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National projections of time, cost and failure in implantable device identification: Consideration of unique device identification use

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ABSTRACT

Background: U.S. health care is responding to significant regulation and meaningful incentives for higher quality care, patient safety, electronic documentation and data exchange. FDA's Unique Device Identification (UDI) Rule, a relatively new regulation aligned with these goals, requires standard labeling of medical devices by manufacturers. This lays the foundation for UDI scanning and documentation in the electronic health record, expected to change the landscape of medical device identification and postmarket surveillance.
Methods: We developed national projections for time, cost and failure in implant identification prior to revision total hip and knee arthroplasty (THA/TKA) using American Association of Hip and Knee Surgeons 2012 membership survey data, Nationwide Inpatient Sample 2011 data and THA/TKA demand projection data.
Results: Our projections suggest that cumulative surgeon time spent identifying failed implants could reach 133,000 h in 2030, representing opportunity to perform over 500,000 15 min established patient office visits. Staff time could reach 220,000 h with a cost of $3.3 m. Failed implants that cannot be identified may be greater than 50,000 preoperatively and 25,000 intraoperatively in 2030.
Conclusion: Study projections indicate significant time, cost and inability to identify failed implants, supporting need for improvement of implant documentation. FDA's UDI Rule sets the foundation for UDI scanning and documentation in the electronic health record, a process poised to serve as the standard system for device documentation.

1. Introduction

Extensive health care regulation and meaningful incentive since 2009 have incentivized health care organizations to implement new systems for improved quality of care, patient safety, efficiency and lower costs. Many organizations have adopted new quality and patient safety processes, electronic health records (EHR), and health information exchange (HIE). Research is indicating progress in these areas.[1–10]

The U.S. Food and Drug Administration's Unique Device Identification (UDI) System Rule is a relatively new health care regulation. The genesis of the Rule and its public health objectives align well with current health system goals and advancement of electronic data capabilities. The Rule mandates manufacturers to label marketed devices with UDI. The UDI compliance date for Class III (highest risk) was September 2014. Compliance date for implantable, life-supporting and life-sustaining devices is September 2015.[11] The Rule lays the foundation for scanning UDI at device use to document device-identifying information in HIT systems.

UDI use, a focus of ongoing research and stakeholder engagement[12–16], is expected to provide the standard for device documentation. Expected is improved device traceability, implant identification, adverse event reporting, recall management, and postmarket safety surveillance. The stakeholder group is broad and includes patients, clinicians, health care delivery organizations, manufacturers, government agencies including FDA and ONC, registries, postmarket surveillance researchers, payers, and supply chain organizations. The UDI Rule has similarities to the Pharmaceutical Barcode Rule, requiring manufacturers to label pharmaceuticals with barcodes containing the national drug code

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(NDC).[17] An important goal was barcode scanning in patient care settings and medication error reduction. Research on barcode electronic-medication administration record (eMAR) systems has indicated statistically significant reduction of medication error.[18] Use of barcode eMAR is a Stage 2 Meaningful Use core objective.[19] Availability of NDC's in claims has additionally facilitated pharmaceutical postmarket surveillance.

Implantable device-requiring procedures are high volume across specialties.[20,21] Until the UDI Rule, manufacturer adherence to a standard system for device identification labeling was not mandated. Hospitals often use proprietary device codes and manual documentation. UDI use and documentation in HIT systems is expected to provide the standard that has been lacking across health care organizations. Quick access to accurate device information is needed prior to revision or emergency surgeries and in recalls. Accuracy of device information is needed to support robust adverse event data at FDA, clinical registries and postmarket safety surveillance.

Due to device intensity, high volume and expectation of exponential increases in demand, total hip and knee arthroplasty (THA/TKA) is the study focus. Approximately 1 million primary and 125,000 revision THA/TKA were performed in 2011.[22] Projections indicate 174% growth in demand for primary THA and 673% growth in demand for primary TKA by 2030; doubling of demand for knee revision by 2015 and hip revision by 2026.[23] Over 10 million patients are living with a hip or knee implant in the US.[24] Recent research has indicated that 30% of revision THA/TKA are done in a different hospital than the patient's primary surgery, increasing to 40% after 3 years.[25] Ease and accuracy in identification of implanted devices is necessary for surgeon revision surgery planning so needed implant components are available, yet has not been comprehensively and efficiently enabled by current device documentation process. Impact of inability to identify failed implants includes increased procedure time, surgical complexity, more implants brought into the case, greater number of components replaced and greater health care costs.[12]

Approximately 50,000 different hip and knee implant components are in the market. (Orthopedic Network News, email January 9, 2015) Over 1300 recalls of hip and knee implant components have occurred in the past 5 years. (Gross T, US Food and Drug Administration, email January 6, 2015) Metal-on-metal hip implants have received significant focus due to patient morbidity.[26,27] A critical step to meet FDA's goal for a national medical device postmarket surveillance system is a UDI system where data is captured in electronic health records.[28]

The aims of this study are to formulate national projections of time, cost and failure in implant identification prior to revision THA/TKA and consider UDI in EHR as the standard for device documentation in THA/TKA and across specialties.

2. Materials and methods

Primary data was collected from a representative survey of 605 orthopedic surgeon members of the American Association of Hip and Knee Surgeons (AAHKS). Survey content and process has been published previously.[12] The survey was designed to query processes used to identify failed implants prior to revision THA/TKA. Methods used by surgeons for implant identification in revision surgery planning were previously reported. Survey response rate was 44.4% with a margin of error of 3%.[12]

Nationwide Inpatient Sample (NIS) 2011[22] and revision THA/TKA demand projection data[23] were used to develop national projections of surgeon time, staff time and implant identification failure from AAHKS survey data. Bureau of Labor Statistics data was used to determine staff time cost.[29] CPT 2013 Professional Edition was used to determine surgeon office visit coding.[30] Medicare reimbursement rates were obtained through personal communication. (Beard K. Revenue Integrity Team Manager, Department of Orthopedic Surgery/Neurosurgery. (Cited 2014 Aug 18)).

2.1. Analysis

Projected surgeon and staff time for failed implant identification prior to revision THA/TKA was estimated using 3 sources of data: (1) median AAHKS survey responses to: "Please estimate the typical amount of time spent identifying components of the failed implant for a revision THA/TKA case. Consider time obtaining & reviewing medical record, evaluating X-ray, talking to manufacturer rep, etc. The time you spend estimated in minutes/The time your staff spends estimated in minutes;" (2) number of revision THA/TKA cases from 2011 NIS data; (3) number of revision THA/TKA cases from demand projection data.[23] Due to the skewed distribution of the identification time, log transformation was used to stabilize time estimates and standard errors. Standard properties of variance were used to calculate total standard error assuming independence of number of THA/TKA cases and reported time.

Cost of staff time was estimated using Bureau of Labor Statistics medical assistant mean hourly wage. Opportunity cost of surgeon time was estimated using CPT code 99213 because it represented typical face-to-face time that best approximates the estimated median surgeon time to identify failed implants (obtained from AAHKS survey data).

Projected number of revision THA/TKA cases where the surgeon was unable to identify a failed implant was also estimated using 3 sources of data: (1) median AAHKS survey responses to the survey question: "Please estimate the percentage of revision THA/TKA cases in which you are unable to identify the failed implant components: preoperatively/intraoperatively;" (2) number of revision THA/TKA cases from 2011 NIS data; (3) number of revision THA/TKA cases from demand projection data.[23] We used a representative percentage of failed identification both preoperatively and intraoperatively from the original survey. We then applied that percentage to the HCUP estimate of total surgeries and demand projection data to estimate the total number of surgeries in which surgeons were unable to identify the failed implant. Due to the skewed distribution of percentage of cases where implants could not be identified, median preoperative and intraoperative percentages were used. Standard error of percentage estimates was calculated using bootstrap distribution for median percentage. Standard properties of variance were used to calculate total standard error assuming the independence of number of THA/TKA cases and reported percentage estimates. Analyses were conducted using R computing software, Version 2.12.1.

3. Results

Demographics of the survey respondent group have been described elsewhere.[12] 98% of the survey respondents were AAHKS fellow members (perform a minimum of 50 THA and/or TKA or osteotomies about the hip or knee annually)[31], representing 61.1% of the AAHKS fellow membership. The survey respondent group performed 30.9% of revision THA cases, 24.2% of revision TKA cases and 27% of revision THA/TKA cases nationally in 2011.

3.1. Time to identify failed implants

Fig. 1 portrays projected cumulative surgeon and staff time to identify failed implants prior to revision THA, TKA and THA/TKA, 2011–2030. Projections indicated cumulative surgeon time (thousands of hours) for revision THA/TKA as 45.3(SE 1.6) in 2011, 68.8 (SE 6.5) in 2020 and 133.0(SE 19.0) in 2030 and cumulative staff