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Dear Colleagues,

We are honored to present the Kaiser Permanente National Implant Registries annual report highlighting significant achievements in patient safety, quality improvement, and comparative effectiveness research.

The registries were first initiated in 2001 to track patient outcomes, identify clinical best practices, and enhance quality of care for our 10 million members nationally. We are currently tracking over 2 million cardiology, cardiothoracic surgery, orthopedics, vascular and neurosurgery implantable medical devices for the lifetime of the patient so that every member receives the best possible care.

Within our learning health care system, the registries provide the cornerstone for patient safety and quality improvement, supporting evidence-based medicine and shared patient decision-making. The implant registries are critical for identifying and sharing clinical best practices and monitoring the impact on clinical practice and outcomes.

Examples of this success are highlighted in our annual report including:

- Reducing length of hospital stay for home-based recovery following surgery
- Tracking and identifying the best performing medical devices for our members
- Redesigning patient educational material and follow-up protocols to reduce emergency room visits by 50%
- Identifying factors associated with hospital readmissions
- Using risk calculators for shared decision making at the point of care

These are just a few examples of the many quality initiatives that are driven by the high-quality data and research findings of our implant registries, led by our dedicated clinicians and frontline staff.

This is the first time we are sharing our annual report externally. Highlighting our outcomes, key clinical findings, and quality improvement initiatives with patients, health care providers, regulators and others beyond Kaiser Permanente is an important milestone. Our surgical outcomes are among the best in the world and we are proud to share these with you in our annual report.

Liz Paxton, MA  
Director, National Implant Registries

Tadashi Funahashi, MD  
Chair, Inter-Regional Implant Registries Committee

Thomas Barber, MD  
Vice-Chair, Inter-Regional Implant Registries Committee
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Jo Carol Hiatt, MD, MBA
Chair, National Product Council
Chair, Inter-Regional New Technologies Committee
Southern California Permanente Medical Group

Murray N. Ross, PhD
Vice President and Director of Institute for Health Policy
Kaiser Foundation Health Plan
Registries play a critical role in enhancing quality of care by identifying variation and clinical best practices and providing feedback to frontline staff and clinicians using a variety of dynamic feedback mechanisms.

- Monitoring patients with recalled implants
- Monitoring outcomes, including revisions, re-operations, and complications
- Identifying the most effective surgical techniques and implant devices for quality improvement and safety
- Assessing patient risk factors for complications using risk calculators at point of care for clinical decision-making
- Providing risk-adjusted hospital outcomes and benchmarking for quality improvement
- Providing confidential feedback to surgeons on their patients’ outcomes
- Tracking implant usage and performance for contract decision-making

What we provide
Accomplishments and collaborations

Accomplishments

The registries have demonstrated value through:

- Successful patient identification, monitoring, and notification of implant recalls/advisories affecting 14,000 patients in 2014-2015.
- Early identification of implants with higher revision rates, resulting in reduced utilization.
- Identification of reasons for emergency department (ED) visits, resulting in redesigned patient-centered educational material, classes, and processes, and a 50% reduction in ED visits.
- Identification of variation in time to Operating Room, leading to development of redesigned clinical pathways and recovery systems to reduce time.
- Feedback to surgeons on techniques/implants resulting in changes in practice.
- Identification of high-tech, more costly implants with no difference in outcomes, informing implant selection and contributing to contract savings.
- Identification of modifiable patient risk factors for complications resulting in changes in surgical indications and peri-operative care pathways.

As a result, revision rates are less than 5% at 10 years for total knee and hip arthroplasty procedures and less than 4% for anterior cruciate ligament reconstruction (ACLR), spine, shoulder and hip fracture surgeries (see Highlights from our registries).

Collaborations

- Full member of International Society of Arthroplasty Registers (ISAR)
- Chair and members of the ISAR Quality Committee responsible for international signal detection, quality metric development, and international risk calculators
- IIRC contribution to the planning board and Medical Device Registries Task Force resulting in key recommendations for the FDA for national medical device surveillance system
- Led International Collaboration of Orthopedic Registries (ICOR) along with Cornell to develop a network of international registries for medical device surveillance
- Anterior Cruciate Ligament Reconstruction (ACLR) registry international collaborations
- Shoulder arthroplasty registry international collaborations

“Our collaborations have identified clinical best practices across countries in order to improve patient care world-wide.”
— Liz Paxton, MA
Kaiser Permanente
By the numbers

7 regions, 8 states representing 10.2 million members

50 hospitals

118 publications in peer-reviewed journals, 24 in 2015

170 posters & presentations at national & international symposia

2,400 surgeons participating in implant registries

14,000 patients with enhanced surveillance due to 17 recalls in 2014-2015

506,000 procedures captured and tracked for the patients lifetime

1.86 million implants registered

620,000+ patients in our registries
Kaiser Permanente members are well informed about the benefits and risks of anterior cruciate ligament (ACL) reconstruction surgery and hip and knee replacement surgeries long before they enter the operating room. “Risk calculators,” powered by the registry data on thousands of patients, help surgeons to show patients considering surgery their likely outcomes, based on their own personal data. “Using the total joint risk calculator, I can show a patient that, at their current weight, they stand a 5% chance of revision within 5 years. Then I can run another calculation to show that if they lose 100 pounds, their revision rate falls to 1%,” said orthopedic surgeon Thomas Barber, MD, Oakland Medical Center. “Suddenly they understand my concern about their weight.”

Surgeons regularly use the risk calculator to counsel their patients about the most appropriate procedure and medical device to optimize outcomes. “We can enter the patient’s age, gender, height, weight, and race and then look at the risks associated with various graft types,” said Gregory Maletis, MD, Baldwin Park Medical Center. “This real-time, shared decision making process is valuable for me and my patients in making informed decisions regarding their surgery.”

KP has published the methods for these risk calculators and plans to make recent versions available to surgeons and patients outside of KP system to share these many benefits with the community at large.

“The ACL risk calculator helps me when I am discussing the risks and benefits of surgery with a patient.” — Gregory Maletis, MD
KP’s registries power patient-centered care: reducing emergency department visits for total joint replacement patients

In the U.S., 10% or more of patients return to an emergency department (ED) following joint replacement. Often, these patients do not go back to the hospital where they had their surgery, so it becomes virtually impossible for surgeons to track which patients return for follow-up care and why.

Kaiser Permanente is in the unique position of being able to find out if a patient returns to the ED, regardless of which KP hospital the patient visits. With an eye toward preventing many of these visits which often burden and inconvenience members, the Total Joint Replacement Registry provides regular reports to all KP medical centers on which patients had ED visits and why.

Orthopedic surgeon and registry lead, Matthew Kelly, MD, Los Angeles Medical Center, looked closely at registry data to better understand why patients were returning. He found that many patients who returned didn’t have a medical emergency but instead returned for redness or swelling that were part of the normal, post-operative total joint replacement healing.

He convened his colleagues to discuss this finding and recommend solutions. As a result, the medical center redesigned its processes, patient materials and classes to provide patients with the support and information they need to recover comfortably, quickly and safely at home, whenever possible. These changes have resulted in a more than 50% decrease in ED visits after hip and knee replacements at Los Angeles Medical Center.

“It’s very gratifying to see how our initiatives are preventing many of those ED visits, as well as readmissions,” said Dr. Kelly. “Equally gratifying is that our colleagues across the country are now implementing similar efforts.”
Kaiser Permanente is already on the low end of the spectrum when it comes to readmitting patients within 30 days after total hip replacement; 3.6% of KP patients are readmitted within 30 days, compared to national rates ranging from 4% to 11%.

At KP, the implant registries help surgeons identify what causes these readmissions so that surgeons can develop programs and clinical practices to maintain and reduce readmission rates. “Through the registry, we identified that surgical wound management comprised a large proportion of the reasons patients were readmitted,” noted orthopedic surgeon Robert Namba, MD, Orange County Medical Center. Based on these findings, many orthopedic surgeons began to use tranexamic acid, a medication that reduces bleeding during surgery. “It is anticipated that the use of tranexamic acid will reduce the incidence of postoperative wound drainage and swelling related to bleeding after surgery,” said Dr. Namba. “We expect that this practice change will likely lead to the reduction of wound-related readmissions.”

The registry also identified male gender, increased patient age, and severe obesity as other important factors associated with readmissions of total joint patients. Surgeons then initiated a number of efforts to address these risk factors prior to surgery, such as weight management programs for obese patients and screening tests and evaluations for patients with chronic conditions. “The use of screening tests and preoperative evaluation by internists has definitely improved the management of my patients who are scheduled to have total hip arthroplasty,” said Dr. Namba. Many KP orthopedic practices have also started conducting post-op drop-in clinics, initiating post-discharge telephone calls and using digital photographs from home health providers to speed evaluation and early resolution of wound-related issues.

Registry data will continue to help surgeons identify the practice and process changes that will help keep patients at home and speed their recovery.
New, minimally invasive surgical techniques, multimodal pain management, and the use of home health and outpatient physical therapy allow patients to spend a greater part of their recovery at home. “We believe it’s valuable for patients to go home earlier, as long as they feel safe and comfortable,” said orthopedic surgeon Ronald Navarro, MD, South Bay Medical Center. “So we wanted to investigate the safety of shorter stays versus longer stays for several procedures.”

Kaiser Permanente’s implant registries provided the data to evaluate the outcomes and determine the optimal length of stay for different types of patients and surgical procedures. For example, the registry showed that patients who stayed two days instead of three following total knee replacement were at no greater risk of being readmitted to the hospital within 30 days. “As a result of this and other studies, we are now routinely releasing our knee replacement patients after a two-day stay,” noted Dr. Navarro. “We also see more patients choosing to go home after one night, and some are even going home the same day.”

Another study showed that same-day discharge following shoulder arthroplasty is as safe as a longer stay, in terms of the risk of short-term readmissions and ED visits. Same-day discharge for shoulder arthroplasty is not yet standard practice, but is being evaluated. “We are embarking on a test of change to see if some patients can go home after one night instead of two and if some can possibly go home the same day,” said Dr. Navarro. “We do not anticipate a same-day discharge for all shoulder patients, but we do see a gradual change to shorter lengths of stay in general.”
Kaiser Permanente regards the poor performance or failure of any medical device as a serious patient safety issue that must be resolved without delay. The registries greatly speed up the process of identifying outlier implants and enable KP to alert the wider medical community to potential problems. “Our goal is to find these implants and notify our surgeons early in the process,” said orthopedic surgeon Thomas Barber, MD, Oakland Medical Center. “This enables our surgeons to choose another implant that will lead to a better outcome for our patients.”

KP played a major role in detecting issues with a hip resurfacing system, which at one time, was widely used as a bone-conserving alternative to total hip replacement. The registry showed that, seven years after being implanted, this procedure had three times the revision rate compared to total hip replacement. KP surgeons responded by significantly reducing use of the device from 261 in 2008, to just 85 in 2012. Today, this implant is used only infrequently, and only in patients who already had the device successfully implanted in the opposite hip.

KP’s registries also clearly demonstrated their value in ensuring patient safety following the recall of a particular implantable cardioverter defibrillator (ICD) lead after it was found to result in serious adverse events, including death. Just one day after the manufacturer issued a recall, KP’s registry identified all KP patients who had the affected implant. “The strength of the registry is that it enabled us to properly identify the patients, notify them and then bring them in for appropriate management,” said electrophysiologist Nigel Gupta, MD, Los Angeles Medical Center. Patients identified through the registry as having this device were continually and closely monitored by their physicians and their devices were frequently interrogated for electrical abnormalities. Many patients were supplied with a home monitoring device to check their implant performance on a daily basis.

In 2012, the registries received the John Eisenberg award for Innovation in Patient Safety and Quality and has worked with the Food and Drug Administration in identifying devices with safety issues. “I’m always reassured to know that the registry is running in the background, looking for device performance,” said Dr. Gupta. “It’s a valuable resource for physicians and hospitals both within and beyond KP.”
Highlights from our registries
Clinical Findings

- In an assessment of age-specific risk factors for revision among 21,304 primary ACLR cases, the registry found that the adjusted revision risk for younger patients was significantly higher than older patients and allografts had a higher risk of revision than patellar tendon autografts in all patients under the age of 40 years (Maletis et al. 2015).
- In a case-control study of 124 primary hamstring autograft ACLRs matched with 367 controls, it was found that within the range from 7.0mm to 9.0mm, there is a 19% decrease in the likelihood of being a revision case with every 0.5mm increase in graft diameter (Spragg et al. 2016).
- In our cohort of 5,968 primary allograft ACLRs, graft irradiation greater than 1.8 Mrad, BioCleanse graft processing, younger patient age, male patients, and patellar tendon allograft were all associated with a higher risk of clinical failure and subsequent revision surgery (Tejwani et al. 2015).
- A study of 636 primary ACLR cases evaluating the association of preoperative Knee Injury and Osteoarthritis Outcome Score (KOOS) and structural injuries reported at the time of primary ACLR found that the KOOS and its subscales are not useful indicators of the pattern or severity of preoperative injury (Inacio et al. 2015).

Quality Initiatives

- The registry provides reports to allow surgeons to appropriately target selection of graft type by age, gender, and activity level.
- In order to continuously identify opportunities for decreasing revision rates, the registry annually provides risk-adjusted revision rates by medical center to orthopedic leaders to address unwanted variation and share best practices from highest performing centers.

Registry Champions: Gregory Maletis, MD; Tadashi Funahashi, MD; Anita Rao, MD; Mark Shaieb, MD; David Gladu, MD; Ron Wyatt, MD
### Anterior Cruciate Ligament Reconstruction
**KP compared to benchmarks**

<table>
<thead>
<tr>
<th>Characteristic n (%)</th>
<th>Kaiser Permanente</th>
<th>Danish Cruciate Ligament Register</th>
<th>Luxembourg National Ligament Register</th>
<th>Norwegian National Knee Ligament Register</th>
<th>Swedish National ACL Register</th>
<th>UK National Ligament Register</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total N</strong></td>
<td>30,398</td>
<td>23,921</td>
<td>349</td>
<td>19,382</td>
<td>32,466</td>
<td>4,811</td>
</tr>
<tr>
<td><strong>Primaries</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td>28,055 (92.3)</td>
<td>21,820 (91.2)</td>
<td>300 (86.0)</td>
<td>17,735 (91.5)</td>
<td>30,422 (93.7)</td>
<td>4,811 (100.0)</td>
</tr>
<tr>
<td><strong>Revisions</strong>&lt;sup&gt;b&lt;/sup&gt;</td>
<td>2,343 (7.7)</td>
<td>2,101 (8.8)</td>
<td>49 (14.0)</td>
<td>1,647 (8.5)</td>
<td>2,044 (6.3)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td><strong>Gender</strong>&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Males</strong></td>
<td>19,087 (62.8)</td>
<td>14,424 (60.3)</td>
<td>246 (70.5)</td>
<td>10,084 (56.9)</td>
<td>18,699 (57.6)</td>
<td>3,464 (72.0)</td>
</tr>
<tr>
<td><strong>Females</strong></td>
<td>11,311 (37.2)</td>
<td>9,497 (39.7)</td>
<td>103 (29.5)</td>
<td>7,651 (43.1)</td>
<td>13,767 (42.4)</td>
<td>1,347 (28.0)</td>
</tr>
<tr>
<td><strong>Age years</strong>&lt;sup&gt;d&lt;/sup&gt; (at time of surgery)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>&lt; 25</strong></td>
<td>13,664 (45.0)</td>
<td>10,543 (44.1)</td>
<td>142 (40.7)</td>
<td>7,804 (44.0)</td>
<td>16,313 (50.2)</td>
<td>1,506 (31.3)</td>
</tr>
<tr>
<td><strong>≥ 25</strong></td>
<td>16,734 (55.0)</td>
<td>13,378 (55.9)</td>
<td>207 (59.3)</td>
<td>9,931 (56.0)</td>
<td>16,153 (49.8)</td>
<td>2,287 (47.5)</td>
</tr>
</tbody>
</table>

### Outcomes following primary ACL reconstruction

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Kaiser Permanente</th>
<th>Danish Cruciate Ligament Register</th>
<th>Luxembourg National Ligament Register</th>
<th>Norwegian National Knee Ligament Register</th>
<th>Swedish National ACL Register</th>
<th>UK National Ligament Register</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reoperations</strong></td>
<td>1,640 (5.8)</td>
<td>1,419 (6.5)</td>
<td>Not reported</td>
<td>657 (3.7)</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td><strong>Contralateral Knee Operations</strong></td>
<td>850 (3.0)</td>
<td>Not reported</td>
<td>5 (1.7)</td>
<td>458 (2.6)</td>
<td>921 (3.0)</td>
<td>Not reported</td>
</tr>
<tr>
<td><strong>Revisions</strong></td>
<td>941 (3.4)</td>
<td>1,002 (4.6)</td>
<td>11 (3.7)</td>
<td>777 (4.4)</td>
<td>975 (3.2)</td>
<td>Not reported</td>
</tr>
<tr>
<td><strong>Revisions 100 person-yrs.</strong>&lt;sup&gt;d&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1 year</strong></td>
<td>0.91</td>
<td>Not reported</td>
<td>1.5</td>
<td>0.95</td>
<td>0.56</td>
<td>Not reported</td>
</tr>
<tr>
<td><strong>3 year</strong></td>
<td>1.21</td>
<td>Not reported</td>
<td>4.9</td>
<td>1.21</td>
<td>0.95</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

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<sup>a</sup> Total number of primary ACL reconstruction procedures registered.

<sup>b</sup> Total number of revision patient(s) registered.

<sup>c</sup> Data available through Norwegian registry for primaries only.

<sup>d</sup> The rate of revisions over the total person-years at risk for the given time period.
Cardiac Device Registry

Clinical Findings

- The cardiac device registry monitors 30 day post-operative procedural complications, surgical site infections, and long term mechanical device complications.
- Surgical site infection (SSI) rate is < 1% for KP patients with cardiac implantable electronic devices. Occurrence of infection can be devastating to the patient and costly to manage. Leveraging KP’s integrated electronic health record, SSI’s of registered patients are identified using an electronic screening algorithm and confirmed via manual chart review by clinical content experts. (Anthony et al. 2015)

Quality initiatives:

- The registry provides an annual report to inform the KP Cardiac Rhythm Management National Contracting Team about devices that are explanted for upgrade or replacement prior to the expected warranty period. In addition, the registry validates re-operations and reports to an interregional cardiology and electrophysiology team about all procedures performed to remove, revise, repair, or reposition the pulse generator or lead.
- Registry data was the foundation for a project in Northern and Southern California to increase the use of remote monitoring of implanted devices. Remote monitoring, as an evidence-based clinical practice, can help lessen time to clinical intervention if a problem arises and can reduce the number of visits for asymptomatic device checks with the physician or clinic staff. The registry identified all patients with devices with remote monitoring capability to support this clinical initiative.

Registry Champions: Nigel Gupta, MD; Kevin Kwaku, MD, PhD; Kelly Richardson, MD; Cesar Alberte-Lista, MD; Angela Morello, MD; Jason Rashkin, MD; Brant Liu, MD; Jitesh Vasadia, MD; Rasoul Mokabberi, MD
### Registry Volume by Device Type (2000-Q2 2015)

<table>
<thead>
<tr>
<th>Device Type</th>
<th># Implants</th>
<th>% Initial</th>
<th>% Replacement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemaker</td>
<td>71,396</td>
<td>75%</td>
<td>25%</td>
</tr>
<tr>
<td>ICD</td>
<td>24,823</td>
<td>70%</td>
<td>30%</td>
</tr>
<tr>
<td>Cardiac Resynchronization Therapy</td>
<td>8,579</td>
<td>62%</td>
<td>38%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>104,798</strong></td>
<td><strong>73%</strong></td>
<td><strong>27%</strong></td>
</tr>
</tbody>
</table>

### Post-Operative Complication Rates by Device Type (2011-Q2 2015)

<table>
<thead>
<tr>
<th></th>
<th>Pacemaker</th>
<th>ICD</th>
<th>CRT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma</td>
<td>0.18%</td>
<td>0.23%</td>
<td>0.44%</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>0.55%</td>
<td>0.19%</td>
<td>0.17%</td>
</tr>
<tr>
<td>Tamponade</td>
<td>0.27%</td>
<td>0.06%</td>
<td>0.22%</td>
</tr>
<tr>
<td>Deep Infection</td>
<td>0.31%</td>
<td>0.48%</td>
<td>0.77%</td>
</tr>
</tbody>
</table>
Endovascular Stent Graft Registry

Description:
This registry was established in 2010 and tracks endovascular stent grafts used for the repair of abdominal aortic aneurysm (AAA). The procedure used to place the stent grafts is endovascular aneurysm repair (EVAR).

Clinical Findings
Most patients undergoing an EVAR are male (83%), Caucasian (71%), BMI < 30, and with a mean age of 74.4 years. The registry leverages the electronic health record to monitor post-operative outcomes. The registry tracks 3 main categories of re-interventions for the lifetime of the registered patients: secondary interventions, revision of stent graft components, and conversion to open repair. Endoleak is the most common reason for re-intervention.

In a study of 2112 EVARs performed between 2010 - 2013, there was a transition in the arterial access surgical approach from femoral artery cutdown to an increase in percutaneous access from 20% of cases in 2010 to 50% of cases in 2013. Overall survival of the cohort was 88% at 3 years. (Hye et al. 2015)

A comparison of open surgical repair and EVAR for the treatment of ruptured AAA showed an improved 30 day survival rate in the EVAR group, but a non-significant difference between the groups at one year. The frequency of complications was higher in the open group. (Chang et al. 2014)

Registry champions: Bradley Hill, MD, Jeffrey Hsu, MD, Nicolas Nelken, MD, Thomas Rehring, MD, Homayon Hajarizadeh, MD, Shyam Krishnan, MD

(In memoriam: Robert J Hye, MD)

| Volume of registry cases by year (all regions) |
|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| 2010  | 2011  | 2012  | 2013  | 2014  | Total  |
| 542   | 574   | 668   | 682   | 595   | 3061   |
Hip Fracture Registry

Description:
Established in 2009, the hip fracture registry tracks primary surgery of the proximal femur. As of year end 2014, 29,414 primary hip fracture cases and 981 revisions were tracked.

Clinical Findings
- A study of 7,585 patients found no difference in mortality rates by anesthetic type. (Brox et al. 2016)
- To measure the association between hospital and surgeon volume with mortality, readmission, medical complications and reoperation, 14,294 procedures from 2009 to 2013 were classified into tertiles (low/medium/high). There was no association between surgeon or hospital volume and mortality (30-day, 90-day, 1-year), reoperation (lifetime), medical complications (90-day) or readmission (30-day unplanned). (Okike et al. 2016)

Quality Initiatives
- Quarterly Quality Reports (QQR), provide performance comparisons from local to region and national rates. Follow up requests, including case level data, are disseminated to facilitate additional investigation into postoperative outcome data over time.
- The Registry supports the work for standardized optimization protocol from ED/Inpatient admission to Operating Room. Dashboard reports across medical facilities are provided quarterly to hip fracture leads and their affiliated leadership to assist in this endeavor.

Registry Champions: Gary Zohman, MD; Christopher Grimsrud, MD; James Jackman, MD; Eugene Toney, MD; Kanu Okike, MD
## Hip Fracture Registry

### KP compared to benchmarks

<table>
<thead>
<tr>
<th>Registry</th>
<th>Annual Volume</th>
<th>Female</th>
<th>Mean Age</th>
<th>Revision Rate</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaiser Permanente (2009-2014)</td>
<td>29,414</td>
<td>68%</td>
<td>78</td>
<td>3.14% lifetime rate</td>
<td>5.3% at 30 days 10.4% at 90 days</td>
</tr>
<tr>
<td>Register of Ortho Prosthetic Implantology Italy Annual Report (2000-2013)</td>
<td>31,725</td>
<td>75%</td>
<td>83</td>
<td>3.2% Unknown follow up time</td>
<td>4.6% during hospitalization</td>
</tr>
<tr>
<td>UK National Hip Fracture Database Annual Report 2015</td>
<td>65,000</td>
<td>75%</td>
<td>83</td>
<td>1.1% Reoperation &lt; 30 days</td>
<td>8.2% at 30 days</td>
</tr>
<tr>
<td>Swedish Arthroplasty Register (2005-2012); Dept of Ortho: Södersjukhuset - Stockholm (1996-2005)</td>
<td>45,362</td>
<td>70%</td>
<td>83</td>
<td>3.4% at 6 mos</td>
<td>13% at 90 days</td>
</tr>
<tr>
<td>Scottish Hip Fracture Audit Report (2008); NHS Quality Improvement Scotland (2009); Scottish Arthroplasty Project (2014)</td>
<td>6,369 (Jan-Dec 2007)</td>
<td>76%</td>
<td>80</td>
<td>27.6% revisions of non-elective cases</td>
<td>9% at 30 days 20.8% at 120 days</td>
</tr>
<tr>
<td>Australian Orthopedic Association (Annual Report 2003-2014)</td>
<td>71,241</td>
<td>72%</td>
<td>84</td>
<td>3.55%</td>
<td>At 1 year: 36% unipolar monoblock 23% unipolar modular 21% bipolar</td>
</tr>
<tr>
<td>Norwegian Hip Fracture Register (2005-2014) EuroHOPE patient database</td>
<td>79, 775 (8,000 avg/yr)</td>
<td>70%</td>
<td>80</td>
<td>11.9% reoperations</td>
<td>8.4% at 30 days 25.3% at 1 year (surgery cases in 2009)</td>
</tr>
<tr>
<td>Hip Fracture Registry</td>
<td>Time to Surgery</td>
<td>Length of Stay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------</td>
<td>---------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kaiser Permanente</td>
<td>28.6 hours</td>
<td>5.19 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2009-2014)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Register of Orthopedic Prosthetic Implantology</td>
<td>Mean: 2.9 days (2013)</td>
<td>not reported</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Italy Annual Report (2000-2013)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK National Hip Fracture Database</td>
<td>72% within 2 days</td>
<td>20.3 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual Report 2015</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swedish Arthroplasty Register</td>
<td>Mean: 1.2 days</td>
<td>10.7 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scottish Hip Fracture Audit Report (2008); NHS Quality Improvement Scotland (2009); Scottish Arthroplasty Project (2014)</td>
<td>95% within 24hrs</td>
<td>Median 10 days admitted from a care home, 24 days from own residence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Norwegian Hip Fracture Register (2005-2014); EuroHOPE patient database</td>
<td>85% within 48 hrs (2014) (excluding THAs)</td>
<td>9.8 days</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Clinical findings

- Findings of elective primary shoulder arthroplasties: In 6,336 primary cases: female (56%), white (81%), average age of 70 years. The reason for primary procedures included osteoarthritis (60%), acute fracture (17%), rotator cuff tear arthropathy (15%). All cause revision was 4% with glenoid wear the most common reason.

- Surgeon-specific risk factors for periprosthetic deep infection: in 8,056 shoulder arthroplasties, the incidence of deep infection was 1.1% with a median follow-up of 38.8 months. Longer operative time, age <60 years and RTSA were associated with postoperative infection. There was an association of deep infection with shoulder arthroplasty procedures lasting longer than 150 minutes, with a 19% increase in risk with each additional 30 minutes exposure.

- Same day discharge is not inferior to longer length of stay in shoulder arthroplasty: when compared to longer length of stay counterparts, same-day discharge had 0.78 lower odds in 30-day readmission, and 0.51 lower odds in 90-day readmission. For unplanned emergency visit within 30 days, same day discharge had 0.52 lower odds (UCL=0.75, p for non-inferiority <0.001).

Quality initiatives

- The registry identified complication rates higher in patients <59 years of age with osteoarthritis treated with a hemiarthroplasty procedure compared to TSA.

- The registry provided individualized reports to each surgeon detailing volume, technique, implant, and outcomes information that is benchmarked against the region and program-wide.

- Surgeons are using findings from current research to reduce the length of stay at the time of elective TSA and RTSA procedures in the appropriate patient population.

Registry Champions: Ronald Navarro, MD, Mark Dillon, MD, Mark Shaieb, MD, Terrill Julien, MD, Darin Allred, MD, Matthew Budge, MD, Anita Rao, MD
## Shoulder Arthroplasty Registry

### KP compared to benchmarks

<table>
<thead>
<tr>
<th></th>
<th>Kaiser Permanente</th>
<th>Australia Orthopaedic Association Shoulder Arthroplasty</th>
<th>The New Zealand Joint Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Volume</strong></td>
<td>10,983</td>
<td>27,236</td>
<td>5,528</td>
</tr>
<tr>
<td><strong>Gender, Female</strong></td>
<td>56.3%</td>
<td>62.7%</td>
<td>63.49%</td>
</tr>
<tr>
<td><strong>Mean Age (years)</strong></td>
<td>71.21</td>
<td>74 (Female)</td>
<td>70.79</td>
</tr>
<tr>
<td><strong>Revision Rate</strong></td>
<td></td>
<td>TSA:0.77/100 obs yrs. RTSA:1.58/100 obs yrs. (2014 Annual Report)</td>
<td>TSA:1.88/100 obs yrs. RTSA:1.35/100 obs yrs. (2014 Annual Report)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.04/100 obs (observed component yrs.)</td>
</tr>
<tr>
<td><strong>Top 3 Reasons for Primary</strong></td>
<td>Fracture</td>
<td>Osteoarthritis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rotator cuff arthropathy</td>
<td>Rotator cuff arthropathy Fracture</td>
<td>Osteoarthritis Cuff tear arthropathy Fracture of proximal humerus</td>
</tr>
<tr>
<td><strong>Top 3 Reasons for Revision</strong></td>
<td>Glenoid wear after hemi Rotator cuff tear Glenoid component loosening</td>
<td>Not reported</td>
<td>Pain Dislocation/instability Sub acromial cuff impingement</td>
</tr>
<tr>
<td><strong>Outcome</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>0.9%</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>DVT</td>
<td>0.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulmonary Embolism (PE)</td>
<td>0.5%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Clinical Findings

- Risk factors associated with 30-day readmission: in 14,941 patients with longer operative time (>200 min), length of stay > 6 days, surgical complications and diagnosis of: depression, hypothyroidism, deficiency anemia, rheumatoid arthritis and malignancy were all risk factors for readmission.
- Bone Morphogenetic Protein (BMP) usage and posterior cervical fusion: the use of BMP had no effect on operative nonunion rates in the posterior cervical fusions for the subaxial cervical spine and the cervicothoracic spine in 1,158 patients.
- Anterior Cervical Discectomy and Fusion (ACDF) and operative nonunion rate: 1,054 patients followed for >2 years were found to have reoperations for nonunions of 0.2%, 2.9%, and 6.5% for 1-level, 2-level and 3-level ACDFs respectively. This is significantly less than previously reported for radiographic nonunions.

Quality initiatives

- Registry research found no difference in operative fusion rates with and without BMP. Guidelines were developed to target appropriate use of BMP in spine fusion. These guidelines have resulted in a drop in the use of BMP in fusion procedures from 63% in 2009 to 29% in Q1 2015. At the same time, national averages have remained constant.
- Using findings from research supported by the registry, several facilities implemented a post-discharge protocol to stratify the patients based upon diagnosis and severity of the index procedure. This grouping determines appropriate clinical care once the patient leaves the hospital.

Registry Champions: Kern Guppy, PhD, MD, Johannes Bernbeck, MD, Harsimran Brara, MD, Loren Jenkins, MD.
## Spine Surgery
### KP compared to benchmarks

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Volume</strong></td>
<td>19,348</td>
<td>81,885</td>
</tr>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>57.9 years</td>
<td>Not reported</td>
</tr>
<tr>
<td>Gender</td>
<td>52.9 Female</td>
<td>Not reported</td>
</tr>
<tr>
<td>BMI &lt;30</td>
<td>64.7%</td>
<td>~60%</td>
</tr>
<tr>
<td>Current Smokers</td>
<td>10.7%</td>
<td>~40%</td>
</tr>
<tr>
<td>Diagnosis – Degenerative</td>
<td>61.3%</td>
<td>80%</td>
</tr>
<tr>
<td><strong>Fusion Approach</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anterior</td>
<td>31%</td>
<td>Not reported</td>
</tr>
<tr>
<td>Posterior</td>
<td>52%</td>
<td>Not reported</td>
</tr>
<tr>
<td>Combined</td>
<td>17%</td>
<td>Not reported</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dural Tear</td>
<td>2.7%</td>
<td>4.7%</td>
</tr>
<tr>
<td>Infection</td>
<td>1.3%</td>
<td>~3%</td>
</tr>
<tr>
<td>Reoperation Rate – nonunion</td>
<td>4.3%</td>
<td>~18%</td>
</tr>
<tr>
<td>Reoperation Rate - ASD</td>
<td>2.8%</td>
<td>~23%</td>
</tr>
<tr>
<td><strong>Use of BMP or Similar Product</strong></td>
<td>29%</td>
<td>&lt;10%</td>
</tr>
</tbody>
</table>
Clinical findings

- A study of 30,499 Total Knee Arthroplasty (TKA) patients suggests fondaparinux and warfarin are more effective than aspirin in the prevention of pulmonary embolism with a comparable risk of major bleeding.

- Research with 23,726 TKA patients found that at least 41% of patients continued using opioids beyond 90 days. Younger age, liver disease, pre-operative NSAID use, anxiety, substance abuse, diabetes, and pre-operative opioid use were associated with greater opioid prescriptions at all time periods.

- A study of 12,859 Total Hip Arthroplasty (THA) patients indicated that persistent use of opioids beyond 90 days was associated with revision THA surgery and could be used as an early indicator of potential risk of 1 and 5 year revision.

- In 11,118 patients with advanced bilateral knee arthritis, research indicated that bilateral simultaneous TKA (bilateral knee procedures completed on the same day) was not found to increase risk of immediate complications such as death, cardiac event, VTE or stroke or revision rates compared to bilateral staged TKA (bilateral knee procedures completed at least 90 days apart).

Quality initiatives

- Distribute quarterly TJRR quality reports that include complications (DVT/PE, deep surgical site infections, revisions, emergency department visits, readmissions) and mortality by medical center, region, and program-wide to orthopedic chiefs, clinic department administrators, infection control, perioperative directors, quality committees, risk management, and quality personnel.

- Provide individualized reports to each surgeon annually, detailing volume, technique, implant, and outcomes information that is benchmarked against their medical center, the region and program-wide.

- Provide detailed case level data for in-depth review by medical center quality leaders for continuous quality improvement and use in evaluating interventions to reduce complications.

- Provide surveillance of TJRR implant performance, identifying devices and combination of devices associated with high and low revision rates. Both statistical analysis and case review by clinical leaders guide recommendations and further monitoring.

Registry Champions: David F. Wiener, MD, David L. Boardman, MD, Eric Yue, MD, Erik W. Kroger, MD, Monique A. Grey-McBride, MD, Matthew P. Kelly, MD, Maurice Cates, MD, Michael L. Reyes, MD, Thomas Stoll, MD, Thomas C. Barber, MD
### Total Hip Arthroplasty: 2015 Annual Report Results
#### KP compared to benchmarks

<table>
<thead>
<tr>
<th>Registry</th>
<th>Kaiser Permanente Total Joint Replacement Registry</th>
<th>Australian Orthopedic Association National Joint Registry</th>
<th>National Joint Registry UK</th>
<th>Swedish Hip Arthroplasty Register</th>
<th>Norwegian Arthroplasty Register</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Criteria</td>
<td>THA primaries</td>
<td>THA OA diagnosis</td>
<td>TKA primaries</td>
<td>THA primaries</td>
<td>THA primaries</td>
</tr>
<tr>
<td>Total Cases</td>
<td>66,991</td>
<td>262,454</td>
<td>708,311</td>
<td>99,022</td>
<td>163,690</td>
</tr>
<tr>
<td>Age</td>
<td>25,310 age 70+ (37.8%)</td>
<td>79,922 age 75+ (30.5%)</td>
<td>214,333 age 75+ (30.3%)</td>
<td>87,718 age 75+ (24.4%)</td>
<td>69.0 mean age</td>
</tr>
<tr>
<td>Female</td>
<td>38,334 (57.2%)</td>
<td>143,197 (54.6%)</td>
<td>422,862 (59.7%)</td>
<td>57,356 (57.9%)</td>
<td>110,327 (67.4%)</td>
</tr>
<tr>
<td>10 Yr Survival % (CI)</td>
<td>95.3 (95.0-95.5)</td>
<td>94.8 (94.6-94.9)</td>
<td>94.4 (94.3-94.5)</td>
<td>94.7 (94.4-94.9)</td>
<td>93.1 (95.0)</td>
</tr>
</tbody>
</table>

### Total Knee Arthroplasty: 2015 Annual Report Results
#### KP compared to benchmarks

<table>
<thead>
<tr>
<th>Registry</th>
<th>Kaiser Permanente Total Joint Replacement Registry</th>
<th>Australian Orthopedic Association National Joint Registry</th>
<th>National Joint Registry UK</th>
<th>Swedish Knee Arthroplasty Register</th>
<th>Norwegian Arthroplasty Register</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Criteria</td>
<td>TKA primaries</td>
<td>TKA OA diagnosis</td>
<td>TKA primaries</td>
<td>TKA primaries</td>
<td>TKA primaries</td>
</tr>
<tr>
<td>Total Cases</td>
<td>127,286</td>
<td>432,833</td>
<td>772,818</td>
<td>108,489</td>
<td>62,561</td>
</tr>
<tr>
<td>Age</td>
<td>53,048 age 70+ (41.7%)</td>
<td>125,486 age 75+ (29.0%)</td>
<td>236,996 age 75+ (30.37%)</td>
<td>101,578 age 55+ (93.6%)</td>
<td>68.7 mean age</td>
</tr>
<tr>
<td>Female</td>
<td>78,636 (61.8%)</td>
<td>245,247 (56.7%)</td>
<td>440,506 (57.0%)</td>
<td>64,150 (59.1%)</td>
<td>40,540 (64.8%)</td>
</tr>
<tr>
<td>10 Yr Survival % (CI)</td>
<td>95.4 (95.2-95.6)</td>
<td>94.5 (94.4-94.6)</td>
<td>95.5 (95.4-95.6)</td>
<td>96.01 (92.96-96.24)</td>
<td>92.6 (95.0)</td>
</tr>
</tbody>
</table>
### Total Hip Arthroplasty: 2015 Annual Report Results
#### Annual THA Revision Burden

<table>
<thead>
<tr>
<th>Year</th>
<th>KP</th>
<th>AJRR</th>
<th>NJR</th>
<th>NAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>8.2%</td>
<td>Not reported</td>
<td>10.9%</td>
<td>14.9%</td>
</tr>
<tr>
<td>2012</td>
<td>10.0%</td>
<td>Not reported</td>
<td>11.7%</td>
<td>14.3%</td>
</tr>
<tr>
<td>2013</td>
<td>9.1%</td>
<td>Not reported</td>
<td>10.4%</td>
<td>13.9%</td>
</tr>
<tr>
<td>2014</td>
<td>8.7%</td>
<td>Not reported</td>
<td>10.0%</td>
<td>13.7%</td>
</tr>
</tbody>
</table>

### Total Knee Arthroplasty: 2015 Annual Report Results
#### Annual TKA Revision Burden

<table>
<thead>
<tr>
<th>Year</th>
<th>KP</th>
<th>AJRR</th>
<th>NJR</th>
<th>NAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>5.3%</td>
<td>Not reported</td>
<td>5.6%</td>
<td>8.2%</td>
</tr>
<tr>
<td>2012</td>
<td>5.9%</td>
<td>Not reported</td>
<td>6.1%</td>
<td>8.5%</td>
</tr>
<tr>
<td>2013</td>
<td>5.7%</td>
<td>Not reported</td>
<td>5.6%</td>
<td>7.9%</td>
</tr>
<tr>
<td>2014</td>
<td>5.7%</td>
<td>Not reported</td>
<td>5.2%</td>
<td>7.5%</td>
</tr>
</tbody>
</table>

**Registries:**
- KP: Kaiser Permanente Implant Registries
- AJRR: American Joint Replacement Registry
- NJR: National Joint Registry, UK
- NAR: Norwegian Arthroplasty Register
### Management Team
- **Liz Paxton, MA** Director
- **Jessica Harris, MS, RD** Manager
- **Mary-Lou Kiley, LCSW, MBA** Manager

### Administrative Team
- **Betty Jo Alfstad, MS** Staff Specialist
- **Donna Leck** Research Administrative Analyst

### Biostatisticians/Research Scientists
- **Guy Cafri, PhD, MStat** Research Scientist Biostatistician
- **Priscilla Chan, MS** Biostatistician II
- **Heather Prentice, PhD, MPH** Research Scientist Investigator
- **Wei Wang, PhD, MS** Biostatistician III

### Database Administrators
- **Jon Javines, BS** Senior Application Programmer/Analyst
- **Kim Phan, BA** Senior Application Development Technical Specialist

### Data Consultants/Programmers
- **Uma Bommakanthy, MA** Data Consultant
- **Yuexin (Cindy) Chen, BS** Senior Data Consultant
- **Ming Huang, MBA** Data Consultant
- **Tony Huon, BS** SAS Programmer II
- **Alan Schepps, MS** Data Consultant
- **Hong (Maggie) Sun, MS** SAS Programmer II

### Data Quality
- **Jalessia Moore** Research Associate I
- **Chelsea Reyes** Project Analyst
- **Nicole Sankowski, BS** Research Associate I

### Project Managers
- **William Burfiend, BS** Project Manager III
- **Brian Fasig, PhD** Project Manager III
- **Jessica Hunt, MA** Project Manager II

### Quality Reporting
- **Rebecca Love, MPH, RN** Senior Consultant
- **Anna Ritko, MA, MPhil** Research Application Development Analyst II

### Research Associates
- **Janine Cruz, BA** Research Associate II
- **Kristen Mays, MA** Research Associate III
- **Tia Mullane, BA** Research Associate II
- **Andrew (Scott) Thomas, BS** Research Associate II
Anterior Cruciate Ligament Reconstruction

2015


2014


2013


Anterior Cruciate Ligament Reconstruction

continued from page 30

2012


2011


2009

2008


2007

2005


2003

Anterior Cruciate Ligament Reconstruction

continued from page 31

2002

Cardiac Device

2015

Endovascular Stents

2015

Heart Valve Replacement

2013

Hip Fracture

2015

Shoulder Arthroplasty Replacement

2015


2014


2013

Shoulder Arthroplasty Replacement

continued from page 32

2007

2005

2003

Spine

2015


2014

Total Joint Replacement

2015


Total Joint Replacement
continued from page 33


2014


2013


2012


2011


Total Joint Replacement

continued from page 36

2010


2009

2008


2007

2006

2005


2004


2003
Multi-Registry

2013


2012

2011

Other Related Research

2015

2014

2013

2012

2010

2005