The Kaiser Permanente Implant Registries: Effect on Patient Safety, Quality Improvement, Cost Effectiveness, and Research Opportunities

Elizabeth W Paxton, MA; Maria CS Inacio, MS; Mary-Lou Kiley, MBA

Abstract

Introduction: Considering the high cost, volume, and patient safety issues associated with medical devices, monitoring of medical device performance is critical to ensure patient safety and quality of care. The purpose of this article is to describe the Kaiser Permanente (KP) implant registries and to highlight the benefits of these implant registries on patient safety, quality, cost effectiveness, and research.

Methods: Eight KP implant registries leverage the integrated health care system’s administrative databases and electronic health records system. Registry data collected undergo quality control and validation as well as statistical analysis.

Results: Patient safety has been enhanced through identification of affected patients during major recalls, identification of risk factors associated with outcomes of interest, development of risk calculators, and surveillance programs for infections and adverse events. Effective quality improvement activities included medical center- and surgeon-specific profiles for use in benchmarking reports, and changes in practice related to registry information output. Among the cost-effectiveness strategies employed were collaborations with sourcing and contracting groups, and assistance in adherence to formulary device guidelines. Research studies using registry data included postoperative complications, resource utilization, infection risk factors, thromboembolic prophylaxis, effects of surgical delay on concurrent injuries, and sports injury patterns.

Conclusions: The unique KP implant registries provide important information and affect several areas of our organization, including patient safety, quality improvement, cost-effectiveness, and research.

Introduction

Each year approximately 773,000 total joint replacements, 358,000 operations to implant pacemakers and pacemaker leads, and more than 310,000 intervertebral disk excision or destruction procedures are performed in the US. The use of these devices and procedures has increased greatly. For example, in the last 2 decades use of cervical spine fusion increased by 90% in the non-Medicare population and by 206% in the Medicare population. Similarly, pacemaker implantation has increased by 19% between 1997 and 2004, and implantable cardioverter-defibrillator (ICD) use has increased by 60% during the same period. Projections indicate additional increases in total joint replacement procedures, with a 174% increase in total hip replacements and 673% increase in knee replacements expected between 2005 and 2030.

These high-volume procedures involve ever more technologically advanced, innovative, and costly devices. In 2009, the US Food and Drug Administration Center for Devices and Radiologic Health approved 740 new devices, a 52% increase from 2001. The cost of some of the latest introduced devices can include, according to conservative estimates, an increase of $1000 in knee replacements, $800 in hip replacements, or more dramatically $15,000 in spine surgery. Often, these new and more costly devices are introduced into the market with little to no evidence of enhanced clinical effectiveness.

In addition, new technology sometimes fails, requiring recalls of medical devices. In 2011 a total of 41 Class 1 recalls happened in the US. Recalls of medical devices can put patients at major risk of complications and mortality. Although some recalls require only patient consultations, others can require close monitoring of patients, and in some more serious cases a high-risk reoperation. Early identification of device failures is therefore necessary to prevent implantation of defective devices and harm to patients.

Considering the high cost, volume, and patient safety issues associated with medical devices, monitoring of medical device performance is critical to ensure patient safety and quality of care. One method for tracking these devices is the use of patient registries. A patient registry is defined as “an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.”

Patient registries provide a unique opportunity to enhance patient safety, quality of care, cost effectiveness, and research. As such, Kaiser Permanente (KP) developed and implemented several orthopedic (total knee and hip replacement, hip fracture, shoulder arthroplasty) and cardiac registries (ICD, pacemaker, heart valve) to monitor these high-risk implantable devices within our health care system. The registries were specifically developed for the following reasons: 1) to identify...
procedure incidence and implantable device utilization; 2) to evaluate patient and device outcomes; 3) to identify patients at risk of poor clinical outcomes; 4) to identify and monitor devices in a recall/advisory situation; 5) to evaluate comparative effectiveness of devices; and 6) to serve as a foundation for quality improvement and research studies.

The purpose of this article is to describe the KP implant registries and to highlight the benefits of these implant registries on patient safety, quality, cost effectiveness, and research.

**Methods**

The KP device registries leverage our integrated health care system’s administrative databases and electronic health records (EHR) system. Some of the registries include data collection at the point of care (eg, Total Joint Replacement Registry), and others are virtual registries with data collected completely behind the scenes (eg, Hip Fracture Registry and Spine Registry).

**Data Collection**

The registries were initially designed to capture data at the point of care through standardized paper-based forms at preoperative, intraoperative, and postoperative encounters. These forms not

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**Table 1. Registry volumes, time periods, 2010 voluntary participation rate, contributing surgeons, KP Regions, and targeted population of each registry (as of December 31, 2010)**

<table>
<thead>
<tr>
<th>Registry name</th>
<th>Start of data collection</th>
<th>Volume</th>
<th>Participation rate (%)</th>
<th>Surgeons</th>
<th>KP Regions</th>
<th>Targeted population</th>
<th>Outcomesa</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Orthopedic registries</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Joint Replacement Knee</td>
<td>2001</td>
<td>76,853</td>
<td>95</td>
<td>&gt;400</td>
<td>7</td>
<td>Total, unicompartmental, and bicompartamental knee replacement</td>
<td>Standard only</td>
</tr>
<tr>
<td>Total Joint Replacement Hip</td>
<td>2001</td>
<td>43,031</td>
<td>90</td>
<td>&gt;400</td>
<td>7</td>
<td>Total hip replacement, hip resurfacing</td>
<td>Standard only</td>
</tr>
<tr>
<td>Total Shoulder Arthroplasty</td>
<td>2006</td>
<td>6000/290b</td>
<td>100/53b</td>
<td>54</td>
<td>2</td>
<td>Total shoulder replacement, hemi replacement, humeral head resurfacing, reverse total shoulder replacement</td>
<td>Standard only</td>
</tr>
<tr>
<td>ACL Reconstruction</td>
<td>2005</td>
<td>13,008</td>
<td>93</td>
<td>218</td>
<td>5</td>
<td>Graft type, fixation technique, concurrent procedures</td>
<td>Reoperation</td>
</tr>
<tr>
<td>Hip Fracture</td>
<td>2009</td>
<td>11,242</td>
<td>100c</td>
<td>648</td>
<td>6</td>
<td>Fracture category by orthopedic trauma proximal femur classification</td>
<td>Reoperation, dislocation, myocardial infarction, pneumonia</td>
</tr>
<tr>
<td>Spine</td>
<td>2009</td>
<td>9247</td>
<td>100c</td>
<td>&gt;100</td>
<td>4</td>
<td>Pedicle screws, total disc replacement, anterior cervical plates, bone morphogenic protein</td>
<td>Reoperation</td>
</tr>
<tr>
<td><strong>Cardiac registries</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac device</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICD</td>
<td>2000</td>
<td>7702d</td>
<td>100c</td>
<td>&gt;200</td>
<td>7</td>
<td>Single, dual, and biventricular pulse generators Explants: revision, replacement, upgrade</td>
<td>Mechanical failure, hematoma, pneumothorax tamponade, battery longevity</td>
</tr>
<tr>
<td>Pacemakers</td>
<td>2000</td>
<td>12,002a</td>
<td>100c</td>
<td>&gt;200</td>
<td>7</td>
<td>Implanted with device or lead only procedure</td>
<td>Dislodgement, perforation, insulation failure, conductor fracture</td>
</tr>
<tr>
<td>Leads</td>
<td>2000</td>
<td>85,579</td>
<td>100c</td>
<td>&gt;200</td>
<td>7</td>
<td>Mitral, aortic, pulmonic, tricuspid Tissue vs mechanical mitral valve survival</td>
<td>Rheumatic-valve failure, endocarditis, vegetation</td>
</tr>
<tr>
<td>Heart valve</td>
<td>1999</td>
<td>58,765c</td>
<td>100c</td>
<td>N/A</td>
<td>4</td>
<td>Graft tear/fracture, limb occlusion/kinking, AAA rupture, endoleak, stenosis, myocardial infarction, hematoma</td>
<td></td>
</tr>
<tr>
<td>Endovascular stent graft</td>
<td>2008</td>
<td>1733</td>
<td>100c</td>
<td>132</td>
<td>5</td>
<td>AAA</td>
<td>Rheumatic-valve failure, endocarditis, vegetation</td>
</tr>
</tbody>
</table>

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In addition to the outcomes collected by all registries: revisions, death, surgical site infection, and thromboembolic events.

6000/100% is the number of cases captured electronically and retrospectively (from 2006 onwards). 290/53% is the number of cases with both paper and electronic information available (from 04/2010 onwards).

All cases are captured electronically.

Other data sources include device manufacturers, the National Cardiovascular Data Registry and other proprietary data repositories.

Data extraction from comprehensive and mandatory Society for Thoracic Surgeons database.

AAA = abdominal aortic aneurysm; ACL = Anterior Cruciate Ligament; ICD = implantable cardioverter defibrillators; KP = Kaiser Permanente.
only standardized chart documentation but also allowed registry data collection of patient characteristics, device information, surgical procedures, and outcomes. In addition to the standardized registry forms, administrative and claims databases were used to supplement the registry database. These standardized forms are now electronically captured in our EHR system. With the full implementation of our EHR system in 2009, it provided an opportunity to capture data completely from our EHR for several registries. Integration of EHRs and database development has been described elsewhere. A brief summary follows. Data from all data sources are extracted and sent to the registries’ centralized office, where they are assembled and managed, and quality control routines are applied to them. Outcomes are identified using electronic screening algorithms and then adjudicated by clinical content experts. All KP Regions are eligible to participate in the registries. Most Regions participate in the registries, and the ultimate goal of each registry is to include cases from all Regions. Because of the implementation schedule of features of our EHR, some Regions may not have the electronic forms available at this time, but the development is under way in all participating Regions.

Quality Control and Validation

For all registries, there are rigorous quality control and data validation processes. Continuous quality control is carried out by automated computer algorithms that flag data anomalies, which are then reviewed by data quality personnel. These routines are supplemented by quarterly logical and cross-validation checks. The denominators of the registries are based on an International Classification of Diseases, Ninth Revision, Clinical Modification procedure code algorithm to identify cases (see Registry denominator identification algorithms online at: www.thepermanentejournal.org/issues/2012/spring/4554-implant-registries.html#padf). Validation of case capture centers on the forms received and manual chart review. For postoperative complications, electronic algorithms have been developed internally (ie, infection, reoperation, and revision) or with support of external algorithms, such as the Agency for Healthcare Research and Quality’s inpatient quality indicator algorithm for pulmonary embolism and deep venous thrombosis. After possible cases are flagged using the electronic algorithms, patient charts are manually reviewed and confirmed by specially trained content experts.

Analyses

Several analytical strategies are used to analyze the registries’ data. Each registry produces an annual report with frequencies and proportions of the cases registered, basic demographics, surgical techniques, and implant utilization. In this same report, multivariable analytical approaches, such as regression and survival analyses, are performed to identify and to assess risk factors, to determine populations at risk, and to assess device performance. Complex analytical projects have required data imputation, propensity scores analysis, and sensitivity analysis, among other sophisticated techniques employed by the analytical staff.

Results

Registry Overview

KP currently has eight implant registries. The first of the KP implant registries developed, the Total Joint Replacement Registry, is now the largest total joint replacement registry in the US. Established in 2001, it was designed as a postmarket surveillance system for elective total hip and knee replacement. This model was replicated to create other registries for orthopedic implants, including the Anterior Cruciate Ligament (ACL) Reconstruction Registry, Spine Registry, Hip Fracture Registry, and Shoulder Arthroplasty Registry. We expanded our scope into cardiac and vascular surgery to create ICD and pacemaker, heart valve replacement, and endovascular stent graft registries.

Table 1 describes how long each registry has been implemented, its current volume, participation rate, targeted population, and outcomes of interest. Common data elements included in all registries are patient demographics (age, sex, body mass index, race), diagnosis, devices used, and membership enrollment history. Surgical outcomes tracked for all registries include revision procedures, surgical site infection (deep or superficial), thromboembolic events (deep venous thrombosis and pulmonary embolism), and death. All suspected surgical complications are validated through KP’s EHR by clinical content experts to determine if they meet preestablished criteria.

The KP implant registries have been instrumental in enhancing patient safety, quality, cost-effectiveness, and research. The contribution of the registries in each of these areas is highlighted below.

Figure 1. Recall/alert list from implant registries Web site.
Enhancing Patient Safety

Recalls and Advisories: The registries are uniquely designed to efficiently identify cases. Therefore, when recalls and advisories occur, quick tracking of patients with the device or biologic is possible, along with any patient-specific adverse events and the status (whether the implant was revised or not). In addition, a recent enhancement to monitoring implant performance is the development of real-time, proactive tracking of adverse trends. As a result of this surveillance, the Cardiac Device Registry detected an adverse trend in the performance of a particular defibrillator lead and alerted our physicians in advance of a recall of that lead by the US Food and Drug Administration. Although the registries do not handle the recall management, they work in sync with the KP National Product Recall Department to identify patients, identify their postoperative outcomes, and develop case management tools for patient surveillance if necessary. Information on all the recalls assisted by the registries can be found at an internal KP Web site.14

Since the first components started to be tracked, at least 40 recalls occurred, and since 2008 (when most registries were ongoing), the registries assisted in 19 recalls and advisories (Figure 1). These recalls included 2 advisories (Warsaw, Indiana–based Zimmer’s Versys Femoral Head in the Total Joint Replacement Registry, and Medtronic’s (Minneapolis, Minnesota) Kappa 600/700/900 Series and Sigma 100/200/300 Series Implantable Pulse Generators in the Cardiac Device Registry.

Risk Factors: Identification of variables that are associated with increased or decreased risk of failures, adverse events, and other outcomes are of special interest to the registries, and extensive work has been done on this topic. Annual reports of the registries and specific projects have investigated risk factors.16-19 For example, in the 2010 Total Joint Replacement Registry annual report, risk factors identified for aseptic total knee replacement revision included younger age, diabetic status, black race, unresurfaced patella, and certain types of mobile bearing implants. Bilateral procedures were found to be at a lower risk of revision. Similar multivariable analysis was conducted for the identification of risk factors associated with revision procedures in ACL reconstructions, and age, race, and graft type were found to be associated with risk of revision. Analyses are under way in the registries to identify risk factors for all-cause revisions and specific types of revisions, as well as for infection and thromboembolic events.

Risk Calculators: Using the detailed multivariable analyses that are carried out for the identification of individual risk factors for adverse events, the registries have developed prognostic tools that can be used by surgeons and patients for decision making at the point of care. These

![Figure 2. Risk calculator for risk of revision after total hip replacement.](Image 368x238 to 502x340)

Table 2. Crude incidence of revision and complication of primary orthopedic surgeries for all KP Regions (percentage)

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision surgery</td>
<td>2.0</td>
<td>2.0</td>
<td>1.6</td>
<td>2.9</td>
</tr>
<tr>
<td>Deep surgical site infection</td>
<td>0.7</td>
<td>0.5</td>
<td>0.2</td>
<td>0.4</td>
</tr>
<tr>
<td>Superficial surgical site infection</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
<td>0.1</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>0.4</td>
<td>0.7</td>
<td>0.1</td>
<td>0.4</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>0.5</td>
<td>0.5</td>
<td>&lt;0.1</td>
<td>0.4</td>
</tr>
</tbody>
</table>

ACL = anterior cruciate ligament reconstruction; KP = Kaiser Permanente.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Implantable cardiac defibrillators</th>
<th>Pacemakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deep surgical site infection</td>
<td>0.7</td>
<td>0.6</td>
</tr>
<tr>
<td>Superficial surgical site infection</td>
<td>&lt;0.1</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Tamponade</td>
<td>0.3</td>
<td>0.2</td>
</tr>
<tr>
<td>Hematoma</td>
<td>0.3</td>
<td>0.2</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>0.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Mechanical failures</td>
<td>1.2</td>
<td>0.3</td>
</tr>
<tr>
<td>Lead failures</td>
<td>2.6</td>
<td>1.8</td>
</tr>
</tbody>
</table>

KP = Kaiser Permanente.
prognostic tools work much like the more commonly known cardiovascular event risk calculators developed by the Framingham Heart Study. Surgeons have access to these tools via the internal KP Web site. During any consultation, physicians can give patients the probability of an event given certain patient characteristics that have been found to be associated with the risk of that event happening. Currently a risk calculator for joint replacement revision (Figure 2) is deployed, and a risk calculator for deep surgical site infection is being implemented.

Infection and Adverse Event Surveillance: The registries contribute to patient safety through ongoing surveillance, validation, and reporting of complications, revisions, and reoperations. These outcomes are monitored and reported to the locations on a quarterly basis. Tables 2 and 3 describe the main outcomes reported by the registries. Infection surveillance reports are now provided with detailed case level information to the participating centers as well as through tools such as statistical process control charts (Figures 3 and 4). These charts can be used to monitor the variation in events over time, allow for the detection of variation that should be addressed, and assist with the elimination of unwanted variation.

Quality Improvement

Communications and Report: Registry findings about clinical best practices or quality improvement opportunities are communicated to widespread audiences of surgeons, administrators, and clinical staff through chiefs of service and administrator meetings, the internal Web site, individualized physician practice profiles, site visits, newsletters, e-mails, and presentations at regional or national conferences. This dynamic feedback within KP’s collaborative culture is an integral part of surgical quality improvement initiatives and yields measurable objective improvements in care.

Medical Center-Specific Results and Surgeon Profiles: One of the main tools used to communicate with specific stakeholders is the medical center- and surgeon-specific reports that the registries provide. The medical center-specific reports from the Total Joint Replacement and ACL Reconstruction registries are

Figure 3. Southern California regionwide total hip replacement surgical site infection rates (2008 quarter 2 to 2010 quarter 1).

Figure 4. Southern California Regionwide total knee replacement surgical site infection rates (2008 quarter 2 to 2010 quarter 1).

Figure 5. Kaplan-Meier Survival curves with 95% confidence intervals for patients undergoing primary total hip replacement, by femoral head size (April 2001 to March 2009).
available via an internal KP Web site. All other registries can provide this information via e-mail on request and are expected to be available in the internal Web site shortly. Surgeon-specific reports can be obtained as well by secure communication if requested by the surgeons themselves. These targeted reports can be used to compare information among locations, Regions, and even nationally, creating an opportunity for benchmarking and learning.

**Changes in Practice:** We present four examples of changes in KP practice associated with registry findings and other published studies. First, the number of uncemented total knee replacement and unicompartmental knee replacement surgeries was reduced because of higher failure rates. Second, the use of small femoral head sizes for total hip replacement decreased after superior performance was demonstrated with larger head sizes (Figures 5 and 6). Third, KP had decreased use of DePuy LCS mobile bearing knee replacements after lower survival of this prosthesis type was observed (Figures 7 and 8). Fourth, use of the conventional polyethylene hip insert was essentially terminated after its performance was shown to be inferior to that of other hip insert materials (Figures 9 and 10).

A more large-scale observation has been the overall decrease in the burden of total hip replacement revision since the implementation of the KP Total Joint Replacement Registry in 2001 (Figure 11).

We expect to see changes in practice and similar contributions following the dissemination of findings from the other registries as they mature. The registries also verify adherence to national practice guidelines, such as indications for ICD implantation as established by the American Academy of Cardiology.

**Cost-Effectiveness**

In addition to the registries’ contributions to improvements in quality and patient safety, there is demonstrated cost effectiveness. The registries provide device performance evaluations comparing similar implants and patient and surgical characteristics. These analyses are critical in new technology adoption or for cost-benefit analysis of similar implants, or both.
Each registry monitors trends in implant performance. These comparative evaluations directly influence contract and purchasing decisions. Registry representatives are integral partners with the content experts and procurement staff of the national Sourcing and Standards Teams. In turn, these national teams provide consultation to the KP National Product Council for the development of national purchasing contracts. The ability of KP to negotiate favorable device contracts with suppliers benefits from its economies of scale and evidenced-based implant performance and longevity studies.

Another cost-effectiveness strategy directly resulting from registry data use was the development of formularies for total joint replacement and cardiac devices. Physician leaders within orthopedics and cardiology created formularies on the basis of best practices. The purpose of the formularies is to maximize treatment benefits and value of devices by educating physicians, standardizing device selection and ensuring contract compliance. In collaboration with KP’s Procurement and Supply Team, the registries produce timely device utilization reports that verify adherence to formulary guidelines and purchasing agreements and support monitoring of any unique contract features such as warranties, rebates, or volume discounts.

**Research**

Registry data provide the basis for myriad research studies, including comparative effectiveness studies, something the registries are naturally set up to perform. These external contributions are driven by our commitment to the dissemination of quality research and information, and to the promotion and enhancement of national evidence-based practice guidelines.

Most of the registries have contributed to different studies in some capacity. All the studies have shown how these community-based samples are of much interest to the external community and can help address important questions. The Total Joint Replacement Registry has made contributions in the areas
of short-term complications \cite{6,18,19} and resource utilization, \cite{14} risk factors associated with infections, \cite{17} thromboembolic prophylaxis, \cite{22,25} and registry structure and methods. \cite{31,32,33} Staff with the Total Joint Replacement Registry are working on publications regarding the topics of mobile knee bearings, hip bearings, risk factors for deep surgical site infection after hip and knee arthroplasty, and risk factors for unicompartamental knee revision surgery. The ACL Reconstruction Registry has helped study the epidemiology of ACL reconstruction in the organization, \cite{45} as well as looked into the effect of surgical delay on concurrent injuries, \cite{26} variables that are associated with graph selection. \cite{27} The ACL Reconstruction Registry staff are working on publications about the risk factors associated with aseptic revision, comparing the current population with the Norwegian Ligament Registry population, \cite{28} and sport-specific injury patterns. The other registries, despite being younger, are also starting to contribute to research and have provided data presented at major national meetings and congresses.

**Discussion**

KP’s integrated health care system, administrative databases, and comprehensive EHR provide a unique opportunity for implant registries to enhance patient safety, quality, cost-effectiveness, and research. The implant registries have been critical for early identification of device failures. Similarly, the registries provide an important function during implant recalls and advisories allowing us to immediately identify and notify patients with specific implants and monitor patient follow-up to ensure that our patients receive the best possible care. Patient safety is also enhanced through the use of risk calculators that allow patients and surgeons to make clinical decisions at the point of care. The registries also are important for quality improvement, providing tools for practicing evidenced-based medicine through identification and dissemination of clinical best practices to our physicians. Quarterly quality reports provide yet another method for monitoring infection and other complications at the medical center level. In addition to enhancing patient quality and safety, the implant registries have provided clinical outcomes to our contracting teams to allow for identification of the best implants for our patients. Finally, registries provide an opportunity for conducting research that has been translated into clinical practice in implant selection and techniques.

Registries have limitations that should be recognized. Data from registries are observational in nature, and analyses deriving from such data cannot control for all confounding factors. Multivariate analyses can attempt to control for known confounding factors; however, other factors may exist. In addition, registry data are not experimental and therefore cannot be used to establish causal relationships. Despite this limitation, registries are important in investigating associations of exposures and outcome in real-world settings and provide important feedback regarding implant performance. Registries are also limited to the number of variables and detail of procedures that can be captured. The number of data points captured by registries is limited to the most important factors associated with procedures, which can restrict potential analyses. This minimal dataset is advisable in order to minimize the burden of data collection, management, and validation and to guarantee maximum participation and data quality.

Finally, registries can be limited because of attrition of their covered population, which, if not properly accounted for, can bias results and information from the registry. Bias introduced with the loss to follow-up is accounted for in our system through active surveillance of our covered cohorts and by conducting sensitivity analysis with best- and worst-case scenarios.

The implant registries provide an important function in monitoring and tracking the large number of devices implanted in our population of more than nine million members. To continue to provide high-quality information and maintain the success described in this article, KP is exploring new ways to achieve the overall goals of the registries. These include creating interactive registry components, where patients and surgeons can communicate and use information from the registry on a real-time basis. We also hope to expand patient-reported outcomes. Participation of patients in the care and assessment of their procedures is deemed very important in our organization, and the registries are implementing this self-reported type of assessment to the measurements of success of our procedures. Another area we are aggressively pursuing is the development of automated postmarket surveillance. Two methods of ascertaining device failure or early warning signs are being explored using registry data, and we hope they will be implemented internally by the end of 2012. Finally, with the success of the revision risk calculator for joint replacement surgery and the large body of research we have on other outcomes tracked by the registries, we are now investing in developing other prognostic calculators for our surgeons and patients.

**Acknowledgments**

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Pieces of the Puzzle

The operation of a health service depends upon a complex interaction between the patient, the environment in which care is provided and the people, equipment and facilities that deliver that care.

— Medical Mishaps: Pieces of the Puzzle, Sir Liam Donaldson, b 1949, Chief Medical Officer of England