An acceptable UDI is identified when the DI of the scanned barcode matches the DI manually entered in the Supply Record.<sup>iii</sup>
- HIBCC – To identify an acceptable UDI, the DI of the scanned device is first parsed by a utility in Cupid; the extracted model/catalog number is then matched to the model/catalog number stored in the Supply Record.

If a valid UDI is not identified even after the appropriate barcode on the device package has been scanned, the “One Time Implant” feature is used. A “One Time Implant” is a device that is not currently available for selection from the Supply Record (i.e. a Supply Record does not exist for that item). The item may not have been included in PeopleSoft or could be “trunk stock”, brought in by the vendor for the procedure. A Cath Lab technician or operating nurse in the OR can add a “One Time Implant” to the list of available supplies to be associated with that case. Epic will open the Implant Record window where the nurse or technician is asked to fill out information about the supply. Once the information is entered, the Implant Supply will show on the patient’s Implant Record. The DI, however, is not currently entered at the POU.

If the item will be carried in inventory for regular usage, the nurse or technician contacts Materials Management and the Cupid Application Coordinator requesting that the item be added to PeopleSoft and the DI added to the Supply Record. As a result, the next time that device is used, the device name, manufacturer and UDI components can populate the Implant Record. A device that will not be regularly carried in inventory will not have a DI entered in the Implant Record. We are in the process of trying to rectify this situation.

#### **Step 1d – Storing of UDI data in Epic**

If the match is successful, the following data, extracted from the barcode on the device package, is stored in the Cupid implant record:

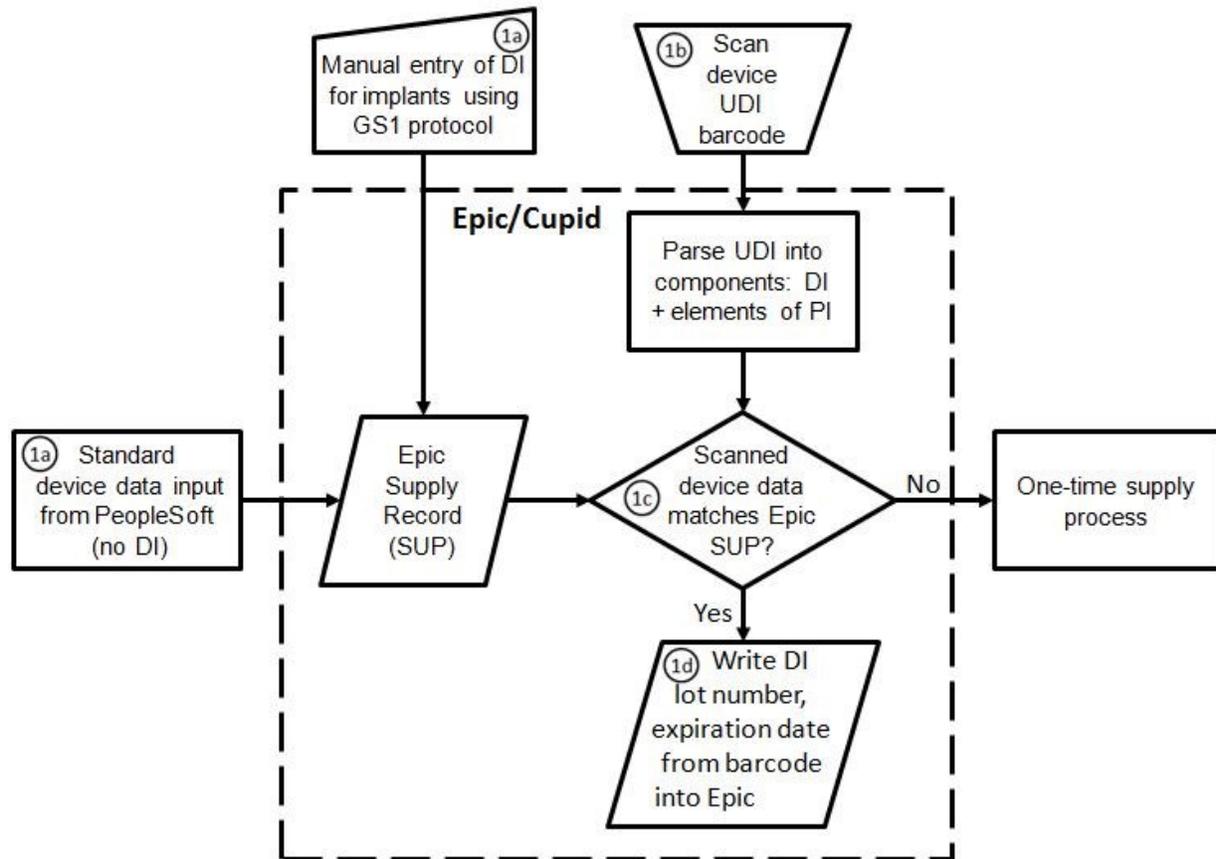
- The DI (For GS1, this is often referred to as the GTIN [Global Trade Item Number].)
- The lot or batch number
- The expiration date

In addition to the above three data elements, the implant data is associated with the patient’s medical record within Epic. Thus, the following data elements may also be retrieved:

- The description, name, and manufacturer of the implanted device, imported from the Supply Record
- Model or catalog number, imported from the Supply Record
- The date of the procedure
- The name of the physician who performed the procedure
- Whether the device was implanted, explanted, wasted or adjusted. (Note that the scope of the project includes only implantation.)
- A link to the GUDID, created by Epic allowing information from the database be pulled into the EHR.

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<sup>iii</sup> Note that a valid DI should only be verified when checked against the GUDID. This is not currently being done.

**Figure 1 - Data Flow**

**Figure 1** depicts the processes described above. The numbers correspond to the steps in the process. If the device DI were stored in PeopleSoft and included in the routine uploads to Epic's Supply Record, the need for manual entry of the DI for devices labeled using the GS1 protocol and the match, regardless of labeling protocol could be based on the device DI.

This process of incorporating the DI into the Supply Record required a modest amount of work initially. The UDI was obtained directly from the packaging and the DI was manually entered into the Supply Record for each device. However, from a maintenance perspective, the Cath Lab staff and Epic Cupid Application specialists report there are only two to three devices a month that need to have their DI manually loaded into the Supply Record. The Cath Lab technicians have now been using the barcode scanners for approximately a year and report that it is very easy to use and an improvement over the previous manual process.

## Step 2. How the UDI will be transmitted to and stored in the hospital billing/revenue cycle), and with what other information

Currently, the BWH information systems lack the capability to transmit the DI beyond the Implant Record. Thus, to enable the DI to be transmitted to the hospital's revenue module, known as Rolute, an extension rule (custom code) is being developed by programmers from the Extension Team at Partners eCare. The Extension Team did this programming after extensive analysis by Epic technical support to ensure that this would not compromise the regular transfer of billing data, and with recognition by Epic that the Partners eCare team is large and well supported. The actual effort to create the code by the hospital team was not substantial, although testing the code requires more resources.

The rule instructs the system to first look at encounters with a 278 revenue code, which designates a procedure involving an implant; next to look at the subset of these procedures that were performed in the Cath Lab (and eventually the Vascular Operating Rooms); and finally to

select those whose payer is BCBSMA. For each qualifying procedure, the extension rule reads the data residing in the DI field of the Implant Record and writes it into a designated field in Resolute, the Epic billing module, along with the patient identification number.

The next step is to populate a claim with the DIs in Resolute. For this step, we require the 837 Claim Form, a standard developed by the X12, and used in all provider-payer transactions to transmit claims electronically. It consists of two principal parts: The first, known as the header, contains all data and information other than charges; the charges constitute the second part. In addition to the patient's name and the name of the providing institution, the header may contain much additional data and information, all stored according to the standards established by the X12.

Because the X12 has not yet established a standard for storing the DI in the 837 Claim Form, Partners' staff and BCBSMA decided – for the purposes of this pilot – to enter the DI in the note field of the header, a free format field that can hold up to 80 characters and be repeated up to 10 times. Formally, the note field is known as Loop 2300, NTE segment; it was selected by Partners' staff because it is not used in current Partners-BCBSMA transactions. Since the note field is format-free and may be used for other purposes in addition to storing the DI, the DI in the note field will be preceded by the Data Qualifier (also known as the Note Reference Code) “UPI” to signal that the data that follows is associated with the DI. In most cases, the note field will contain the DI. However, for purposes of ongoing analysis associated with our pilot study, we need a method for dealing with situations in which the DI was simply missing from the Implant Record or the implanted device was to be used only once and thus did not have its DI entered into the Supply Record. When the DI is missing in the Implant Record, 14 zeros – the default value – will appear in the note field. However, for certain situations we will need the tech or nurse to enter a custom code, and we are currently working on the following plan. For one-time devices, the numeral 1 will be entered by the nurse or the technician in the DI field of the Implant Record. Finally, if other problems are encountered with the scan, the nurse or technician will be asked to enter the numeral 2. We plan to implement this protocol to distinguish the above situations from a case in which the UDI was not scanned.

The advantages of using the note field are that (1) it is an established part of the claim form; (2) it is format-free; (3) it can accept the three DI protocols; and (4) it can accept multiple DIs if more than one implant is used in a case. In addition, as explained above, the note field is restricted to patient-level data in contrast to line-level data, which is usually associated with a charge.<sup>iv</sup>

The method we used to add the DI in the claim's note field occurs downstream and separate from the chargemaster, and therefore there is minimal risk of unanticipated consequences to the billing process. In the future, the UDI could in theory be incorporated onto the claim by the chargemaster, similar to how national drug codes (NDCs) are added to claims. This process would require further design and ultimate approval through the X12 standards process.

### Step 3. How the UDI is transmitted in the claim form to the payer, including the field used

In the final step, the DI in the claim note field will be transmitted from Partners to BCBSMA, using standard Electronic Data Interchange (EDI). BCBSMA will store the data to enable an assessment of the quality and reliability of the new process.

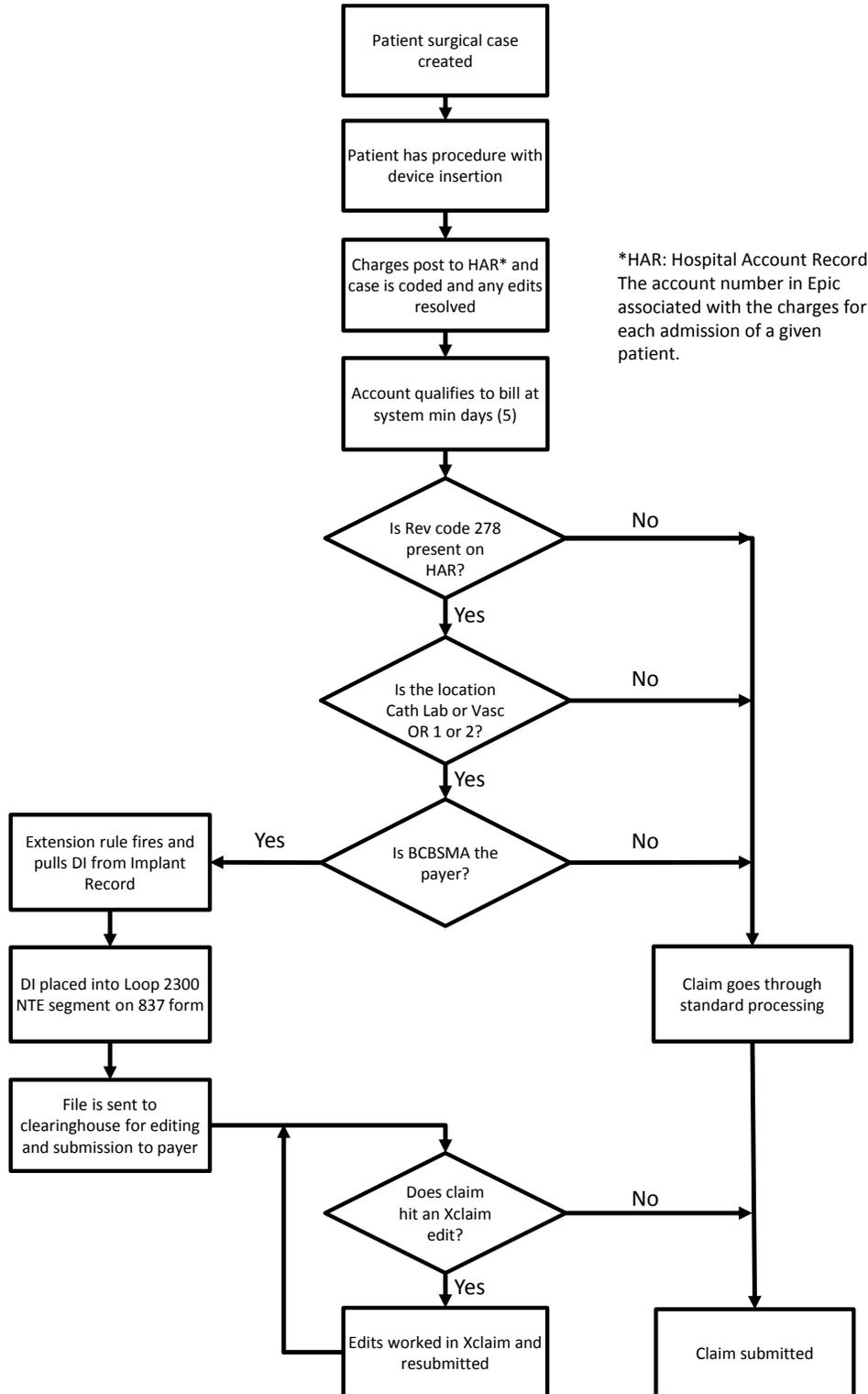
As mentioned earlier, the process described above was negotiated between Partners and BCBSMA in absence of a standard. Fortunately, the X12 has recognized the need for a standard for storing DIs. Accordingly, it recently developed a proposal for transmitting DIs from provider to payer. It proposes to reserve up to eight fields for DIs in the header, in the location known as Loop 2300, CR8 segment. The proposed standard also requires the provider to indicate whether the device is an implant or explant; this will be accomplished using a binary

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<sup>iv</sup> Geisinger was considering inserting the DI into a patient address field but decided against it.

qualifier. Our pilot study, however, is restricted to implants. **Figure 2** is a flowchart describing the details of Steps 2 and 3.

**Figure 2 - Data flow of the DI from the Point of Use (POU) to the insurance claim**



## Discussion

Transmitting the DI from the EHR to the claim form and then to the payer appears to be straightforward, enabled by the requirements for a UDI field for certification of the EHR by ONC and the use of the existing format-free note field of the 837 claim form. Issues that remain to be addressed include quality control of the data at each stage of the process and the retrieval of the DI from BCBSMA for analysis.

Creating a reference database of several hundred DIs to enable the scanned DI to be matched to a DI stored in the database required a modest amount of time and effort because the data had to be manually entered into the Supply Record of Epic. This work was done with the hospital-based Cath lab staff and the Partners eCare staff with technical support from Epic. Maintenance of the database is also performed by hospital staff and Partners eCare staff. Meanwhile, Cath Lab staff already acknowledge that the barcode scanning of supplies and devices has reduced the effort associated with recording of the data. In subsequent conversations with the OR staff, who have yet to implement the pilot, we learned that before the use of the current EHR system, the nurses would remove the sticker from the implant package and place it in the paper record. With the advent of the new EHR, they have been manually entering data into the record. Thus, they are looking forward to the use of scanners to automate their workflow.

The extension rule, created to pull the DI from the procedures into the claim form, required a modest amount of custom programming by the Partners Epic staff working with technical support from Epic. Transmitting the DI to BCBSMA will require that BCBSMA be prepared to accept and store that data, but it is facilitated by using the established note field in the 837 form.

The preferred method for incorporating the UDI into the EHR would be to include it in materials management inventory data, e.g., PeopleSoft. Since manufacturers are required to put a UDI on their devices and submit data to GUDID, that data, along with the other essential information about a device, could be downloaded into the materials management system and then routinely uploaded into the EHR. This would eliminate the labor-intensive (and error prone) step of manually entering the DI into the Supply Record.

As described above, X12 is proposing a change to the 837 form to include the DI. Only a minor change to our current solutions for transmitting the DI to the claim would be required if the X12 proposal were implemented. Similarly, the Chargemaster would not be affected since the data would be at the patient-level, not the line-level.

Initially we explored including the full UDI, i.e., DI and PI, in the insurance claim. Our rationale was that if a product were recalled, the lot number would be as important as the device identifier. Given that the X12 only recommended creating a field for the DI, we did not pursue this option. Moreover, after examining the FDA's archives for recalls (<https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm>) we noted that most recalls are for all affected devices or for a broad range of production dates. If the DI is more broadly available to payers in the future, some thought should be given to who will be responsible for contacting affected patients should a recall be required: the manufacturer, healthcare system, implanting physician, payer, or all working in together.

## Conclusion

Medical devices contribute in important ways toward improving health outcomes and saving lives. Yet occasionally they fail, and there is a general lack of comparative information on their effectiveness. The FDA has mandated the use of UDIs by device manufacturers, but to take advantage of their substantial benefits, including the ability to perform surveillance and assure patient safety, most experts believe UDIs must be incorporated into insurance claims. The purpose of the UDI2Claims project is to demonstrate the feasibility of doing that. This paper is a report on the planning stage of this project.

We are confident that the processes we have described above for capturing the DIs of implanted devices into the patient's EHR, and ultimately transmitting them to the insurance

claim and ultimately to the payer, will work. Our confidence stems from the following: (1) the existing method for capturing UDIs of implanted devices data into the patient's Implant Record after the device is implanted; (2) the established method for including data in the header portion of the universal claim form and transmitting it to the payer; and (3) the straightforward custom process designed to read the DI in the Implant Record and place it on the claim form. Whereas the process we intend to use takes advantage of the fact that Partners HealthCare and BCBSMA do not currently use the note field of the claim form, it is unlikely that this is the situation between other institutions. By opening up a field reserved for DIs, the X12 proposal creates a new universal link between providers and payers. For the two institutions involved in our project, it would be straightforward to accommodate the proposed change. Therefore, based on our experience to-date, if the proposal of the X12 is adopted, it should be relatively easy for all providers to transmit DIs to payers. As a result, it would become possible for all stakeholders to derive the benefits of having DIs in claims. Patients would be assured of receiving high-quality implants and timely alerts in case of recalls. Clinicians could learn about the most appropriate devices for their patients. Manufacturers would receive more complete data on their devices, enabling them to design appropriate improvements. Payers would have more complete information regarding devices delivering the best outcomes. And, researchers would have better data on which to base policy recommendations.

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All statements in this report, including its findings and conclusions, are solely those of the authors and do not necessarily represent the views of the stakeholder panel, The Pew Charitable Trusts, the Patient-Centered Outcomes Research Institute (PCORI), or its Board of Governors or Methodology Committee.

## References

1. Downing NS, Shah ND, Aminawung JA, et al. Postmarket safety events among novel therapeutics approved by the US Food and Drug Administration between 2001 and 2010.
2. U.S. Food and Drug Administration. FDA's sentinel initiative. <http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm>. Accessed December 12, 2015.
3. U.S. Food and Drug Administration. Welcome to mini-sentinel. <http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm>. Accessed December 12, 2015.
4. U.S. Food and Drug Administration. National medical device postmarket surveillance plan. <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm>. Accessed January 2, 2016.
5. U.S. Food and Drug Administration. Food and drug administration safety innovation act (FDASIA). <http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentsToTheFDCAAct/FDASIA/ucm20027187.htm>. Accessed January 2, 2016.
6. Food and Drug Administration. Unique device identification system [Final Rule Sept 24]. *Fed Regist.* 2013;78(185):58786-58828.
7. U.S. Food and Drug Administration. Compliance dates for UDI requirements. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/CompliancedatesforUDIREquirements/default.htm>. Accessed November 10, 2015.
8. U.S. Food and Drug Administration. Global unique device identification database (GUDID). [www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf). Accessed December 21, 2015.
9. Food and Drug Administration. Strengthening our national system for medical device postmarket surveillance. Silver Spring, MD: Center For Devices And Radiological Health. 2013. <https://www.fda.gov/downloads/medicaldevices/safety/cdrhpostmarketsurveillance/ucm348845.pdf>; Accessed April 12, 1953.
10. Office of the National Coordinator for Health Information Technology. ONC health IT certification program: Enhanced oversight and accountability [Final Rule; Oct 19]. *Fed Regist.* 2016;81(202):72404-72471.
11. Office of the National Coordinator for Health Information Technology. 2015 edition health information technology (health IT) certification criteria, 2015 edition base electronic health record (EHR) definition, and ONC health IT certification program modifications [Final Rule; October 16]. *Fed Regist.* 2015;80(200):62602-62759.
12. Centers for Medicare & Medicaid Services. Medicare and Medicaid programs; electronic health record incentive program-stage 3 and modifications to meaningful use in 2015 through 2017 [Final Rule, Oct 16]. 2015;80:62761-62955.
13. Slavitt A. Transcript of hearing before the House Ways and Means Committee. <https://waysandmeans.house.gov/event/hearing-on-the-implementation-of-the-medicare-access-chip-reauthorization-act-of-2015-macra/>. Accessed November 15, 2016.
14. Grassley CE. Grassley, Warren Seek Update on Unique Device Identifier for Medical Devices in Medicare. <https://www.grassley.senate.gov/news/news-releases/grassley->

- [warren-seek-update-unique-device-identifier-medical-devices-medicare](#). Accessed April 10, 2017.
15. Levinson DR. Letter to Andrew Slavitt re: Including UDIs in claim forms. <http://www.meddeviceonline.com/doc/hhs-inspector-general-urges-cms-to-include-udis-in-revised-claim-forms-0001>. Accessed November/15, 2016.
  16. Tcheng JE, Crowley J, Tomes M, et al. Unique device identifiers for coronary stent postmarket surveillance and research: A report from the Food and Drug Administration Medical Device Epidemiology Network Unique Device Identifier Demonstration. *Am Heart J*. 2014;168(4):405-413. e2.
  17. Drozda JP, Dudley C, Helmering P, Roach J, Hutchison L. The Mercy Unique Device Identifier Demonstration Project: Implementing Point of Use Product Identification in the Cardiac Catheterization Laboratories of a Regional Health System. 2015.
  18. Resnic FS, Normand ST. Postmarketing surveillance of medical devices—filling in the gaps. *N Engl J Med*. 2012;366(10):875-877.
  19. Zeitler EP, Al-Khatib SM, Drozda JP, et al. Predictable and Sustainable Implementation of National Cardiovascular Registries (PASSION) Infrastructure: A Think Tank Report from the Medical Device Epidemiological Network Initiative (MDEpiNet). *Am Heart J*. 2016;171(1):64-72. e2.
  20. Reed TL, Drozda JP, Baskin KM, Tcheng J, Conway K, Wilson N, Marinac-Dabic D, Heise T, Krucoff MW. Advancing medical device innovation through collaboration and coordination of structured data capture pilots: Report from the Medical Device Epidemiology Network (MDEpiNet) Specific, Measurable, Achievable, Results-Oriented, Time Bound (SMART) Think Tank. 2016.
  21. Food and Drug Administration. UDI formats by FDA-Accredited Issuing Agency, v. 1.3 [January 27]. 2017. <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/UDIIssuingAgencies/UCM489869.pdf>. Accessed April 1 2017.