

Kaiser Permanente National Implant Registries



2017 Annual Report

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Leadership message

Dear Colleagues,

It is an honor and a privilege to present the 2017 **Kaiser Permanente National Implant Registries** annual report highlighting significant achievements in surgical outcomes, clinical research findings, and quality improvement initiatives. Our registries monitor patient characteristics, surgical approaches, implant characteristics, and clinical outcomes for more than 2.2 million cardiac, neurosurgery, orthopedic, and vascular implants for the lifetime of our 12 million members.

The registries' longitudinal tracking of implant performance provides the foundation for optimal surgical care through identification and dissemination of clinical best practices, translating registry findings into clinical care, and continuous monitoring of patient outcomes. We are proud to announce that our impact on quality of care was recognized in 2018 with the prestigious **Orthopaedic Research and Education Foundation Clinical Research** award for outstanding Anterior Cruciate Ligament reconstruction (ACLR) research. Our ACLR registry's translation of research findings into clinical care are highlighted in this year's annual report along with other key implant registry accomplishments:

- Decreased use of high-risk allografts and decreased use of allografts in young ACLR patients.
- Identification of medical devices at higher risk for complications and revisions
- Reduction of elapsed time from the time a hip fracture patient is admitted to the hospital to the time they have surgery.
- Increased use of total shoulder arthroplasty same-day discharge as a way to improve outcomes, enhance the patient experience, and reduce health care costs.
- Implementation of strategies to reduce unsafe prolonged opioid use among total joint replacement patients, with a marked reduction of opioid use for more than 90 days after surgery.

The success of our implant registries program is a reflection of the excellent Kaiser Permanente physician leadership and strong evidence-based medicine culture transforming quality of care. Our implant registries are enhancing quality and patient safety not only for our members but nationally and worldwide as we help set the standards for clinical best practices and implant performance.

Liz Paxton, MA

Director, National Implant Registries

Tadashi Funahashi, MD

Chair, Inter-Regional Implant Registries Committee

Inter-Regional Implant Registries Committee Members

IIRC Membership

Scott H. Adelman, MD, FACC

Chair-Cardiology Core Group/National Product Council

Chair-NCal Cardiovascular Technology Committee

Senior Technology Advisor-Innovation and Advanced Technology

Ralph G. Brindis, MD, MPH, MACC, FSCAI

Clinical Professor of Medicine

Department of Medicine & the Philip R. Lee Institute for Health Policy Studies

University of California, San Francisco

Eric Cain, MD, MBA

Physician-in-Chief, TPMG

Greater Southern Alameda Area

Patrick Courneya, MD

Executive Vice President, Hospitals

SVP, Hospitals, Quality and Care Delivery Excellence

Chief Medical Officer

Christopher M. Grant

Chief Operating Officer

Permanente Federation, Program Offices

Jo Carol Hiatt, MD, MBA

Chair, National Product Council

Assistant Medical Director, SCPMG Business Administration

Bradley B. Hill, MD, FACS

Chair, TPMG Vascular Surgery Chiefs Group

Chief of Vascular Surgery

Margaret Mentakis, MD, FACS

Department of Surgery, South Sacramento

KPHC Procedural and Perioperative Services

TPMG Technology Leader

Ronald Navarro, MD

Asst. Area Medical Director Surgical Services

Inter-regional Orthopedic Chief

Murray N. Ross, Ph.D.

Vice President and Director, Institute for Health Policy

Kaiser Foundation Health Plan Enhancing Patient Safety and Quality of Care

What we provide

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.





Accomplishments and collaborations

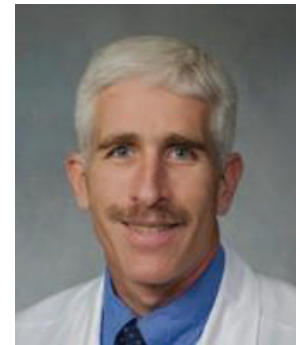
Kaiser Permanente Registry Work Receives National Recognition

Permanent Medicine physicians and Kaiser Permanente ACL Reconstruction Registry (KPACLRR) have been recognized by the American Academy of Orthopaedic Surgeons with the prestigious Orthopaedic Research and Education Foundation (OREF) Clinical Research Award.

Translating registry findings into evidence-based clinical practice is the goal of a clinical registry. Furthermore, a registry's success heavily relies on continued participation from physicians, as well as the administrative team who organize, validate, and communicate the findings. Kaiser Permanente currently maintains eight such registries: cardiac, vascular, and six in orthopedics (total hip, total knee, ACLR, shoulder, hip fracture, spine). By tracking patients and procedures, measuring which factors improve or are detrimental to patient care, and then sharing this information with physicians, the Registry program has identified a direct correlation to improved outcomes over time.

Gregory Maletis, MD, Lead Physician for the Kaiser Permanente ACLR Registry, emphasizes the impact of registries on patient care: "With most research it is difficult to determine whether the findings from a specific study actually change the way clinicians practice. Registries are unique in that one can identify risk factors for good or poor outcomes and provide that information to clinicians. It is then possible to track the positive change in practice patterns which lead to improved patient outcomes."

The Registry program at Kaiser Permanente was inspired by Sweden's own healthcare registries that trace health data spanning many decades. Given Kaiser Permanente's integrated care model and ongoing encouragement of physician collaboration, physicians leaders believed that KP was well positioned to model these similar efforts and build a registry internally.

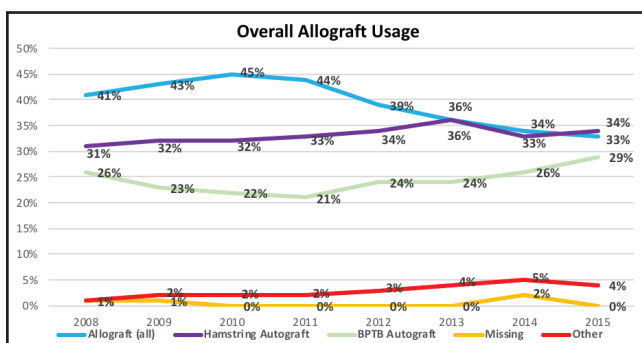


Gregory Maletis, MD
was well positioned to model these similar efforts and build a registry internally.

The Kaiser Permanente ACL Reconstruction Registry (KPACLRR) is one such example at Kaiser Permanente that has allowed Permanent Medicine physicians to continually improve the treatment of patients with anterior cruciate ligament (ACL) injuries. With over a decade of data collection and analysis, KP clinicians and patients have contributed to making the KPACLRR the largest ACL registry in the United States and have successfully demonstrated its direct impact on the quality of outcomes for patients.

The ACLR Registry work was recently acknowledged by the American Academy of Orthopaedic Surgeons in the form of the prestigious Orthopaedic Research and Education Foundation (OREF) Clinical Research Award.

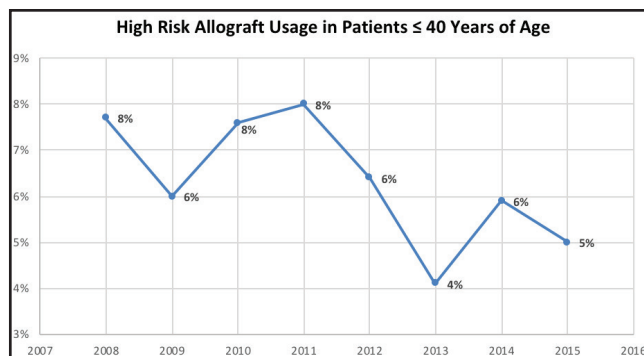
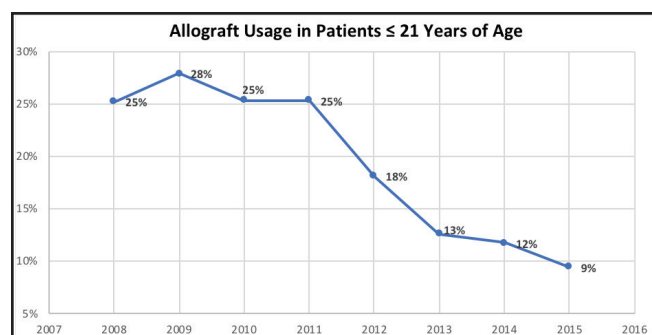
Tadashi Funahashi, MD, Assistant Regional Medical Director and Chair, Kaiser Permanente Inter-Regional Implant Registries, reflected on the award and the journey to get there: "We founded the Registries with the aspiration of building a reputation for Kaiser Permanente Orthopedic Surgery that brought pride to every orthopedic surgeon. The foundational idea was that collaboration and integration, a hallmark of Permanent Medicine, could create a world class orthopedic registry. After over a decade of effort and contributions, this recognition is shared by every orthopedic surgeon, and is a tremendously proud moment for all of us."



Every patient across eight KP regions who undergoes an ACLR is entered in the Registry, and is prospectively monitored using strict privacy controls. In addition to standardized Registry documentation, the ACLR Registry uses EHR, claims data, and other existing administrative databases, to capture patient demographics, comorbidities, anthropometric measures, surgical procedure detail, implant information, and outcomes.

This information is validated and analyzed by the Registry team, who then pass the findings through a variety of feedback mechanisms designed to influence clinical practices of orthopedic surgeons. To aid in behavior change, surgeons receive confidential individualized reports with benchmarking metrics they can use to compare their personal activity to that of the medical center, region, and organization. In addition, quality reports, annual registry reports, comparative effectiveness studies, risk calculators, and many other resources are also made available.

In disseminating feedback to physicians, the KPACLR team has, in multiple instances, demonstrated behavior change that has led to improved quality of care and outcomes. For example, analysis of Registry data on graft choice for ACL Reconstruction demonstrated that allograft use was associated with a three times higher risk of revision compared to the use of bone-patellar tendon-bone (BPTB) autografts. Furthermore, the analysis indicated that patients ≤ 21 years of age were at an elevated risk of revision

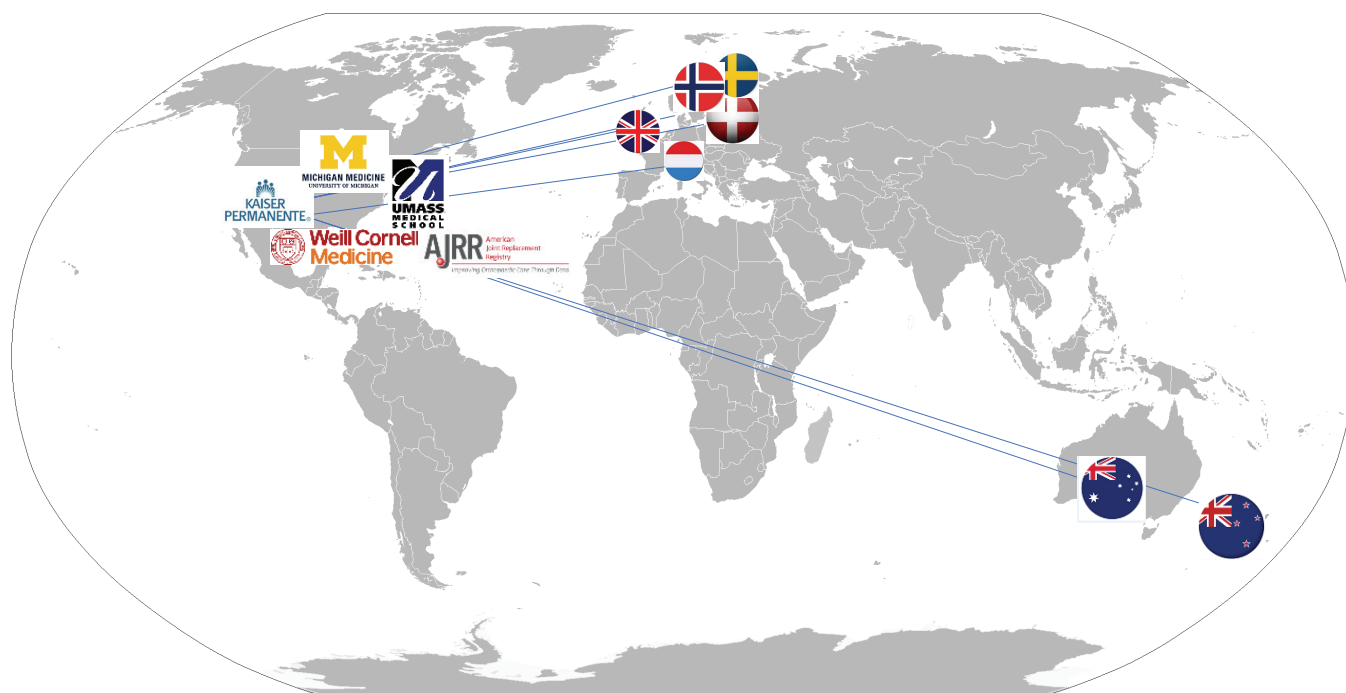


if allograft tissue was employed. This information was spread to surgeons and ultimately led to a decrease in both general allograft use (45%, 2010; 33%, 2015) and in allograft use for high-risk patients (28%, 2009; 9%, 2015).

The benefits of this work are not limited to KP patients. The potential to improve outcomes for patients receiving care elsewhere exists in the tools developed and published externally. For example, the KPACLR team has published a risk calculator accessible to anyone that helps predict which graft will have the best survival rate, and therefore allows for any ACLR patient to benefit from over a decade of longitudinal data cultivated by KP's Registry team.

When discussing what other organizations can learn from KP's Registry experience, Liz Paxton, Director of the Kaiser Permanente National Implant Registries, highlights physician engagement as a critical component to the success of any registry: "Physician involvement, conceptualization, and ownership have all been key to getting our physicians to trust and act on the data. With the support of our electronic health record, we have been able to integrate additional documentation needs into the current work flow and thus reduce additional burdens on staff. Even though every contribution is relatively small or brief in nature, the cumulative impact has allowed us to create the infrastructure that has resulted in meaningful research and insights."

Source: Carly Marker, Communications Consultant, Quality



Collaborations

- Full member of International Society of Arthroplasty Registries (ISAR). <http://www.isarhome.org/>
- 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.
- Orthopedic Coordinated Registries Network (Ortho CRN): collaboration with other US registries to create a mechanism for national post-market surveillance.
- Led International Collaboration of Orthopedic Registries (ICOR) along with Cornell to develop a network of international registries for medical device surveillance. <http://www.icor-initiative.org/>
- Medical Device Epidemiology Network (MDEpinet): Ongoing collaboration with FDA and regulators, academia, other health systems, and industry to build a national medical device evaluation system by enhancing the current infrastructure for real-world data, development of innovative methodologies, and conducting clinical studies (mdepinet.org).
- Build on international collaborations with Anterior Cruciate Ligament Reconstruction (ACLR) and Shoulder Arthroplasty Registries to detect surgical best practices based upon implant selection and surgical techniques to help deliver the highest quality of care.

National Implant Registries: By the numbers

8 regions, 9 states representing
11.7 million members

50 hospitals

133 publications in peer-reviewed journals
15 in 2016

170 posters & presentations at national &
international symposia

2,400 physicians participating in implant registries

2,584 patients with enhanced surveillance due to 11
recalls in 2015-2016

445,000+ patients in our registries

550,000+ procedures tracked for the patient's lifetime

2.15 million implants registered



ACLR Registry feedback leads to reduction in allograft use



A sprain or tear of the anterior cruciate ligament (ACL) is one of the most common knee injuries especially among athletes who participate in sports such as soccer, football, and basketball. Some people can cope with an ACL deficient knee, but those wishing to return to pivoting and twisting sports often require ACL reconstruction (ACLR).

Many factors may contribute to the outcome of ACLR surgery, including graft choice. The two main graft options available to patients for ACL reconstruction consist of autografts (donated from the patient themselves) and allografts (donated from human cadaver tissue).

The Kaiser Permanente National ACLR Registry tracks the outcome of all allograft and autograft cases performed by KP surgeons across the United States.

By 2008, the registry showed that the annual proportion of ACLR cases using an allograft was on the rise at Kaiser Permanente, hitting a peak of 45% by 2010.

That upward trend began to change in 2012 when registry findings showed a three times higher risk of revision if an allograft was used rather than a bone-patellar tendon-bone (BPTB) autograft. In subsequent studies of allografts, the registry identified poorer results with BPTB allografts compared to soft tissue allografts. Data also showed that patients ≤ 21 years

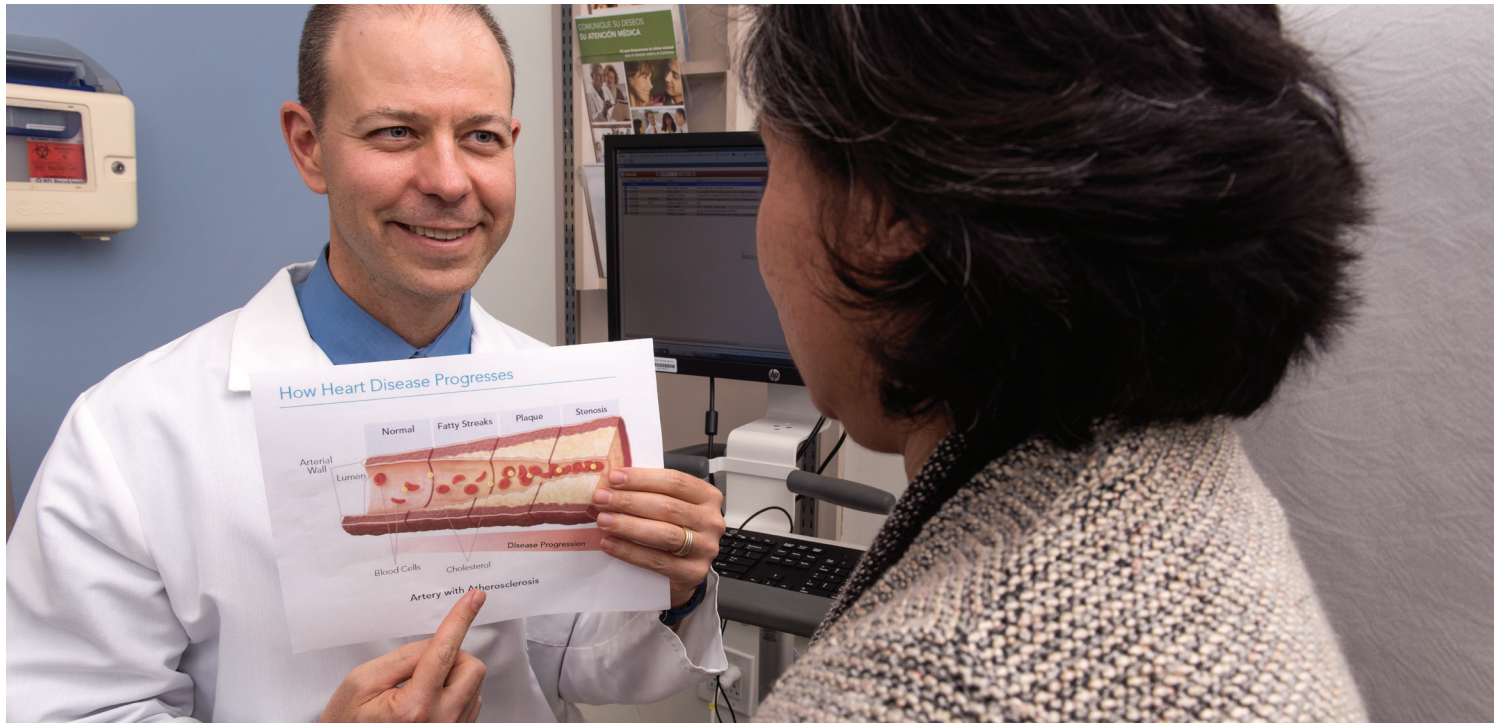
of age were at increased risk for revision when allograft tissue was used.

Findings were widely disseminated to surgeons using a variety of means including peer-reviewed publications; internal and external meetings and conferences; newsletters of study findings; risk calculators; and confidential individualized reports of surgeons' outcomes. In addition, surgeon champions set a quality improvement goal to reduce allograft usage overall and specifically to decrease the use of high-risk grafts and usage in high-risk patient groups. "By getting this information out to surgeons, we have seen decreased use of high-risk allografts and decreased use of allografts in young patients," said Greg Maletis, MD, chief of orthopedics, Baldwin Park Medical Center and ACLR physician lead. "These changes have led to better outcomes for our patients with a decreased risk of revision."

Registry data also showed that BPTB autografts have the lowest revision risk. "As a result, I am doing more BPTB autografts than in the past," said Maletis. "The registry has definitely changed my practice and that of my colleagues as well."

Kaiser Permanente has been awarded the 2018 Orthopaedic Research and Education Foundation Clinical Research Award for its ACLR Registry work.

Cardiac Device Facilitating New Technology Decision Making



Implant registries provide product performance and utilization data to the National Product Council, Kaiser Permanente's device procurement arm, to support the selection of the highest quality implant products and technologies. Innovation and new technology are encouraged, but only to the extent that they produce improved patient outcomes.



"Before any decisions are made regarding new products, we can use the registry to see if the proposed benefits would be realized in our own KP population, rather than relying on third party information or even research that may not be valid either for our patient population

or our health care delivery model," said Nigel Gupta, MD, director, Regional Cardiac Electrophysiology Services, Los Angeles Medical Center.

Dr. Gupta serves as chair of the Cardiac Rhythm Management, Standards and Sourcing Team (CRM-SST), one of many SSTs which advise the National Product Council on contracting decisions. "The primary mission of the SSTs is to govern selection decisions on products and services, always keeping the patient in mind as our first goal, with value as an

added benefit," said Dr. Gupta. "The registry can, at times, reveal information to us that is the deciding factor for a contract or vendor."

The Cardiac Rhythm Management group used registry data in considering procurement of a "leadless" pacemaker that promised a reduction in infection rates when compared with traditional pacemakers.

"The fact that the leadless pacemaker studies quoted a dramatic reduction in infection rates between "historical" infection rates and those using the new pacemaker made it tempting," said Dr. Gupta. "However, when we pulled our own data from the registry we realized that our actual rates of infection were already extremely low, approaching those achieved by the new technology, even without using the new technology."

Registry data showing little difference in the infection rates between leadless and traditional pacemakers was instrumental in the decision to hold off adopting the new technology. "This persuaded us as a group to delay further large deployment until we could realize other benefits to merit the cost and risks of the leadless device," said Dr. Gupta. "Without the registry data we would not have realized the potential benefit of our current position."

Post Market Surveillance of Stent Graft Implants



In the rare event of a medical device recall or safety advisory, the registries enable Kaiser Permanente to quickly identify all patients with that device and bring them in for appropriate management.

The Kaiser Permanente Product Recall Department contacts the registries when informed of a recall or advisory. “Each surgeon is then contacted regarding his or her own patients, so the appropriate action can be taken,” said orthopedic surgeon Mark Dillon, MD, Sacramento Medical Center. “In this way, our registry serves as an additional safety net for our patients and, as a surgeon, it makes me feel more confident in the choices I make in the operating room.”

Since the implant registries were first initiated in 2001, they have been instrumental in helping to manage 78 implant recalls and advisories, affecting 106,263 Kaiser Permanente members nationwide.

Among the safety advisories received by Kaiser Permanente in 2016 was one issued regarding a Type III endoleak in an endovascular AAA (abdominal aortic aneurysm) system. An endoleak is a complication that occurs when blood flows into the aneurysm cavity from an aorta treated with a stent, thereby increasing

the risk of aneurysm rupture and death. At the time of the advisory, several hundred systems had been implanted in patients across all KP regions.

“The registry proved invaluable in identifying patients at risk,” said Bradley Hill, MD, Chief of Vascular



Surgery, Santa Clara Medical Center. “We used the list to reach out to all the patients and make sure they were getting the surveillance they needed and had a management plan in place.” Patients with the system now receive routine, clinically appropriate imaging based on physician expertise to monitor device integrity and detect an endoleak, should it develop.

“This device problem has enabled us to fully utilize the registry for its intended purpose – to ensure the safety of our patients with AAA endografts,” said Dr. Hill. “Our patients are followed longitudinally by the registry as long as they remain KP members. As a result, our registry follow-up duration and data quality tend to be better than most other registries.”

Using the Hip Fracture Registry for Benchmarking Patient Care



Kaiser Permanente registries improve quality of care by providing feedback to physicians. Registry input allows individual surgeons and medical centers to benchmark or compare their performance against others within Kaiser



Permanente and, if needed, adjust their practices to improve. "The registries are very useful for clinicians, and they're also very useful for patients and their families," said orthopedic surgeon, Gary Zohman, MD, Anaheim Medical Center.

"People want to know about infection rates or complications or the time it takes to get someone into surgery after a hip fracture — and that's something registry data can tell them."

The elapsed time from the time a patient is admitted to the hospital for a fractured hip to the time they have surgery is among the data captured by Kaiser Permanente's hip fracture registry. Hip fractures can lead to a host of other serious and life-threatening conditions in the elderly population where they most often occur. "Research has shown that the best way to reduce complication and mortality rates is to stabilize a hip fracture as soon as possible after the patient has been medically optimized," said Dr. Zohman. "That's why we made the time from admission to surgery as one of our benchmarks."

Kaiser Permanente established a benchmark of 48 hours as the target time for getting hip fracture

patients into surgery. "As it turns out, registry data showed us that the vast majority of our medical centers were getting 91% of our hip fracture patients into surgery within 48 hours," noted Dr. Zohman. "The question now was, can we do even better."

The hip fracture registry, like all registries, enables each medical center to clearly see their performance in relation to the 48-hour benchmark, the first step in identifying opportunities for improvement. "Right now, we're at the point of showing our clinicians whether they are meeting the benchmark and help them determine if not, why not," said Dr. Zohman. "We don't have those results yet because this is such a new benchmark but we do have everyone focused on the goal and helping us to smooth the process."

Getting people into emergency surgery for hip fractures is a complex process that involves the emergency department, the medical team optimizing the patient for surgery, and the operating room itself. The registry will help identify practices at each step of the way that either delay or speed the process from admission to surgery.

"It can be very unsettling when there are delays in stabilizing a hip fracture and families are very appreciative when things are done promptly," said Dr. Zohman. "We want families to know that Kaiser Permanente is looking after their loved ones and doing everything we can to fix those hips as quickly as it's safe to do so."

Monitoring Length of Stay for Shoulder Procedures



Although shoulder joint replacement is currently less common than knee or hip replacement, its use is increasing, especially as more elderly patients are becoming candidates for the procedure. In the U.S., the number of total and partial shoulder replacements increased from about 18,000 in 2000 to more than 45,000 in 2013, according to the American Academy of Orthopaedic Surgeons.

With the rate of total shoulder arthroplasty (TSA) rising, same-day discharge is gaining interest as a way to improve outcomes, enhance the patient experience, and reduce health care costs.



Kaiser Permanente shoulder surgeons have been progressively shortening the length of stay (LOS) following shoulder replacement surgery. The LOS was around 2 days from 2010 to 2013; it declined to 1+ days in the 2013 to 2016 timeframe. "We have now begun sending some

patients home the same day and wanted to assess the practice with the rigor that a peer-reviewed study would provide," said Ronald Navarro, MD, Regional Coordinating Chief of Orthopedic Surgery, South Bay Medical Center.

The Kaiser Permanente Shoulder Arthroplasty Registry conducted a study to compare same-day discharge patients with those staying one or more nights. The study showed that same-day discharge following shoulder replacement is not inferior to longer length of stay with regards to 30-day emergency visits and 90-day readmission.

Study results have contributed to an increase in same-day discharge for shoulder arthroplasty. "Same-day discharge is not yet standard practice nor do we anticipate same-day discharge for all shoulder patients," said Dr. Navarro. "We are currently testing a same-day discharge program that we will soon be rolling out to a wider audience."

Kaiser Permanente supports home recovery for same-day patients using a national program called Enhanced Recovery after Surgery (ERAS) that includes multimodal pain medications, gastric attention to avoid nausea, and attention to IV fluid volume administration to avoid bladder fullness.

"We have shown that same-day total shoulder arthroplasty is a safe and economical procedure," said Dr. Navarro. "This information provides evidence that same-day shoulder arthroplasty can provide equivalent safety and financial savings for any health care system."

Opioid use before and after total joint replacement



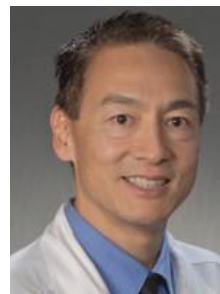
Total knee and hip replacement surgeries are among the most common and effective treatments for patients with impaired function and severe pain in these joints. Opioids have traditionally been, and remain, a component in postoperative pain relief for total joint replacement (TJR) patients as a part of perioperative multimodal pain protocols.

But while opioids can be a valid course of treatment to manage acute pain, they carry the risk of addiction and overdose. Starting in 2010, Kaiser Permanente implemented a Safe and Appropriate Opioid Prescribing Program to reduce over-prescribing of opioids.

As part of ongoing clinical care improvement efforts and to support safe and appropriate prescribing of opioids for TJR patients, Kaiser Permanente's TJR Registry conducted some of the first studies looking at the effects of preoperative and postoperative opioid use on TJR patients. These studies identified how many patients were using opioids and factors associated with an increased risk for prolonged opioid use.

The studies showed that preoperative opioid use is associated with prolonged opioid use after TJR. The studies also found that continued opioid use after the first 90-day postoperative period is associated with a higher revision risk and warrants close patient follow-up.

These findings have led to the implementation of strategies at Kaiser Permanente to reduce unsafe opioid use among TJR candidates and recipients.

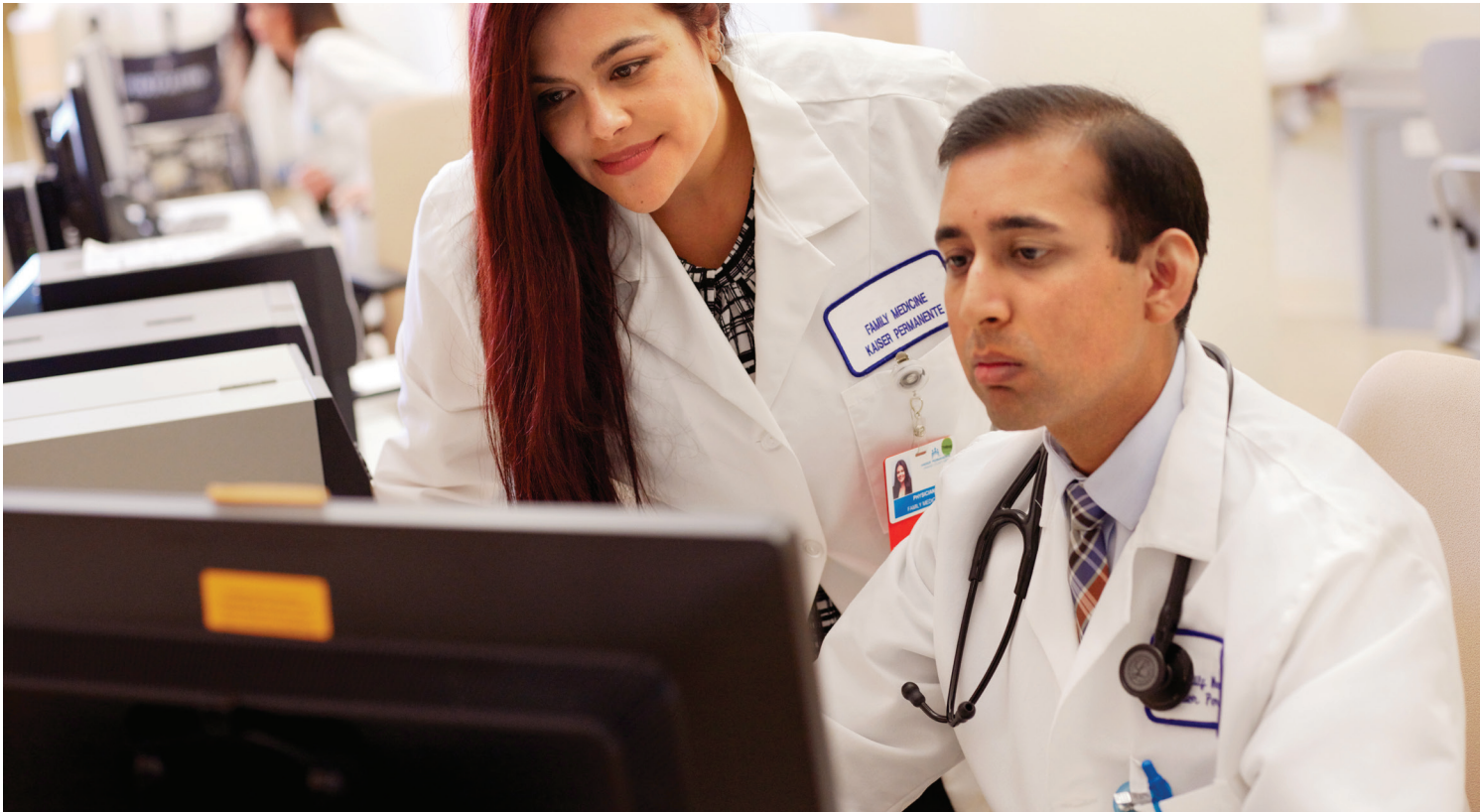


"We have identified the cessation of opioids 90 days after TJR as one of the process improvement goals at our medical center," said orthopedic surgeon Robert Namba, MD, Irvine Medical Center. "There is now increased awareness among our surgeons that patients requesting refills over 90 days after surgery merit closer follow-up."

At the Irvine Medical Center, dissemination of study results has led to a marked reduction of prolonged opioid use. Between 2015 and May of 2017 at the medical center, total hip replacement patients using opioids more than 90 days after surgery declined from 34% to 12%. During the same time period, total knee replacement patients using opioids more than 90 days after surgery dropped from 39% to 19%.

"All healthcare providers are challenged with addressing the opioid epidemic in the U.S.," said Dr. Namba. "Excess dispensing of opioids is not only a risk factor for our TJR patients, but also increases the quantity of opioids which may be taken and disseminated unwittingly to the friends and families of our patients."

ACLR Registry Overview



Description:

The anterior cruciate ligament reconstruction (ACLR) registry was established in 2005 and tracks implants and outcomes of ACLR cases. As of year-end 2016, there were 40,666 cases in the ACLR registry.

Clinical Findings

- In our cohort of 10,190 primary ACLRs using allografts, 8425 (82.7%) received a processed allograft and 1765 (17.3%) received a non-processed allograft. The overall incidence of deep infection after ACLR was very low (0.15%). No difference in the likelihood of infection between processed and non-processed allografts could be identified. Allograft tissue is often irradiated and/or chemically processed. Studies have identified an association between this processing and a higher risk for revision; whether processing decreases infection risk has yet to be determined.
- In our cohort of 4,087 primary ACLRs, with no meniscal injury at the time of index surgery and contralateral knee normal, there was a 3.73 times higher likelihood of subsequent meniscal surgery

in the index knee compared with the contralateral knee. Compared to BPTB autografts, allografts and hamstring autografts were risk factors for subsequent meniscal surgery in the index knee. This information should be considered when determining the appropriate graft choice for ACL reconstruction, and meniscal surgery after ACL reconstruction should be considered as an outcome variable when comparing various ACL reconstruction techniques.

- When BPTB allograft tissue was used for ACLR, an overall 4.54 times adjusted higher risk of revision was observed compared with surgery performed with a BPTB autograft. Whether the tissue was irradiated with either high- or low-dose radiation, chemically processed, or not processed at all made little difference in the risk of revision. The differences in the revision risk were also consistent in younger and older patients. Surgeons and patients should be aware of the increased risk of revision when a BPTB allograft is used for ACLR.

Registry Champions: Gregory Maletis, MD; Tadashi Funahashi, MD; Anita Rao, MD; Mark Shaieb, MD; Ron Wyatt, MD; Terrill Julien, MD; Anne Denys, MD; Mark Davies, MD; Darin Allred, MD

Anterior Cruciate Ligament Reconstruction Registry

Anterior Cruciate Ligament Reconstruction KP compared to benchmarks

Characteristic n (%)	Kaiser Permanente	Danish Cruciate Ligament Register	Norwegian National Knee Ligament Register	Swedish National ACL Register	UK National Ligament Register
Start Date	Feb-05	Jul-05	Jun-04	Mar-05	Dec-12
Total N	40113	30714	25624	40252	9002
Primaries	35524 (88.6)	26457 (86.1)	23337 (91.1)	37618 (93.5)	9002 (100.0)
Revisions	4589 (11.4)	2603 (8.5)	2287 (8.9)	2634 (6.5)	0 (0.0)
Gender					
Males	24962 (62.2)	16013 (60.5)	13179 (56.5)	23037 (57.2)	6481 (72.0)
Females	15147 (37.8)	10444 (39.5)	10158 (43.5)	17215 (42.8)	2521 (28.0)
Age years (at time of surgery)					
<25	17968 (44.8)	11667 (44.1)	10328 (44.3)	20048 (49.8)	Not Reported
≥25	22145 (55.2)	14798 (55.9)	13009 (55.7)	20204 (50.2)	Not Reported

Outcomes

Reoperations	3762 (10.6)	Not Reported	769 (3.3)	Not Reported	Not Reported
Contralateral Knee Operations	1238 (3.5)	Not Reported	729 (3.1)	1442 (3.8)	Not Reported
Revisions 100 persons-yrs	1209 (3.4)	Not Reported	1105 (4.7)	1601 (4.3)	Not Reported
1 year	0.91	Not Reported	0.84	Not Reported	Not Reported
3 year	1.21	Not Reported	1.19	Not Reported	Not Reported

Cardiac Device Registry



Description:

The cardiac device registry was established in 2000, and tracks pacemakers (PM) and implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy (CRT). As of Q4 2017, there are 128,038 devices in the registry (93,414 initial and 34,624 replacements). The registry volume by device type is noted on page 20.

Summary:

- **Device Revisions:** The registry tracks all devices undergoing a procedure to explant or replace the device for any reason. Normal battery depletion (ERI) is an expected replacement procedure. Device explant reasons other than ERI include: premature battery depletion, device upgrade/downgrade, mechanical complication of the pulse generator, mechanical complication of a lead, infection, device recall/advisory, pocket erosion/device migration, pocket pain and other patient anatomy issues. Data is available for quality reporting, research, and medical center specific requests. The overall complication rate for devices, excluding normal ERI, implanted from 2007-2017 is noted on page 20.

- **Lead Revisions:** The registry tracks all leads undergoing a procedure to replace, reposition, or repair the lead due to a mechanical malfunction including: lead dislodgement, perforation, conductor fracture, insulation failure, high/low thresholds, oversensing, undersensing, non-capture, extracardiac stimulation, and lead noise. The overall revision rate for leads implanted from 2007-2017 is noted on page 20.
- **Remote Monitoring:** Many cardiac devices have remote monitoring capability which allow the device to transmit data to clinicians without the patient needing to physically come in to the office; therefore, reducing time, effort, and burden on the patient. In collaboration with medical centers in several regions, the registry has identified cardiac device patients who are currently enrolled in remote monitoring and those who still need to be enrolled. Through this feedback mechanism the rates of remote monitoring has increased significantly.

Registry Champions: Nigel Gupta, MD, PhD; Kelly Richardson, MD; Cesar Alberte-Lista, MD; Angela Morello, MD; Jason Rashkin, MD; Brant Liu, MD; Jitesh Vasadia, MD; Rasoul Mokabberi, MD

Cardiac Device Registry

Registry volume by device type (2007-2017)

Device	# Implants	Initial Volume	Replacement Volume
Pacemaker	86,827	65,508	21,319
ICD	29,824	20,965	8,859
CRT	11,387	6,941	4,446
Total	128,038	93,414	34,624

Overall complication rate implanted, for devices (excluding normal ERI) (2007-Q2 2017)

Device	Total Volume	Complications	% Complication Rate
Pacemaker			
Dual	48,518	538	1.1
Single	7,962	54	0.67
Leadless	20	1	5
ICD			
Dual	10,516	171	1.62
Single	9,493	80	0.84
CRT			
D	8,201	466	5.68
P	849	25	2.94

Overall complication rate implanted, for leads (2007-Q2 2017)

Function	Total Volume	Complication Volume	% Complication Rate
BRADY	89,923	1,777	1.97
HF	6,352	201	3.16
TACHY	19,537	614	3.14

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). Currently the registry tracks 3,716 primary and 329 revision procedures.

Clinical Findings

- Aneurysm size is of clinical importance in evaluating the need for an EVAR procedure. In a total number of 3717 EVAR cases in the registry, the most common aneurysm size for initial EVAR procedures was size 6.0 cm or greater (32.7%) in males, and size 5.0 to 5.9 cm (42.1%) in females. The highest number of reinterventions (16.72%) took place in patients with aneurysm size of 6.0 cm or greater. Registry findings in regard to aneurysm size support regular surveillance and tracking of aneurysm size in patients with known AAAs prior to an EVAR procedure.

- Revisions, secondary interventions, and conversion to open repair are tracked by the registry data. The most common reason for reintervention was endoleak (225 reinterventions out of 3717 total cases). Revisions of the stent graft occurred in 3.61% of all cases (134 revisions out of 3717 total cases). Other reasons for revision can include device malfunction/migration, thrombosis, infection, rupture, etc.
- The majority of patients (58.8%) had a hospital length of stay of 0 to 1 days, with the next highest length of hospital stay being 2 days (18.2% of patients).

Safety Advisory

- The registry continued to support surgeons in responding to an Endologix Safety Advisory due to higher than anticipated type III endoleaks. By providing KP surgeons and medical centers with a list of patients with affected implants, the registry identified patients at risk, so patients receive appropriate post-market surveillance of their device and treatment as needed.

Registry Champions: Bradley Hill, MD; Jeffrey Hsu, MD; Nicolas Nelken, MD; Thomas Rehring, MD; Homayon Hajarizadeh, MD

Hip Fracture Registry



Description:

Established in 2009, the hip fracture registry tracks primary surgery of the proximal femur. As of year end 2016, 44,221 primary hip fracture cases and 1,587 revisions were tracked.

Clinical Findings:

- When compared with Regional Anesthesia (RA), General Anesthesia (GA) is associated with a higher risk of in-hospital mortality, shorter time-to-in-hospital mortality, lower home discharge, and longer time-to-home or health care facility discharge. Also, the previously underrepresented Conversion from Regional to General Anesthesia group demonstrated a higher risk of in-hospital mortality and a shorter time-to-in-hospital mortality when compared with RA. The choice of anesthesia technique can affect in-hospital outcomes, and RA may offer advantages over GA for fragility hip fracture surgeries when possible. (Qiu et al. 2018)
- Use of general anesthesia and conversion from regional to general anesthesia were found to be

associated with a higher risk of mortality during the in-hospital stay compared with regional anesthetic techniques, but this higher risk did not persist after hospital discharge. General anesthesia was also found to be associated with a higher risk of all-cause readmission compared with regional, but no other differences were observed in risk for complications. Findings suggest regional anesthetic techniques may be preferred when possible in this patient population. (Desai et al. 2018)

- A study of 39 pediatric patients, < 21 years old at the time of hip fracture, were treated surgically for the hip fractures between 2009 and 2012 in a large integrated health care system. Patient characteristics, type of fracture, surgical treatment, and short-term complications were identified. Hip fractures in a pediatric population were rare, complication rates were low, and few patients had any comorbidities. Hip fractures were more common in boys and Hispanic patients. Intertrochanteric fractures (Delbet Type IV) were the most frequently observed type. (Prentice et al. 2017)

Registry Champions: Gary Zohman, MD; Christopher Grimsrud, MD; James Jackman, MD; Kanu Okike, MD

Hip Fracture Registry

Hip Fracture KP compared to benchmarks

REGISTRY	Kaiser Permanente 2009-2017	National Hip Fracture Database (NHFD) Annual Report 2017: UK-Wales-Northern Ireland 2007-2016	Swedish Hip Arthroplasty Register 2000-2016	Irish Hip Fracture Database National Report 2014-2016	Australian & New Zealand Hip Fracture Registry (ANZHR)	Norwegian Hip Fracture Register 2005-2016
Data Period	2017	2016	2016	2016	2015-2016	2016
Volume	44,221	500,000	6,158	3,159	12,219	96,597
Female	69%	Not Reported	59%	69%	AUS: 70% / NZ: 68%	70%
Mean Age	Male: 80 Female: 85	Not Reported	Male: 80 Female: 82	Male: 79 Female: 81	AUS: Mean: 82 Median: Male 83, Median: Female: 85 NZ: Mean: 83 Median: Male 85 Median: Female: 85	Mean: Overall: 80 Female: 82 Male: 77
Time to Surgery	Median 21.5 hours 90% within 48 hours	Mean: 32.9 hours Median 24.1 hours 71% within 2 days	Mean: 1.2 days Median: 1 day	75% within 48 hours 59% within 36 hours 41% within 24 hours	AUS: Median 29 hours 82% within 48 hours NZ: Median 24 hours 77% within 48 hours	85% within 48 hours (excluding THAs)
Length of Stay	Mean: 4.8 days	Mean: 16.6 days Median: 12 days	Mean: 10.7 days Median: 9 days	Mean: 20days Median 12days	AUS: Median 7.7 days NZ: Median 5.8 days	Mean: 9.8 days
Revision Rate	3.59%	Not Reported	3.30%	5% within 30days	Not Reported	4.00%
Mortality	11.0%	6.7%	13.0%	Not Reported	5% before discharge, additional 15-20% within 1 year	Not Reported

Shoulder Arthroplasty Registry



Description:

Kaiser Permanente tracks elective and urgent shoulder arthroplasty procedures including total shoulder arthroplasty (TSA), reverse total shoulder arthroplasty (RTSA), hemiarthroplasty (HA) and humeral head resurfacing (HHR) procedures. Between 2005 and year end 2016, the shoulder registry has captured information for 14,301 primary procedures.

Clinical Findings

- In 5,121 Shoulder Arthroplasties 75.6% of patients were opioid users 1-year pre-operatively: 92.5% were opioid users in Q1 post-operatively, 40-44% were opioid users in Q2-Q4 post-operatively. Risk factors found to be associated with increased opioid utilization 1-year postoperatively: Preoperative opioid utilization, age >60, opioid dependence, anxiety, history of substance abuse, and general chronic pain. These findings emphasize the need for surgeon and patient awareness, and education in the management of postoperative opioid usage associated with the indicated conditions.
- In 5,487 Shoulder Arthroplasties, infection risk was significantly lower in TSA procedures using antibiotic-laden irrigation but not in RTSA or HA. There was no association of infection prevention with antibiotic cement in TSA and RTSA. Spacersuit use was not associated with infection risk in TSA, RTSA, or HA. Further prospective investigations are needed to identify safe and effective ancillary antibiotic administration practices.
- In 7,421 primary Shoulder Arthroplasties, diabetes was not associated with short-term revision, deep infection, VTE, or rehospitalization after shoulder arthroplasty. No significant association was found between these complications and glycemic control, as measured by preoperative and postoperative HbA1c, in diabetic patients. The strict application of thresholds of acceptable preoperative HbA1c levels may not be an effective method of reducing infection rates and other possible diabetes associated complications in shoulder arthroplasty.

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

Shoulder Arthroplasty KP compared to benchmarks			
	Kaiser Permanente	Australia Orthopaedic Association Shoulder Arthroplasty	The New Zealand Joint Registry
Time Period	2005-2016	2004-2016	2000-2016
Volume	14301	38265	8250
Gender, Female	55.12%	62.10%	63.14%
Mean Age (yrs)	69.61	71.4	71.11
Revision Rate	TSA: 0.70/ 100 obs yrs RTSA: 1.21/ 100 obs yrs	1.70/ 100 obs yrs 1.23/ 100 obs yrs	0.99/ 100 obs yrs
Top 3 Reasons for Primary	Osteoarthritis Rotator Cuff Arthropathy Fracture	Osteoarthritis Rotator Cuff Arthropathy Fracture	Osteoarthritis Cuff Tear Arthropathy Fracture of Proximal Humerus
Top 3 Reasons for Revision	Instability/Dislocation Infection Rotator Cuff Tear	Instability/Dislocation Loosening Rotator Cuff Insufficiency	Pain Instability/Dislocation Subacromial Cuff Impingement
Outcome			
Infection	0.90%	Not Reported	Not Reported
DVT	0.65%	Not Reported	Not Reported
PE	0.52%	Not Reported	Not Reported

Spine Registry



Description

Implemented in 2009, this registry tracks over 23,790 instrumented and non-instrumented spinal procedures performed by the Neurosurgery and Orthopedic Spine surgeons as of year-end 2016. This represents more than 80,000 total implants.

Clinical Findings

- Every 5 kg/m² increase in BMI is associated with a significant increase in surgical time (7.8 minutes), estimated blood loss (EBL) (36.5 mL), risk of deep infection (OR =1.7 times), and deep vein thrombosis (DVT) (OR =1.5). BMI was not associated with increased incidence of other intraoperative or health-related complications. Rate of re-operation was 1.1 times higher with every 5 kg/m² increase in BMI, but rate of re-operation due to adjacent segment disease (ASD) was not associated with BMI in our spine patient population. (Akins, et al. 2017)

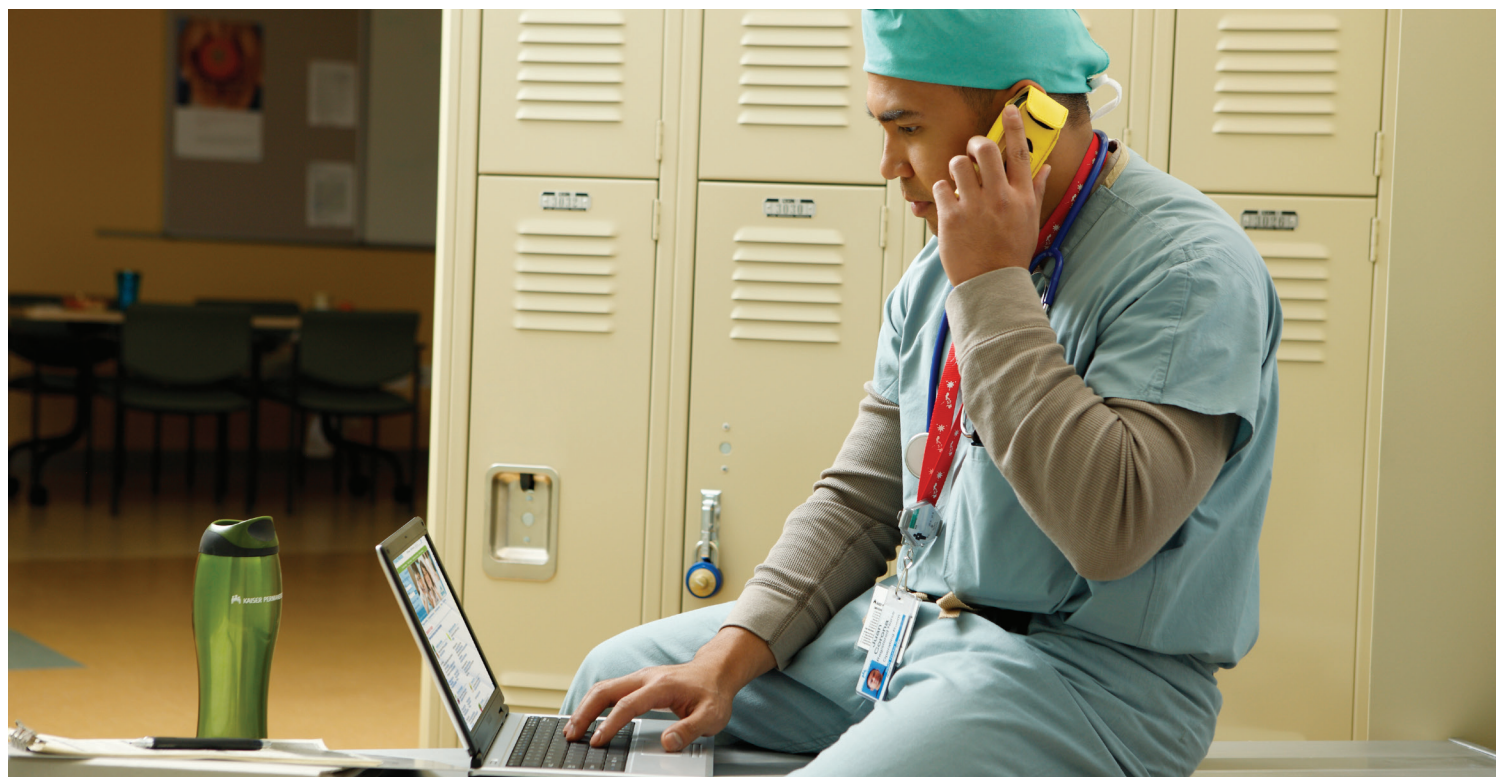
- In 10,416 patients our preliminary study found no evidence that exogenous, local BMP administration during spine fusion influences subsequent cancer risk. Additional studies and longer follow-up is necessary to definitively conclude our findings. (Bains, et al. 2017)
- In a cohort of 1158 posterior cervical spine fusion patients reoperation rates for symptomatic nonunions in subaxial spine (C2-7) with more than 1 year of follow-up were found to be 1.1% with BMP and 0.7% without BMP. There was no significant difference in the reoperation rates for symptomatic nonunions with or without BMP. (Guppy, et al. 2016)

Registry Champions: Kern Guppy, PhD, MD; Johannes Bernbeck, MD; Harsimran Brara, MD

Spine Surgery Registry

Spine Surgery KP compared to benchmarks		
Variable	Kaiser Permanente	EUROSPINE
Time Period	2009-2013, 2016	2006-2016
Volume	23,790	102,025
Demographics		
Age (Mean)	57.7 years	56.8
Gender	51.9% female	50.9% female
Current Smoker	7.6%	Not Reported
Diagnosis - Degenerative	70.6%	80.3%
Fusion Approach		
Anterior Only	24.5%	Not Reported
Posterior Only	63.5%	Not Reported
Combined	12%	Not Reported
Outcomes		
Dural Tear	3.2%	4.8%
Superficial Infection	0.6%	2.2%
Deep Infection	0.6%	4.4%
Nonunion	1.6%	20.9%
Adjacent Segment Disease	4.4%	25.6%

Total Joint Replacement Registry



Description

The Total Joint Replacement Registry (TJRR), established in 2001, collects patient and surgical implant information and patient outcomes. The TJRR now tracks over 250,000 procedures through December 2016 (242,469 primary total joint replacements and 6,992 revision cases).

Clinical findings

- In 47,523 primary THA cases, 95.2% and 4.8% had Osteoarthritis and Osteonecrosis, respectively. The osteonecrosis cohort had higher crude incidence of 90-day mortality, SSI, unplanned readmission and revision. Compared to OA, a diagnosis of osteonecrosis was associated with worse outcomes post-THA. A detailed preoperative discussion including the risk of complications is needed for informed consent from patients with osteonecrosis. (Sindh et al. 2017)
- In a study evaluating risk of all-cause revision in metal versus ceramic femoral heads when used with an highly cross-linked polyethylene liner, including an evaluation of the effect of head size; and dislocation in metal versus ceramic femoral heads when used

with an HXLPE liner, for all-cause revision, there was no difference between ceramic versus metal heads in combination with an HXLPE liner. Smaller metal head sizes of <32 mm were associated with increased risk of revision relative to 36 mm. For dislocation, ceramic heads increased risk relative to metal at < 32 mm only. Head sizes < 32 mm were associated with increased risk of dislocation relative to 36 mm for metal and ceramic heads. The results did not provide evidence for use of one femoral head material over another when used with HXLPE liners for the outcome of revision, but for dislocation, metal performed better than ceramic with < 32-mm heads. Overall, the findings suggest increased risk of revision/dislocation with head sizes < 32 mm. (Cafri et al. 2017)

- Based on study results, fondaparinux, enoxaparin, and warfarin was not found to differ from aspirin in the prevention of PE, DVT, or VTE. Furthermore, aspirin was not found to differ from the alternative chemoprophylactics with respect to safety endpoints. When specifically testing for noninferiority, enoxaparin was found to be as safe as aspirin with respect to bleeding and fondaparinux as safe as aspirin for risk of wound complications. (Cafri et al 2017)

Registry Champions: Mark Melberg MD; Le-Don A Robinson MD; Gregory Y Lee MD; Maurice Cates MD; Adrian D Hinman MD; Erik W Kroger MD; Matthew P Kelly MD; Thomas Stoll MD

Total Joint Replacement Registry

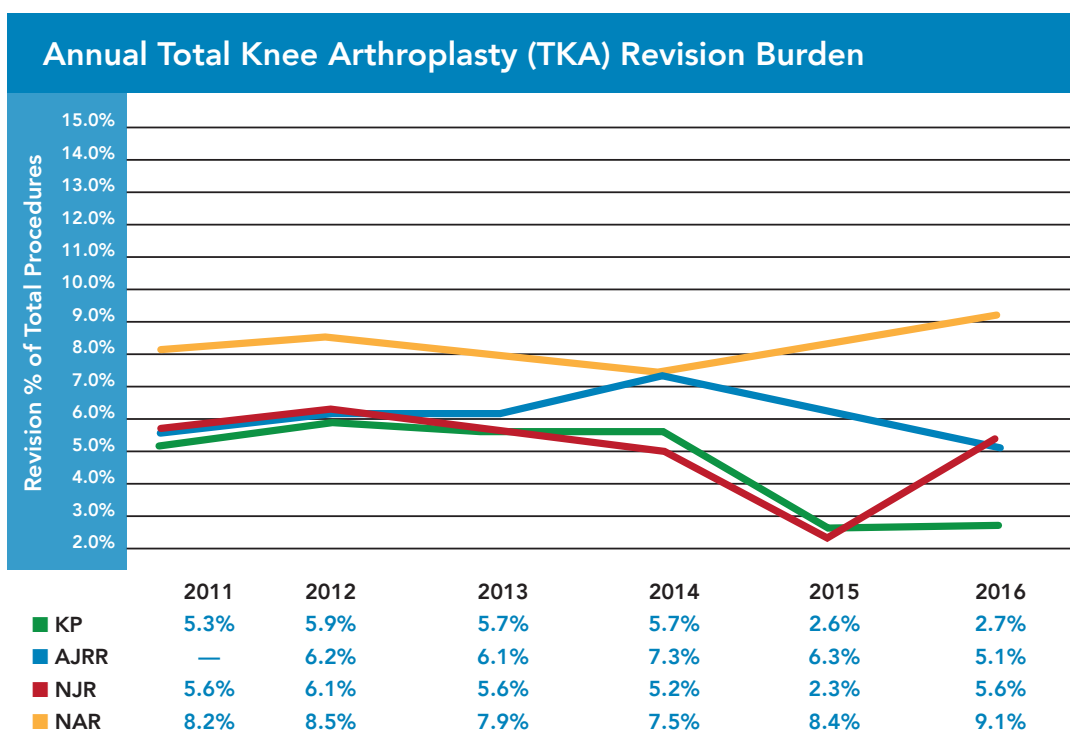
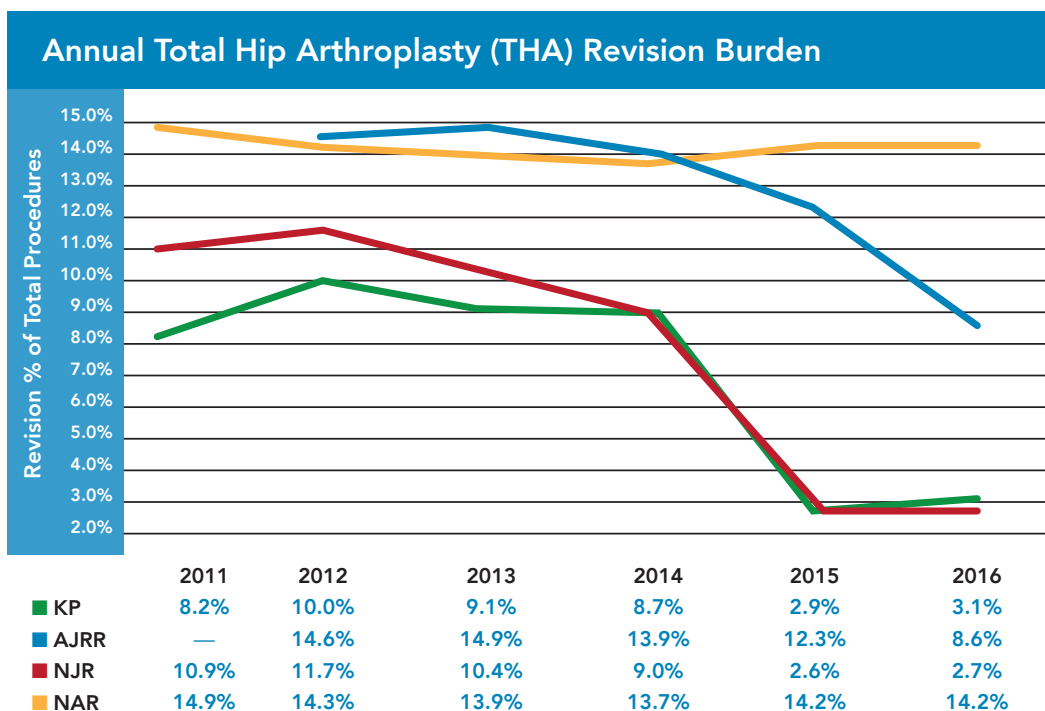
Total Hip Replacement KP compared to benchmarks

Registry	Data	Total Cases	Revision % Period	Age	Female %	10-yr. Survival % (CI)
Kaiser Permanente	2001-2016	86,376	3.1%	65.5 mean age	50.8%	95.1 (94.8-95.3)
Australia	1999-2015	346,782	4.3%	67.7 mean age	55.1%	93.4 (93.2-93.5)
United Kingdom	2003-2016	890,681	2.7%	69 median age (61-76 IQR)	59.8%	94.79 (94.71-94.87)
Sweden	1991-2015	163,341	5.6%	Mean age: Male 67.3, Female 70.0	60.0%	94.7 (94.4-94.9)
Norway	1987-2016	181,048	8.7%	Mean age: Male 67.1, Female 69.9	67.1%	91.5 (91.3-91.7)

Total Knee Replacement KP compared to benchmarks

Registry	Data	Total Cases	Revision % Period	Age	Female %	10-yr. Survival % (CI)
Kaiser Permanente	2001-2016	163,093	2.7%	67.3 mean age	54.7%	95.7 (95.5-95.8)
Australia	1999-2015	494,571	9.8%	68.6 mean age	56.9%	94.7 (94.6-94.8)
United Kingdom	2003-2016	975,739	5.6%	69 median age (63-76 IQR)	56.8%	96.61 (96.55-96.67)
Sweden	1999-2015	163,120	4.3%	68.6 mean age	59.7%	96 (95.9-96.1)
Norway	1994-2016	75,229	5.9%	Mean age: Male 67.4, Female 69.2	63.5%	92.2 (92-92.4)

Total Joint Replacement Registry



Registries:

KP: Kaiser Permanente Implant Registries
 AJRR: American Joint Replacement Registry
 NJR: National Joint Registry, UK
 NAR: Norwegian Arthroplasty Register

Implant Registries Staff

Management Team

Liz Paxton, MA	Director
Jessica Harris, MS, RD	Manager
Kenneth Sucher, MS	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,	Data Consultant
Heather Prentice, PhD, MPH	Research Scientist Investigator
Wei Wang, PhD, MS	Biostatistician III

Database Administrators

Kim Phan, BA	Senior Application Development Technical Specialist
Buu Truong, BS, MIS	Senior Application Program Analyst

Data Consultants/Programmers

Yuexin (Cindy) Chen, BS	Senior Data Consultant
Tomy Huon, BS	SAS Programmer III
Michael Reyes, BS	SAS Programmer II
Craig Salman, BS	SAS Programmer II
Xueyan (Sophie) Su, BS	SAS Programmer II
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 Burfeind, MAS	Project Manager III
Brian Fasig, PhD	Project Manager III

Quality Reporting

Anna Ritko, MA, MPhil	Senior Data Consultant
-----------------------	------------------------

Research Associates

Janine Cruz, BA	Research Associate II
Kristen Mays, MA	Research Associate III
Tia Mullane, BA	Research Associate II
Juan Ruiz	Research Associate II
Andrew (Scott) Thomas, BS	Research Associate II

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