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Transmitting Device Identifiers of Implants From the Point of Care to Insurers: A Demonstration Project

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Background: For implanted devices, an effective postmarket surveillance system does not exist. For medications, the Food and Drug Administration's Sentinel Initiative plays that role, relying mainly on drug codes in insurance claims. Unique device identifiers (UDIs) could play an analogous role for implants, but there is no mandate for providers to include UDIs in claims or for payers to record them. Objections have been raised to incorporating UDIs into claims based on a potential burden on providers.

Methods: To assess this purported barrier, we modified information systems at 2 provider-payer dyads to allow for the transmission of UDI data from provider to payer. In addition, to illustrate the potential benefit of including device data in claims, we used our data to compare rates of 90-day adverse events after implantation using the electronic health record (EHR) alone with the EHR plus claims.

Results: The software system modifications were modest and performed as designed. Moreover, the level of difficulty of their development and implementation was comparable to that associated with a typical new release of an existing system. In addition, our data demonstrated the ability of claims-based data plus EHR data to reveal a larger percentage of postprocedure adverse events than data from EHRs alone.

Conclusions: Modifying information systems to allow for the transmission of UDI data from providers to payers should not impose a substantial burden on either. Implementation of a postmarket surveillance system based on such data in claims will require, however, the development of a system analogous to Sentinel.

Key Words: unique device identifier, UDI, implantable device, postmarket surveillance, 837 claim form, Sentinel, medical implant, NEST, patient safety, adverse events, real world evidence

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At present, there is no reliable, national system for determining whether patients with a particular medical implant are experiencing suspiciously high rates of implant-related adverse events. Reporting of adverse events associated with implants[a] is currently performed through a variety of voluntary and mandatory reporting mechanisms, all having substantial limitations.[1] A serious shortcoming is that they report events, not rates. The calculation of the latter requires a denominator, that is, the total number of the devices that have been implanted. For drugs, the situation

[a]We use "implant" and "implanted device" interchangeably.

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is different. The Food and Drug Administration (FDA)'s Sentinel Initiative was established[2,3] to monitor the safety and comparative effectiveness of drugs by leveraging national drug codes[4] recorded at the point of care (POC) or the point of sale and transmitted to payers via insurance claims. Sentinel data are mainly derived from claims, which conform to a standardized format and allow patients to be tracked as they move among providers. Although Sentinel's purview includes devices, the FDA recently took steps to establish the National Evaluation System for Health Technology (NEST).[5] Among NEST's proposed objectives is to build an infrastructure and generate evidence on the postmarket performance of implanted devices. In addition to discovery of adverse events, the data stored in insurers' information systems could provide real-world evidence for studies such as comparative effectiveness research, and would complement data stored in registries.[6]

Until recently, one major barrier to device surveillance was the lack of a standard identification system. In 2013, the FDA published a final rule requiring manufacturers to label medical devices with the unique device identifier (UDI).[7] A UDI is a 2-part code consisting of a device identifier (DI), which indicates the manufacturer and model, and a production identifier, which can include production information such as lot number and expiration date. To encourage providers to use UDIs, the Office of the National Coordinator for Health Information Technology has ruled that electronic health records (EHRs) must have the capability to record UDIs to receive certification, but there is no mandate for providers to use this capability.[8]

A second major barrier to implant surveillance is the absence of a designated device field on the current standard electronic 837 claim form. This barrier may be eliminated, however, as over the past several years, the X12,[9] the body responsible for the 837 form, has been developing its next version. The latest draft, released in July 2020, includes a proposal to accommodate only the DIs—up to 9 per claim—for high-risk implantable devices and to be used in exchanges by willing provider-payer partners.[10] Implementation of this version, assuming the changes are approved, is not expected until 2023 or later.

A third barrier to nationwide postmarket device surveillance, and the focus of this work, is the design of processes to complete the "last mile" of data transmission: from POC to insurer. As part of such a system, providers would need to record DIs at the POC and transmit them to health insurers[b] via the claim form. Important stakeholders have held different positions on including DIs in claims. The American Hospital Association conditioned its support on the inclusion of certain features of the new claim form,[11] and these conditions have been met in the proposed version. The Centers for Medicare & Medicaid Services, after initially giving it support,[12] seems to have later changed its position, and the current perspective has not been made clear.[13] The device trade association AdvaMed and the American Medical Association are opposed. They base their opposition in part on the belief that including DIs in claims would impose an unnecessary burden on providers. They support postmarket surveillance based on UDIs in EHRs or local registries.[14,15]

To assess the barriers and facilitators to putting DIs in claims, we posed 3 questions:

1) What process changes and information system enhancements would providers and insurers need to make to add DIs of implants to insurers' claims-processing systems?
2) How difficult would it be to make these process changes compared with typical information system enhancements?
3) What benefits accrue from including DIs in claims compared with tracking devices through EHRs or EHR-based device registries?

To answer the first question, we conducted demonstrations at 2 hospital-payer dyads—Brigham and Women's Hospital (BWH), a member of Mass General Brigham, formerly known as Partners HealthCare, with Blue Cross and Blue Shield of Massachusetts (BCBSMA), and Geisinger Health (GH) with Geisinger Health Plan (GHP). To answer the second question, we interviewed those responsible for introducing the new processes, for modifying the software systems, and for the daily use of the new processes and systems. To answer the third question, we examined the rate of adverse events identified in EHRs plus claims compared with locally generated data from EHRs.

INFORMATION SYSTEM MODIFICATIONS

Method

The planning and design of process changes and modifications of software systems required to transmit DIs, recorded at the POC, to payers' systems took place from October 2016 to September 2017. We described the modifications in a previous publication.[16] Our project focused on 2 essential capabilities: (1) transmission of the DIs, recorded at the POC, to the billing systems that populate the claim form, and (2) enhancement of payers' information systems to accept the DIs and to make data available for subsequent analysis. At BWH, the project included the catheterization laboratory (cath lab), the electrophysiology laboratory (EP lab), and vascular operating rooms (OR), whereas at Geisinger, we restricted the project to the cath lab. Scanning was already in place in the cath lab and EP lab at BWH and the cath lab at GH. In addition, we arranged for the training of the nurses in the vascular ORs at BWH in scanning UDIs of implants.

For transmitting DIs from providers to payers, we selected—in the absence of a designated field for DIs in the current 837 institutional claim form[17]—the notes segment of the form.[c] Because that field was not used to support any claims-adjudication transactions between BWH and BCBSMA, the notes segment could accommodate up to 10 DIs. However, because GH and GHP were already using the notes segment for some transactions, only 2 DIs could be accommodated. In view of this constraint, we decided to transmit the 2 most expensive items scanned per case at GH, recognizing that some of these might not be implants.

Appendix A contains data-flow diagrams and descriptions of the information systems whose modifications were described in our previous publication.[16] The most obvious difference between the data flows in the 2 dyads is that different vendors are used for the main categories of information systems (e.g., inventory management, and billing and claims processing). The most significant process difference is that UDIs scanned at GH were stored in the inventory management system, whereas UDIs scanned at BWH were stored in the implant record of the EHR.

At BWH, the billing module was modified to retrieve the DIs from the EHR and include them on the claim. At GH, modifications to the inventory management system enabled it to select the DIs of the 2 most expensive items and transmit them to the billing system. In addition, minor modifications were made to the billing system to append this information to the notes segment of the claim. The level of effort required at BWH and GH was sufficiently low that formal requests for resources were deemed unnecessary.

To accommodate the DIs transmitted by BWH, BCBSMA made complementary modifications to one of its systems to identify patients whose claim forms contained DIs, and added a data table for these patients to its data warehouse. Because GH and GHP were

[b] We use "insurer," "health insurer," and "payer" interchangeably.

[c] Formally known as NTE segment, Loop 2300

already exchanging data in the notes segment, GHP did not have to modify its systems to accept DIs.

Results

Our primary performance objective was to successfully transmit the DIs of devices scanned at the POC to the payers. For the BWH/BCBSMA dyad, this meant that up to 10 DIs, scanned at the POC, would be recorded by BCBSMA. At GH/GHP, we wished to demonstrate that the DIs of the 2 most expensive items scanned at the POC—or the most expensive item, if there was only one—would be recorded by GHP.

Over the assessment interval for BWH/BCBSMA, which extended from November 1, 2017, to May 31, 2019, DIs for 347 patients covered by BCBSMA were correctly transmitted and received. We found that all DIs recorded in the cath lab were correctly received by BCBSMA, but because of an error in the programming logic, DIs for pacemakers and implantable cardioverter defibrillators from the EP lab were not. We also found that DIs of devices implanted in the vascular ORs were not being properly recorded; consequently, their DIs were not reaching BCBSMA. After careful assessment, we concluded these issues would be resolved in an institution-driven—as opposed to a research-driven—implementation of UDIs at BWH.

At GH/GHP, the assessment interval was January 1, 2018, to April 24, 2019. During this interval, 760 claims were generated, transmitting 1033 DIs. We found that 77% of these 1033 DIs corresponded to the 2 most expensive items per case, with catheter introducers (nonimplanted) being the most frequent, followed by drug-eluting stents. The remaining 23% of DIs were valid identifiers of products used that had incorrectly superseded more expensive ones. Investigation of these discrepancies led us to conclude that such errors would be eliminated if the claim form could have accommodated more than 2 items, if logic to select device were improved, and if UDI labeling were universal and more consistent. (Some products were drawn from stock that predated UDI introduction or used a different barcode standard).

ASSESSMENT OF DIFFICULTY OF PROCESS AND INFORMATION SYSTEM MODIFICATIONS

Method

We conducted 20 semistructured interviews with participants at the completion of our planning and development and a second set of 20 interviews 10 months after the start of implementation. Two members of the project team conducted the interviews, following an interview guide developed by the study team.

For the interviews conducted at the completion of the planning and development phase, the interviewees at BWH included staff members familiar with the affected information systems, application developers, and those responsible for generating reports on the activities of the cath lab. In addition, we interviewed a senior technician in the cath lab. At BCBSMA, our interviewees included a member of the strategy and planning organization, an expert in electronic data interchange, and a claims domain architect. At GH and GHP, we interviewed members of the inventory systems development organization, billing systems specialists, and a claims information systems specialist.

Ten months after the start of the implementation phase, we interviewed 2 categories of staff members at BWH and BCBSMA. The first category consisted of those responsible for troubleshooting the software modifications, including designers and developers of the information systems modifications, those who generated the regular reports on the patients and the implants they had received, and some of their managers. The second category consisted of technicians in the cath lab and nurses in the vascular ORs.

Our interviews addressed the following topics:

- the degree of difficulty of the task assigned to the interviewee for our project relative to similar projects recently completed, measured on a scale of 1 to 5;
- facilitators and barriers—people or processes that helped or hindered the interviewee in performing the task; and
- the interviewee's perception of the degree of difficulty of implementing similar processes nationally.

The interviews lasted approximately 1 hour and were recorded after securing the interviewee's consent. The interviews and the recording of interviews were approved by institutional review boards at BWH and GH. The research team conducting interviews also took detailed notes and referred back to the audio recordings to ensure accuracy. After independently reviewing their interview notes, 2 members of the research team compared their findings and, through an iterative process, arrived at the results.

Results

Interviews Conducted at the Conclusion of the Planning and Development Phase

At BWH and BCBSMA, interviewees involved in the design and development of the modifications to the information systems told us that the selection of the notes segment in the 837 claim form and the development of the software modifications were technically straightforward but that the tasks were complicated by the need to coordinate with members of multiple departments and organizations to ensure the integrity of claims processing. They acknowledged that the advice from EHR vendor staff was very useful and that weekly project conference calls helped to keep everyone informed regarding progress and problems. The technician in the cath lab, who had been scanning implants and supplies for more than 6 months before our project was launched, told us that she and her fellow technicians much preferred scanning to manual entry.

At GH, the responsibility for developing the necessary software modifications to the inventory management system was assumed by the vendor as part of an ongoing program of enhancing the system. The GH billing team assumed responsibility for developing the software modifications to its systems and coordinated its modifications with the inventory management team. The billing team reported that the level of difficulty encountered in the design and testing of the modifications was comparable to regular system updates.

Interviews Conducted 10 Months After the Start of Implementation

The first category of interviewees, described in the previous Method section, told us that the technical level of difficulty of the implementation phase was relatively low, but that the need to involve members from multiple organizations in troubleshooting raised the overall difficulty to a level comparable to typical implementations of new information system releases. Those who had designed and developed the information system modifications believe that, during a nationwide implementation of DIs in claims, most institutions would need to work with their system vendors to make the modifications necessary to transmit DIs from the POC to payers.

Among the second category of interviewees, the cath lab staff confirmed that scanning implants and supplies continued to be straightforward. They also told us that technicians are dedicated to the cath lab and are only occasionally assigned to the EP lab, where the same processes and software are used as in the cath lab.

The nurses in the vascular ORs, the other group in the second category of interviewees, offered a contrasting perspective. They acknowledged that scanning barcodes is much easier than manual entry of the data; however, because implants were used in only 5 to 10% of cases and were the only items available for scanning during our study, the nurses had to modify their standard process and remember when to scan. To compound the challenge, in contrast to the situation in the cath lab and EP lab, nurses working in the vascular ORs rotated through other ORs where scanning UDIs was not routine practice.

ANALYSIS OF CLAIMS-BASED OUTCOMES

To explore the benefits of using claims-based data that are device-specific, we analyzed data received at BCBSMA and GHP during our demonstration. We first identified the devices from their DIs using the FDA's Global Unique Device Identifier Database,[18] then analyzed all claims for patients during the 90 days after their discharge. We calculated percentages of patients with emergency department visits or rehospitalizations for all-cause, acute myocardial infarction (AMI), or stroke. We estimated these percentages twice: once using only claims from the originating facility and again using claims from *all* facilities where the patient might have been treated 90 days after discharge.

Our results confirmed that many patients receive care in the 90 days after discharge from providers outside the originating system, meaning that these outcomes would only be captured in a claims-based analysis and not in an analysis of EHR data recorded at the originating facility. Appendix B presents results for the 3 most frequent implants. For example, of 213 patients receiving drug-eluting stents, 9% had a rehospitalization at the originating facility, but an additional 12% were rehospitalized at other facilities. For emergency department visits, these percentages were 15% and an additional 10%, respectively.

DISCUSSION

Our study demonstrates that the technical challenges for moving DIs from the POC through the billing system and on to payers should not be a major barrier to establishing a postmarket surveillance system based on DIs in claims. We believe this conclusion is robust because it is based on results at 2 different provider-payer dyads with different systems architectures, requiring different software modifications.

Payers might estimate that the resources required just for adding DIs are sufficiently high to deter them from making the required changes. However, in the next several years, the modified 837 claim form will be introduced. In addition to a field for up to 9 DIs of implanted devices, the modified form will include many other changes, forcing both providers and payers to modify their systems. Therefore, in several years, all providers' information systems should have the capability of transmitting DIs to payers, and payers should have the capability of handling DIs in their claims-management systems.

The challenges encountered in the vascular ORs at BWH were associated, in part, with the need for the vascular OR nurses to make exceptions to their standard process during procedures requiring implants, which represented less than 10% of their cases. Moreover, no other procedure areas through which the nurses rotated had instituted scanning. It is not surprising, therefore, that they might not have remembered to scan implants. Consequently, we believe that the problem encountered in the vascular ORs is not fundamental to these procedure rooms: in a hospital-driven program—in contrast to our research study—in which all items, implants as well as supplies, are scanned, such problems would be resolved. Based on these observations, we speculate that orthopedic ORs, where the procedures may require multiple implant components, including perhaps many screws, processes for scanning the parts will be developed. For institutions that currently wish to institute the use of UDIs in procedure areas, a roadmap was developed by one of the authors (N.A.W.).[19]

One reason for enhancing payers' information systems with claims data for devices is that such data allow for the longitudinal tracking of a patient beyond the institution where the implant procedure was performed. Our comparison of claims generated by the initial provider with claims generated by all providers 90 days after the initial procedure confirms this important benefit.

LIMITATIONS

At both dyads, constraints were placed on resources to make all the modifications desired for an ideal study. At BWH, we did not pursue an additional modification to the billing system to ensure that DIs of pacemakers and ICDs would be transmitted to BCBSMA. At GH, the inventory management system was modified to transmit DIs for the most expensive items scanned, some of which were not implants.

Our study did not include an assessment of the cost to develop and test modifications to the payers' claims processing systems to accommodate DIs. At BCBSMA, no changes were made to the claims-processing system. Only the data warehouse was modified, and programming logic was added to extract the DIs from the notes segment. At GHP, no modifications of the claims-processing system were required because GHP already had the capability of transmitting data in the notes segment, and it would have been difficult to assess the incremental cost of developing that capability.

Finally, in our analysis of claims, we were unable to attribute adverse outcomes to the implanted devices. Our objective was solely to demonstrate the value of claims in this patient population to capture the treatment of adverse events beyond the originating institution.

CONCLUSIONS

Including device-specific information in insurance claims has the potential to greatly enhance postmarket surveillance and to provide essential data for performing research using real-world evidence. Our project, conducted at 2 different provider-payer dyads with different information systems architectures, has demonstrated that the modifications necessary to transmit DIs from the POC to the claim form were modest and relatively easy to implement. Although different modifications may be introduced in a national UDI implementation, we anticipate that they would likewise be achievable. Our study was unable to fully assess the difficulty of modifying payers' claims-processing systems to accept DIs because only one of the payers in our study, GHP, had modified its claims-processing system to accept DIs transmitted in the notes segment of the current 837 claim form. However, in the future, payers will have to modify their systems in response to anticipated changes in the next version of the claim form, which includes, among many other non–UDI-related changes, a field for storing up to 9 DIs per claim.

Even if all providers modify their information systems to permit the transmission of claims with DIs and if payers modify their claims-processing systems to accept DIs, a postmarket surveillance system will not automatically emerge. To fully realize the benefits of including device, DIs in claims will require not only an adequate percentage of payers' claims databases populated with these DIs but also enhancements to either Sentinel or NEST, if it becomes a functioning medical device evaluation system, or some combination of the 2 systems.

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APPENDIX A

Design of data flows incorporating DIs

Here we describe methods to:

1. transmit the DIs captured at the POC to the selected location on the claim form and
2. process claim forms received by the payer to select patients who received implants and to record their DIs.

The DI flows, highlighting the systems that were modified, are shown in Figures A1 and A2 for BWH/BCBSMA and GH/GHP, respectively.

DI flows at BWH/BCBSMA

As shown in Figure A1, at the POC the barcode of the UDI is scanned. If the scanned DI matches a DI that has been previously entered in the supply record (a reference database) of Epic (Epic Systems, Madison, Wisconsin), the scan is valid and the DI, lot number, and expiration date (if appropriate) are entered into the implant record of Epic. (Cupid for the cath lab and EP lab; OpTime for ORs.) Before our project started, UDIs of implanted devices and barcodes of supplies were already been scanned in the cath lab and EP lab but not in the vascular ORs. Because there was no direct link between the materials management system and Epic at BWH at the time of our study, the data required for scanning implants and supplies were manually entered into the Epic supply record.

To read DIs stored in the Epic implant record and to transmit them to BCBSMA, a software development team authorized to make custom modifications to local Epic modules, developed software dubbed the Extension Rule. Although the Extension Rule is depicted as a separate module in Figure A1, it consists of modifications to Resolute, the Epic billing module. The Extension Rule is invoked if:

- The charges in the patient's EHR are recorded by clinicians belonging either to the Cardiovascular Service or to the Vascular Service.
- The Revenue Code 278, designating "other implants," is present.

When these criteria are met, a field added to Resolute as part of the custom solution is populated with the DIs in the patient's implant record. If DIs are missing in the patient's implant record, the field is populated with 14 zeros for each missing DI. We added this feature to help us identify cases in which the UDI was not available for scanning, possibly because the DI was not entered into the Epic supply record.

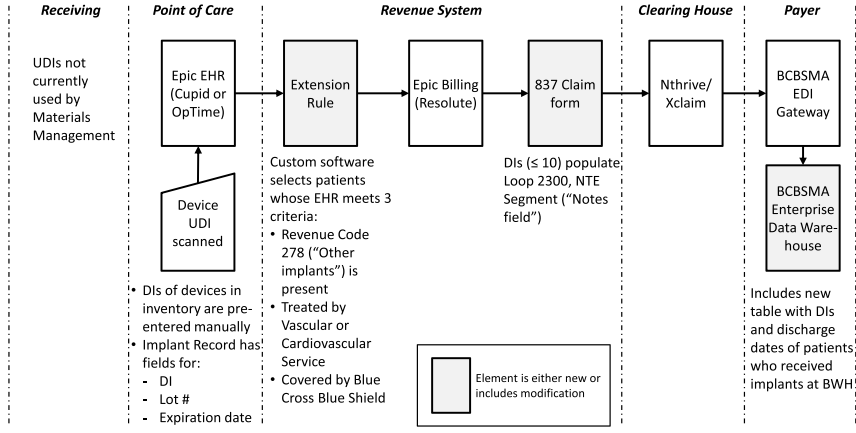
We initially planned to restrict the scope of our project to the cath lab and the vascular ORs. However, it was not possible to restrict it to the cath lab because the Epic EHR distinguishes by category of service, not by procedure room. Because the Cardiovascular Service encompasses both the Cath Lab and the EP Lab, we extended our pilot to include the latter. Moreover, because UDIs were already been scanned in the EP Lab, no incremental effort was required on our part.

The Extension Rule custom software also introduces a modification to Resolute's claim generation logic. The modification stipulates that if the payer is Blue Cross Blue Shield, the DIs of the patient's implants populate the note field of the 837 claim form. After passing through a third-party clearinghouse, claim forms with DIs are copied and their data entered in the BCBSMA Enterprise Data Warehouse (EDW) via a data table developed for our study.

DI flows at GH and GHP

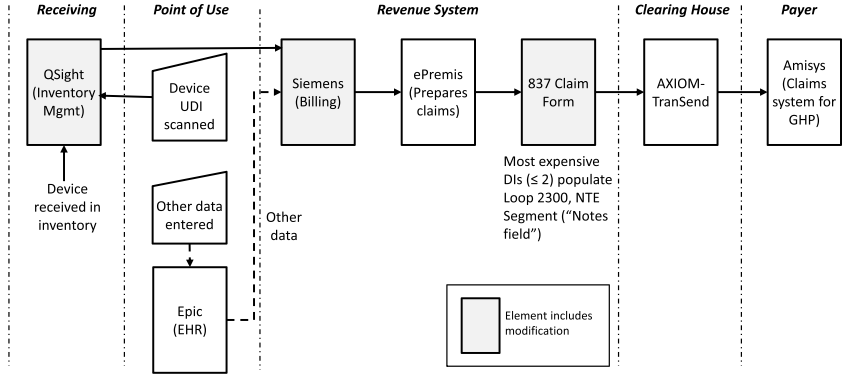
The DI flows at GH/GHP, shown in Figure A2, differ from those at BWH/BCBSMA. The most significant difference is that the UDIs, scanned at the POC, are entered into QSight (QSight, Owens & Minor, Mechanicsville, Virginia), the inventory management system—along with the patient's identification number—not into the EHR. In this architecture, the inventory management system becomes the "source of truth."At GH, a software patch was developed for QSight to enable it to select the DIs of the 2 devices with the highest price and to transmit the data to the revenue system. GH's revenue analysts created automated processes for downloading the files and then transmitting the data to the system that prepares claims, ePremis (RelayHealth, Atlanta, Georgia). Finally, after passing through a third-party clearinghouse, the patient's data, including DIs, are written into Amisys, GHP's claims system. Because GH and GHP already exchange data in the notes segment, Amisys required no modification.

FIGURE A1. DI flows designed for BWH/BCBSMA.



UDI: Unique Device Identifier; DI: Device Identifier; EHR: Electronic Health Record; EDI: Electronic Data Interchange
BCBSMA: Blue Cross Blue Shield of Massachusetts; BWH: Brigham and Women's Hospital

FIGURE A2. DI flows designed for GH/GHP.



UDI: Unique Device Identifier; DI: Device Identifier; EHR: Electronic Health Record;
GHP: Geisinger Health Plan

APPENDIX B

Side-by-side comparison of 90-day event rates for patients receiving different implant types, as estimated from claims from within the originating facility versus claims from any internal or external facility.

90-dEvents	Claims From Originating Facility	Claims From Any Facility	Absolute % Difference	Relative % Difference
Coronary drug-eluting stent (n = 213 patients)				
Readmission, all-cause	19 (9%)	45 (21%)	+12%	+137%
ED visit, all-cause	31 (15%)	53 (25%)	+10%	+71%
AMI	5 (2%)	10 (5%)	+2%	+100%
Stroke	1 (<1%)	7 (3%)	+3%	+600%
Permanent pacemaker electrodes (n = 46 patients)				
Readmission, all-cause	6 (13%)	10 (22%)	+9%	+67%
ED visit, all-cause	0 (0%)	3 (7%)	+7%	∞
AMI	0 (0%)	0 (0%)	+0%	+0%
Stroke	0 (0%)	32 (70%)	+70%	∞
Drug-eluting permanent RV/RA pacemaker electrodes (n = 43 patients)				
Readmission, all-cause	7 (16%)	12 (28%)	+12%	+71%
ED visit, all-cause	1 (2%)	8 (19%)	+16%	+700%
AMI	0 (0%)	2 (5%)	+5%	∞
Stroke	0 (0%)	3 (7%)	+7%	∞