UDI2Claims: Planning a Pilot Project to Transmit Identifiers for Implanted Devices to the Insurance Claim

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Background: In response to problems with the current postmarket surveillance of medical devices, the U.S. Food and Drug Administration mandated device labelers to include a unique device identifier (UDI), composed of a device identifier (DI) and production identifier. Including the DI in insurance claims could be a potent method to monitor implanted devices, yet implementation has lagged because of questions of benefit and operational concerns.

Methods: To illustrate the potential benefit of including DIs in claims, rates of 90-day adverse events after implantation using an electronic health record (EHR) were compared with the EHR plus claims, which capture utilization outside that EHR's health system. To explore operations, we planned a pilot project to transmit the DI of implanted devices from the point of care to the claim at two provider/payer pairs.

Results: By querying claims plus EHR, estimated rates of patients with potential adverse events were as much as 3.75 times higher. For our pilot, our multistakeholder team identified and resolved the following five challenges: (1) capturing the DI at the point of care; (2) selecting a location for the DI on the claim form; (3) transmitting the DI to the claim form; (4) analyzing the claim forms received by the payer; and (5) verifying the quality of the transmitted information.

Conclusions: Including DIs on claims could allow more complete data capture of adverse events for implanted devices than the EHR data. We overcame challenges in transmitting the DI to the claim with attention to planning and multistakeholder involvement.

Key Words: unique device identifier, electronic health record, insurance claim, medical devices, postmarket surveillance, implanted medical device

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Implantable medical devices contribute in important ways toward improving health outcomes and saving lives, yet recent medical device failures have raised concerns regarding limitations in monitoring the performance of devices after implantation.[1–5] The lack of a systematic postmarket system inhibits the ability to use existing digital information collected during health care delivery to generate evidence of device safety and for research.[6,7] Systems using real-world evidence on safety and effectiveness, such the U. S. Food and Drug Administration's (FDA) Sentinel Initiative for drugs, could lead to improved understanding of how medical treatments work and better judgments of their value.[8]

Amid calls to create a similar system for postmarket devices within a learning health care system,[9,10] Congress passed the FDA Amendments Act of 2007 that required manufacturers to create unique device identifiers (UDIs) to facilitate the tracking of devices throughout their distribution and use.[11] In parallel, the Office of the National Coordinator for Health Information Technology required electronic health record (EHR) systems to include documentation of UDIs in a patient's record as a requirement for certification.[12] Deadlines for manufacturers to implement UDIs in the form of machine- and human-readable formats were set by the FDA beginning in September 2014.[13] The UDI is composed of a device identifier (DI) that identifies the manufacturer and the model, whereas the production identifier (PI) provides information such as the expiration date, the batch, or lot number or serial number. The FDA, in collaboration with the National Library of Medicine, also established a publicly accessible database, the Global Unique Device Identifier Database, to serve as a searchable

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reference catalog containing the DI and key safety, regulatory, and supply chain data for every FDA-regulated device.[14,15]

There has been considerable debate regarding how best to use and accelerate adoption of UDIs to accomplish national goals.[10,16] The UDI Demonstration Project demonstrated the feasibility of capturing UDI at the point of care (POC), combining UDI-associated data with relevant clinical data and registry data.[17] The Building UDI Into Longitudinal Data or BUILD initiative is expanding this capability to two other hospital systems and creating a distributed data network.[18,19] Information stored in EHRs and clinical registries, however, are typically accessible only to the healthcare systems where the original procedure was performed. Insurance claims, on the other hand, conform to a more standardized format, can be used to track utilization longitudinally and geographically when patients seek care from multiple providers, and, because of their size, may detect problems that might be missed by small trials or passive reporting systems.[20] Unlike drug codes, however, codes that identify specific devices do not appear on insurance claims because most insurers, including Medicare, pay for devices indirectly when reimbursing for a service or procedure.

The FDA's 2018 Medical Device Safety Action Plan indicates establishment of the UDI system as a key enhancement of a medical device safety system, highlighting UDI as a standard to document device use in health information systems.[21] The adoption of UDIs into claims has been resisted by stakeholders either unaware of their value or unsure of the feasibility of their implementation. In 2015, the leadership of Centers for Medicare and Medicaid Services opposed UDIs on claims, citing "significant technological challenges, costs and risks,"[22] but then showed support in 2016, although it has not yet taken an official stance. In a 2017 letter to the Centers for Medicare and Medicaid Services Administrator Seema Verma, the American Medical Association voiced "significant concerns" around cost and complexity and questioned the value of information on devices in insurance claims. Lacking from these debates has been tangible evidence from real-world experience transmitting UDIs to claims.

We initiated the UDI2Claims project, funded by The Patient-Centered Outcomes Research Institute or PCORI, with two objectives: (1) to inform the evidence gap between using EHR-only data versus insurance claims for postmarket surveillance and (2) to demonstrate the feasibility of transmitting device information from the POC via commercial insurance claims to a payer. The first part of this article therefore presents the approach and results of a retrospective claims analysis. In the second part of the article, we present findings from the planning phases for a pilot demonstration project. Our early experience may provide valuable information for other health systems seeking to initiate similar processes to track UDIs from POC to payer. This research is especially timely because the Accredited Standards Committee X12, the standards organization responsible for the content and structure of electronic insurance claims transactions, is currently considering proposed changes to the claim forms that would include fields for the DI.[23,24]

The Added Value of Claims Over EHRs for Postmarket Device Surveillance

To evaluate the potential benefit of including the DI in the insurance claim, we searched for adverse events (e.g., hospitalizations, reoperations) after device implantation for two common procedures using EHR data only and then EHR plus claims data. Because claims capture utilization at locations external to the one where the device was initially received, we hypothesized that claims would reveal potential adverse events not recorded in the single EHR. Although DIs are not available in claims currently, our goal was to quantify the impact that these events from external providers might have on estimates of adverse event rates once DIs are available. We identified patients who had received a cardiac stent or total hip arthroplasty (THA) from 2004 to 2017 at a Geisinger Health (GH) facility and who had insurance coverage from GH Plan (GHP). Using EHR data, we calculated 90-day rates of all-cause readmissions, emergency department (ED) visits, and prespecified postimplantation diagnoses and procedures (stents: acute myocardial infarction, revascularization procedure, renal failure, bleeding, stroke; THA: removal/revision of joint, infection of joint prosthesis). We then searched for the same events, combining both EHR data plus insurance claims data, because the latter would include care received from external providers (i.e., not using the same EHR).

There were 4924 patients with stent procedures and 2235 patients with THA procedures from 2004 to 2017. For all but one event type examined, using claims captured *additional* events from external providers (Tables 1, 2). For example, the number of stent patients with a new stroke diagnosis within 90 days increased from 4 to 19, representing a percentage increase from 0.1% to 0.4%, a 0.3% absolute risk increase, and 375% relative risk increase. Likewise, the number of stent patients admitted to an ED increased from 949 using EHR data to 1298 according to EHR plus claims, meaning that 349 (27%) of ED visits would have been missed in an analysis of EHR data alone. For THA patients, the number of THA patients with a 90-day rehospitalization increased from 262 to 450, representing 188 missed events, and a percentage increase from 12% to 20% (8% absolute increase; 72% relative risk increase).

Planning the UDI2Claims Pilot

Sites Involved and Identification of Key Challenges

The second objective of our project was to design a process and develop necessary software to capture UDIs associated with implanted devices at the POC and to transmit their DI elements to the payer via a claim. For greater generalizability, we initiated the pilot in two separate provider/payer pairs. One pair was the Brigham and Women's Hospital (BWH), a member of Partners HealthCare (Partners), and Blue Cross and Blue Shield of Massachusetts (BCBSMA); the other pair was GH and GHP. The BWH is a large quaternary referral center in Boston and BCBSMA is a not-for-profit insurance provider. Geisinger Health is a regional healthcare system in Pennsylvania and GHP is a managed care organization with commercial, Medicare, and Medicaid segments. For POCs, we selected the cardiac catheterization laboratory ("cath lab") and vascular operating rooms (vascular ORs) at BWH, and the cath lab at the GH.

For an organization to successfully transmit UDIs to a payer, we identified the following five problems that needed to be resolved:

1. Capture the UDI at the POC.
2. Select a location on the claim form for the DIs of implanted devices.
3. Develop a method for transmitting the DIs captured at the POC to the selected location on the claim form.
4. Develop a method for analyzing claim forms received by the payer to select patients who received implants and for recording the DIs of the implanted device or devices.
5. Develop a method for verifying the quality of the information transmitted.

In our pilot, the provider organizations were responsible for solutions to problems 1 and 3, the payer organization was responsible for

TABLE 1. Side-by-Side Comparison of 90-Day Event Rates for Cardiac Stent Patients, as Estimated From EHR Data Only Versus EHR Data and Claims Data Combined

	Cardiac Stents (N = 4924)			
90-d Events	EHR Only	EHR + Claims	Absolute % Change	Relative % Change
All-cause readmissions	658 (13%)	838 (17%)	**+4%**	**27%**
All-cause ED visits	949 (19%)	1298 (26%)	**+7%**	**37%**
New diagnoses or procedures				
Acute myocardial infarction	150 (3%)	211 (4%)	**+1%**	**41%**
Revascularization procedure	109 (2.2%)	149 (3.0%)	**+0.8%**	**37%**
Renal failure	170 (3%)	235 (5%)	**+2%**	**38%**
Bleeding	38 (0.8%)	59 (1.2%)	**+0.4%**	**55%**
Stroke	4 (0.1%)	19 (0.4%)	**+0.3%**	**375%**

a solution to problem 4, and the provider and payer organizations needed to jointly resolve problems 2 and 5.

Formation of Cross-Departmental Implementation Teams

We formed cross-departmental teams of subject matter experts at each institution. At BWH, UDIs are currently not used by materials management or supply chain in day-to-day operations, but because materials management might ultimately be the source of UDIs for devices, their representation was essential for the team. A technician from the cath lab and application coordinator for the cath lab EHR module were included because cath lab technicians were already scanning UDI barcodes. Because UDIs were not being scanned in the vascular ORs, we recruited the person familiar with their EHR module. Also included were a business analyst familiar with all aspects of the billing process, including details of the universal claim form, and BCBSMA experts in information systems and Electronic Data Interchange. The team was led by the research staff.

At the GH, barcode scanning of products at the POC was already in place in all non-OR procedural areas before this pilot. Electronic transmission of charge information from a point-of-use materials management software system, QSight, (QSight; Owens & Minor, Mechanicsville, VA) to the billing software system was already implemented in the cath lab of the hospital where the pilot was performed. The implementation team was led by the study site's principal investigator and the Director of Supply Chain Technology and Process Engineering; it also included two representatives from the materials management software vendor who specialized in information technology integrations, several systems analysts from the revenue management (i.e., billing) department, and an information technology analyst from the health plan, with support from the health plan's senior medical director.

Solution to Problem 1: Capture the UDI at the POC

At the BWH, planning was slightly different in the two clinical POCs. In the cath lab, after implantation of a device, a technician scans the UDI barcode on the package for the device. If the scan is successful, the following elements of the UDI are entered into the implant record of Cupid, the cardiovascular EHR module of Epic (Epic Systems, Madison, WI): DI, lot or batch number, and expiration date. For a scan to be deemed valid, the scanned UDI must be matched against a reference database of DIs of all implantable devices currently used in the cath lab. Device identifiers in the reference database are entered and updated manually in the supply record of Epic by the Cupid application coordinator, because DIs are currently not transmitted automatically from the BWH Materials Management software, PeopleSoft (Oracle Corporation, Redwood City, CA), to Epic. If the DI for the implanted device has not been entered into the supply record before scanning at the POC, the technician must follow backup processes to enter the DI.

The BWH vascular OR EHR module of Epic, OpTime, possesses the same implant record and UDI barcode scanning capability as Cupid. Consequently, aside from training of nurses, implementing the scanning process in the vascular ORs would only require the manual entry of vascular surgery implantable DIs into the Epic supply record, so the DIs would be recognized when scanned at the POC.

At the GH, QSight manages the item master and matching of the barcode with the required information about the product. Products are scanned into inventory when received and scanned again when opened during a procedure, thereby creating a link between

TABLE 2. Side-by-Side Comparison of 90-Day Event Rates for THA Patients, as Estimated From EHR Data Only Versus EHR Data and Claims Data Combined

	Total Hip Arthroplasty (N = 2235)			
90-d Events	EHR Only	EHR + Claims	Absolute % Change	Relative % Change
All-cause readmissions	262 (12%)	450 (20%)	**+8%**	**72%**
All-cause ED visits	363 (16%)	456 (20%)	**+4%**	**26%**
New diagnoses or procedures				
Removal/revision of joint	36 (1.2%)	41 (1.8%)	**+0.6%**	**14%**
Infection of joint prosthesis	0 (0%)	0 (0%)	**0%**	**0%**

the patient and device at the POC. The software retains the same information about the product as described previously for BWH (e.g., manufacturer, model), including the DI.

Solution to Problem 2: Select a Location on the Claim Form for the DIs of Implanted Devices

The note (NTE) field of the 837 claim form header was selected as the most appropriate location for adding DIs after discussions with the billing departments and payers. The header applies to the entire claim and includes data about patient demographics and the medical provider, but no data regarding charges. The selected location, formally known as Loop 2300 NTE segment, is not used in current transactions between Partners and BCBSMA. It can hold up to 80 characters and may be repeated up to 10 times. Because the NTE field is format free and may be used for purposes other than storing the DI, Partners decided to precede the DIs in the note field with a data qualifier, also known as a note reference code or "UPI" (Updated Information), to indicate that the data that follow are DIs. Geisinger Health was already using part of the NTE segment for additional information on some patients, and GHP stipulated that they did not accept repeats of the segment; as a result, there was only enough remaining space in the segment to transmit two DIs per patient case.

We note that the current ASC X12 proposal to change the standard 837 transaction would reserve up to eight fields for DIs and be at the claim level (i.e., header) for institutional transactions and line level for professional transactions. The proposal would also require the provider to indicate whether the device is an implant or explant using a binary qualifier. Our project was restricted to implants.

Solution to Problem 3: Develop a Method for Transmitting the DIs Captured at the POC to the Selected Location on the Claim Form

At the BWH, no method existed for retrieving a DI from the implant record and sending it to Resolute, the billing module of Epic. A brute-force method, based on inspecting every patient's record during the daily claim-generation process, was judged as impractically burdensome, so a more finely targeted process was required. Because the claim-generation process always

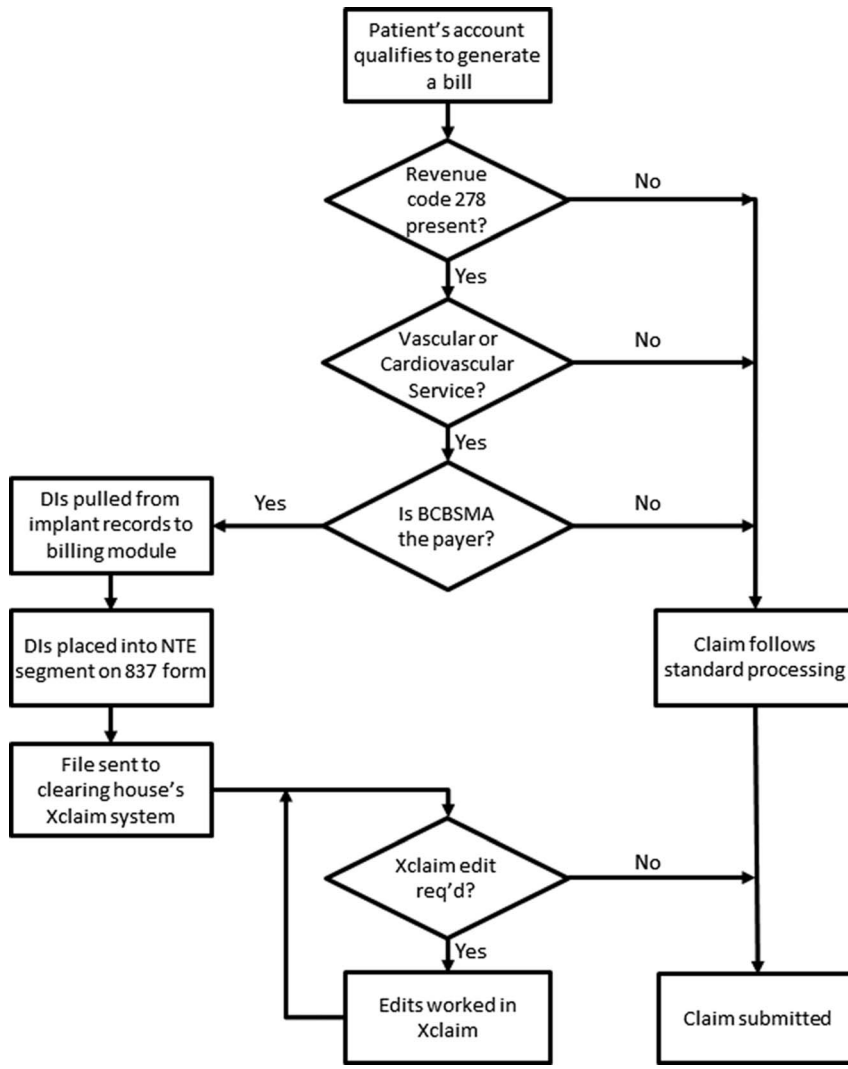

FIGURE 1. Flow diagram the illustrates how the "Extension Rule" software program at BWH pulled the DI from the patient's clinical chart and transmitted it into the NTE segment of the insurance claim form.

reads revenue codes on patients' records, the solution was to create a software subprogram, known as an Extension Rule, that would be implemented within Epic to identify records with the 278 revenue code for implant surgeries in the cardiovascular and vascular services, with BCBSMA as the primary insurer (Fig. 1). It is important to note that this process of conveying the DI to the 837 claim form would flow independently of other data, notably charges calculated from the chargemaster.

At the GH, QSight was already generating batch files (called 28 records) with charge information about products used. These files are automatically downloaded from a remote server to the GH and then uploaded to the billing system (Siemens). For this project, a new specification was created for an additional batch file of similar format that would contain DIs instead of charges for each outpatient case performed in the cath lab. A programmer from QSight created an automated process for generating and uploading files, and GH's revenue analysts created automated processes for downloading the files and integrating them with other 28 records before transmitting the information to the system that prepares claims (ePremis; RelayHealth, Atlanta, GA). If the claim is for an outpatient procedure performed at the participating hospital's cath lab, and the payer is GHP, the claims preparation software automatically adds the DIs to the NTE segment of the 837 claim transaction form. Another programming change ensured that the DIs do not overwrite other information in the NTE segment or fail to be added if other preceding information in the NTE is missing. Because of space limitations on the NTE segment, only two DIs can be added to each claim. Accordingly, it was decided that the process can prioritize the two most expensive products used in the case (assuming that implants would be more expensive than other supplies).

Solution to Problem 4: Develop a Method for Analyzing Claim Forms Received by the Payer to Select Patients Who Received Implants and for Recording the DIs of the Implanted Device or Devices

At the BCBSMA, the solution to this problem hinged on modifying the claim intake process into its Enterprise Data Warehouse. As claims are received, their contents could be extracted into designated locations in the Enterprise Data Warehouse (EDW) while not interfering with the overall claim adjudication process. To accommodate the possibility of up to 10 DIs in the NTE segment, a custom table (DI Table) keyed to patients receiving implants, would be added to the EDW and made accessible to the BCBSMA analytic team. When implants are present on a claim in the agreed upon NTE segment, their unique patient identifier, DIs, date of birth, and date of service/discharge could be extracted to this table. Reports on patients who have received implants would be compiled by linking the contents of the DI Table to the Enrollment Table, which includes the patients' names and sex, to confirm BCBSMA membership.

At the GH, developing new analysis tools for internal use within the health plan was considered out of scope of the present work. The health plan does, however, intend to map this new DI information into secondary databases that it uses for quick analytics, dashboards, quality metrics, and other internal purposes. Thus, the DIs will be stored and easily accessed in the event of a device recall, investigation of a particular outcome, or other use cases. This secondary work is ongoing.

Solution to Problem 5: Developing Methods for Testing the Results

At the request of our funder, we plan to test data quality (completeness and accuracy) at the BWH by examining whether the DIs and their values recorded at the POCs match the number and values of DIs received by the BCBSMA EDW. The first step in the testing process is to determine whether the number of DIs for a given patient is the same in the two reports. Should the number of DIs on the claim form not match the number appearing in the cath lab or vascular OR reports, we plan to examine the patient's implant records for irregularities. Finally, we would consider the possibility of a bug in the Extension Rule code. If the number of DIs in the two reports is the same but the values differ, we will institute a step-by-step analysis of the flow of data from the implant record to the report creation by BCBSMA.

At the GH, materials management will generate monthly files listing every product scanned in the participating hospital's cath

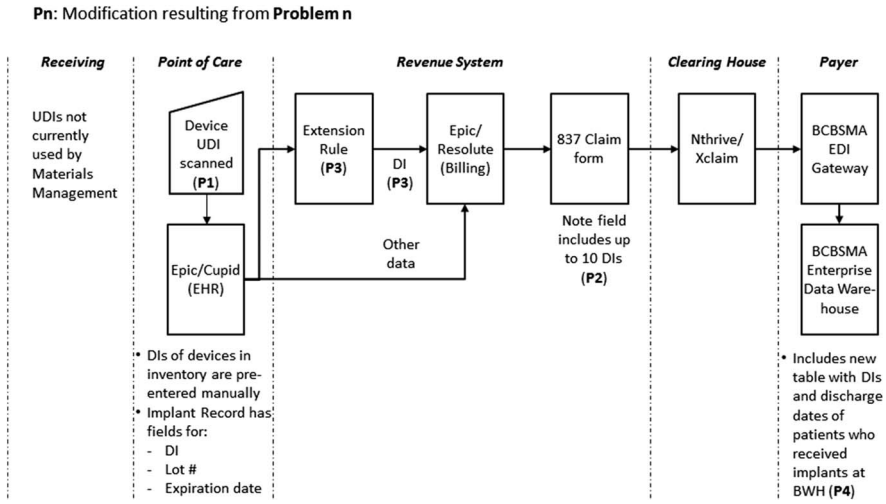

FIGURE 2. Diagram of flow of DI data in the first provider/payer pair, BWH, and BCBSMA. "Pn" identifies the modifications made to address key problems, "Problem n." Problems: 1. Capture the UDI at the POC; 2. Select a location for the DI on the claim form; 3. Develop a method to transmit the DI to the claim form; 4. Develop a method to analyze claim forms.

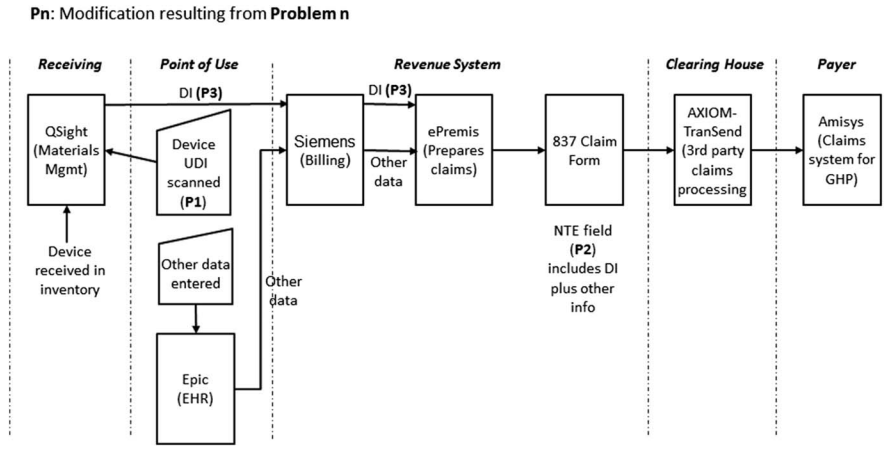

FIGURE 3. Diagram of flow of DI data in the second provider/payer pair, GH and GHP. "Pn" identifies the modifications made to address key problems, "Problem n." Problems: 1. Capture the UDI at the POC; 2. Select a location for the DI on the claim form; 3. Develop a method to transmit the DI to the claim form.

lab. Using this file, the patient identifiers and billing numbers are sent to the health plan to verify whether the DIs have appeared on their finished, adjudicated claims.

Summary: End-to-End Target Processes in Two Health Care Systems

The solutions to the five problems at BWH and GH are illustrated in Figs. 2, 3, respectively. They depict the processes for transmitting DIs from the POC to claims. Their differences highlight the ability of different organizations to take different approaches to achieve the same ends.

DISCUSSION

In this article, we describe the analytic and planning phases of the UDI2Claims project, in the hopes that our experience may inform the ongoing debate over whether UDIs should be included in claims. We found evidence to support the advantage of using insurance claims over just EHRs or single institution registries to track the safety and effectiveness of implantable devices. In planning our pilot, we discovered solutions to problems that may be of use to other healthcare systems seeking to move the DI from the POC to an insurer in real-world terms.

Despite advances in the use of EHRs and registries, our results showed that in the setting of one health system, it is likely that many postprocedural events were not captured within the system where the device was implanted. Given that system (Geisinger) is located in a mostly rural area of Pennsylvania where there are fewer competing hospitals and health systems than in suburban or urban settings, these results suggest that the large number of missed events we observed may be even larger in those other settings. Although we did not verify that any events were directly related to device complications, the increased numbers of events appearing will likely give a more complete, robust picture to inform patients and clinicians about device performance than relying on EHR records only. Postmarket surveillance of devices is important because many devices have been approved via the 510(k) pathway, without clinical trials, because they demonstrate substantial equivalence to an approved device, whereas newer devices avoid testing if they are determined to only have a minor change compared with an approved device. However, many of the postprocedural adverse events occur outside of the organization of the provider who implanted the device or after significant time has elapsed. Thus, we believe that the value of using insurance claims over just EHRs and registry data is now strongly suggested.

The success of our pilot planning phase demonstrates the possibility that transmitting the DI from the POC to the claim form and then to the payer is feasible and straightforward. As noted earlier, the X12 Committee has recently proposed to modify the 837 claim form by adding the capability for transmitting DIs from provider to payer by providing for a location capable of storing up to eight DIs in Loop 2300.[23,24] Because it closely resembles our solutions to problem 3, we believe that only a minor change to the methods we have described would be required if the proposal were implemented.

Still, there are ongoing issues. We explored including the full UDI, DI, and PI, in the claim. We reasoned that if a product were recalled, the lot number would be as important as the DI. In light of the decision of the X12 to recommend creating a field only for the DIs for high-risk implantable devices, we did not pursue this option. Defining the list of "high-risk implantable devices" is important. Moreover, after examining the FDA's archives for recalls, we noted that most recalls are for all affected devices or for a broad range of production dates.[25] If the DI is more broadly available to payers in the future, some thought should be given to who will be responsible for contacting patients during a recall: the manufacturer, healthcare system, physician, payer, or all working together? There have also been concerns about how to label devices with multiple parts.[26]

Our study has certain limitations that may limit its generalizability. Our claims analysis was performed at the GH, which is a unique payer/provider dyad in central Pennsylvania and so may have different patterns of out of state follow-up care than other providers. Our two health care systems may not be representative of other organizations; they are large integrated delivery systems with advanced information technology capabilities and had sufficient interest in the topic to host the UDI2Claims pilot. Notably, the EHR and/or supply chain software enhancements are largely one-time investments. Commercial software vendors may be able to incorporate these features in future releases and therefore make them available to all their customers, rapidly enabling a large number of hospitals and payers to support UDI to claims transmission.

The next step of the project is to implement the pilot fully and evaluate its implementation. We are confident that the processes

described previously will be successfully implemented. Our confidence stems from the following considerations: (1) barcode methods for capturing UDIs of implanted devices data after the device is implanted are already in place at the two hospitals; (2) a simple method has been selected for including DIs in the header portion of the 837 claim form; and (3) the software enhancements that will be required at providers and payers will require only a modest effort.

CONCLUSIONS

Millions of people have medical devices implanted, yet the ability of regulators, providers, manufacturers, and patients to assess their safety and effectiveness is limited by underdeveloped surveillance systems, especially when compared with those that have been developed for drugs. For insurance claim data to be useful in postmarket surveillance of implanted devices, they must contain specific information on implantable devices, such as the DI.

We identified five problems associated with the challenge of capturing UDIs of devices implanted at the POC and transmitting them via the commercial claim form to the payer. Although the solutions, developed at the two provider/payer pairs differ in detail, their relative simplicity suggests that their implementation is likely to be successful.

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