MEDICAL DEVICE SURVEILLANCE AND ASSESSMENT

ANNUAL REPORT 2021

Implant Registries • Implant Surveillance • Recall Identification

MESSAGE FROM THE LEADERSHIP TEAM

It is with great pleasure to introduce the Medical Device Surveillance and Assessment (formerly National Implant Registries) 2021 Annual Report.

This year, the National Implants Registries celebrated our 20-year anniversary. Over the past two decades, we have come a long way and accomplished significant achievements. The registries started as a pilot total joint project in 2001 in the basement of El Cajon in the San Diego Medical Service Area. Based on the success of this, we expanded program-wide to ACL reconstruction, shoulder, hip fracture, spine, cardiac, and vascular devices. Currently, over 3.58 million medical devices are monitored and evaluated nationally. Over 230 research publications have identified clinical best practices and enhanced patient outcomes. The registries have been instrumental in enhancing patient safety, quality of care, and cost effectiveness for our patients and patients worldwide.

The vast achievements of the registries, fueled by Kaiser Permanente physicians and staff, have received national and international recognition with numerous awards and honors over the years including:

- National Vohs Quality and Lawrence Patient Safety Award – National Total Joint Replacement Initiative (2021) Finalist
- Orthopaedic Research and Educational Foundation (OREF) Clinical Research Award for Outstanding Orthopaedic Research (2018)
- American Academy of Orthopaedic Surgeons (AAOS) Award of Excellence for Scientific Exhibit (2018)
- Eisenberg Award for Quality and Patient Safety from the Joint Commission and National Quality Forum (2012)
- ECRI Institute Health Device Achievement Award (2010)
- AAOS Award of Excellence for Scientific Exhibit (2010)
- Innovations Award for Total Joint Virtual Visit Project Kaiser Permanente (2009)
- National Vohs Quality and Lawrence Patient Safety Award – National Total Joint Replacement Initiative (2008)

The orthopedic, cardiac, and vascular registries serve as a model for national and international medical device surveillance. In 2021, we executed several changes to enhance our value to members and Kaiser Permanente including expanding the breadth of medical device surveillance to include additional high-risk medical devices, implementing operational efficiencies, partnering with the Federation, and creating a new funding model through Kaiser Foundation Health Plan. Extending beyond registries to surveillance of other high-risk devices allows us to impact more members and enhance patient safety and quality. We are excited to highlight several of these new surveillance initiatives in our annual report.

As we move towards wider surveillance of implantable medical devices, the National Implant Registries will remain an integral part of our work and are now part of a broader interregional Kaiser Permanente Medical Device Surveillance and Assessment framework. We look forward to the continued success of the National Implant Registries while providing additional medical device surveillance under the new Medical Device Surveillance and Assessment umbrella.

Liz Paxton, PhD, MA
Director, Medical Device Surveillance and Assessment unit of Clinical Analysis

Nolan Chang, MD
Chair, Medical Device Surveillance Committee, Regional Medical Director of Business Management, Southern California Permanente Medical Group

THANK YOU & ACKNOWLEDGEMENTS

We would like to thank and acknowledge the Inter-Regional Implant Registries Committee (IIRC) members and chair Tad Funahashi, MD for exceptional leadership of the National Implant Registries since 2006. The IIRC was responsible for the implementation and expansion of the National Implant Registries, national and international success and recognition of the registries, development of a surveillance model that will inform the new medical device surveillance initiatives, and most importantly improving care for our members system wide using an evidence-based medicine approach.

Inter-Regional Implant Registries Committee Members

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Eric Cain, MD, MBA, FAAOS
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Physician-in-Chief, Kaiser Permanente Fremont Medical Center

Margaret Mentakis, MD, FACS
TPMG Technology Leader
KPHC Procedural and Perioperative Services

NATIONAL IMPLANT REGISTRIES
HIGHLIGHTING 20 YEARS

With 20 years of clinical service and shared success, we are excited to present a few highlights.

Since 2001, the National Implant Registries have monitored patient characteristics, surgical approaches, implant characteristics, and clinical outcomes.

BY THE NUMBERS

12.5 Million Members Monitored Program-Wide

77 Medical Centers with 3,528 Participating Surgeons

239 Publications in 27 Peer-Reviewed Journals

427 Posters and Presentations at National and International Symposia

130,744 Patients with Enhanced Surveillance During 125 Recalls

865,000+ Procedures Captured and Tracked for the Patient's Lifetime

3.58 Million Implants Registered

NATIONAL IMPLANT REGISTRIES
20 YEAR TIMELINE

20 YEARS

Total Joint Replacement Registry
The Total Joint Replacement Registry collects demographic, surgical, and implant information to monitor outcomes, identify best practices, and identify patients in case of a recall. There are 135,165 primary Total Hip Arthroplasty procedures, with an overall revision rate of 3.2%; there are 244,952 primary Total Knee Arthroplasty procedures, with an overall revision rate of 2.9%. When compared to other international registries our outcomes are lower or the same.

16 YEARS

Anterior Cruciate Ligament Reconstruction Registry
The Anterior Cruciate Ligament Reconstruction Registry tracks primary, revision, and reoperation procedures. There are 57,282 procedures in total, including 50,542 primary procedures. Our overall revision rate of 4.0% is similar when compared to other registries. The registry tracks over 5,500 reoperations and, starting in 2017, over 150 anterior cruciate ligament repairs.

Shoulder Arthroplasty Registry
The Shoulder Arthroplasty Registry has captured 24,381 primary shoulder arthroplasty procedures, with an overall revision rate of 4.15%, comparable to other international registries. Both elective and urgent shoulder arthroplasty procedures are tracked including total shoulder arthroplasty, reverse total shoulder arthroplasty, hemiarthroplasty, and humeral head resurfacing, with overall revision rates of 3.29%, 3.44%, 7.58%, and 13.14%, respectively.

14 YEARS

Cardiac Device Registry
The Cardiac Device Registry follows pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization therapy devices. There are 155,908 devices in the registry, which include 104,797 pacemakers, 36,070 ICDs, and 15,041 CRTs. Lifetime tracking of clinical outcomes for both the device and leads are captured in the registry.

12 YEARS

Hip Fracture Registry
The Hip Fracture Registry evaluates hip fracture cases and revision procedures after primary fracture treatment. There are a total of 61,978 hip fracture procedures, including 2,006 THA; 20,848 Hemi; and 39,124 Fixations. Our overall revision rate of 1.6% is comparable to other published literature.

Spine Registry
The Spine Registry monitors over 71,391 instrumented and non-instrumented spinal procedures performed by the neurosurgery and orthopedic spine surgeons. This registry represents 56,241 primary procedures, with a 1.0% nonunion rate and 10.5% lifetime reoperation rate, representing the largest cohort of operative nonunions.

11 YEARS

Endovascular Stent Graft Registry
The Endovascular Stent Graft Registry has effectively assessed the deployment and ensured outcomes surveillance of graft devices used in endovascular aneurysm procedures for the repair of abdominal aortic aneurysms. This registry monitors 5,534 primary and 376 revision procedures with a 6.8% revision rate, similar to other large databases.

NATIONAL IMPLANT REGISTRIES
OUR IMPACT ON CLINICAL PRACTICE

Using a collaborative approach to evidence-based research, the National Implant Registries have supported front-line clinicians, interregional chiefs' groups, and National Product Council purchasing teams in clinical decision-making at the point of care to drive real world change. The registries have significantly improved quality and patient safety through research identifying clinical best practices, dashboards on variations in care and outcomes, feedback on utilization of best practices, collaborative goal development with the chiefs, surgeon profiles, risk calculators, and internal and external communication of registry findings. This has resulted in enhanced outcomes with improved value to patients and significant cost savings for our organization.

Total Hip Replacement Registry

For patients undergoing primary total hip arthroplasty, we have identified the following enhancements in care over the last 20 years:

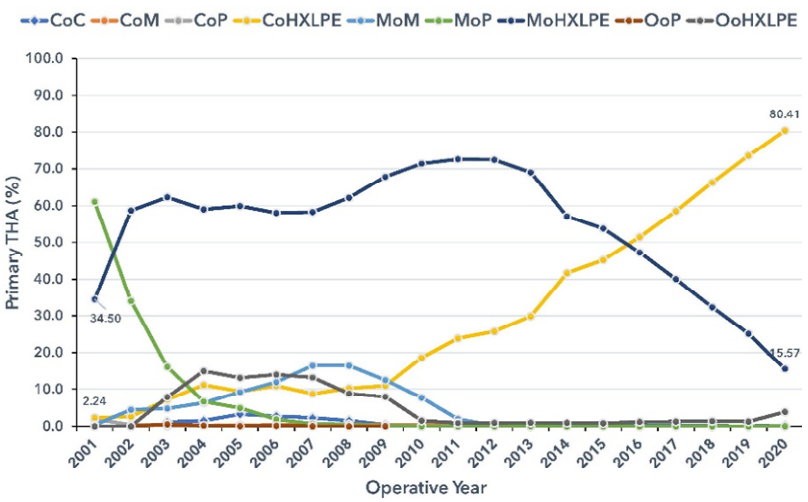
1326% increase in large femoral head diameter (≥36 mm) to 68.7% in 2020.	
1238% increase in aspirin reported for deep vein thrombosis prophylaxis to 88.2% in 2020.	**82% decrease** in 90-day mortality to 0.2% in 2020, equivalent to 482 deaths prevented.
50% decrease in 90-day readmissions to 3.2% in 2020, preventing 1,600 readmissions.	**20% decrease** in 90-day emergency department (ED) visits to 8.7% in 2020, preventing 346 ED visits.
13% decrease in 2-year revision rates to 1.9% in 2018, preventing 123 revision surgeries.	**9% decrease** in 90-day deep surgical site infections to 0.4% in 2020; 77 infections prevented since a peak in 2015

Surgical Approach:

4706% increase in direct anterior approach to 47.1% in 2020	**43% decrease** in posterior approach	**75% decrease** in lateral approach

Bearing Surface:

Registry studies identified a lower revision risk for metal on highly crosslinked polyethylene (HXLPE). A later study also found no difference in revision risk for ceramic versus metal on HXPLE. These findings have resulted in an increase in utilization (Figure).



Paxton EW, Inacio MCS, Namba RS, Love R, Kurtz SM. "Metal-on-conventional polyethylene total hip arthroplasty bearing surfaces have a higher risk of revision than metal-on-highly crosslinked polyethylene: results from a US registry." *Clin Orthop Relat Res*, 2015; 473(3): 1011-21.

Cafri G, Paxton EW, Love R, Bini SA, Kurtz SM. "Is There a Difference in Revision Risk Between Metal and Ceramic Heads on Highly Crosslinked Polyethylene Liners?" Clin Orthop Relat Res, 2017; 475(5): 1349-55.

Total Knee Replacement Registry

Through the addition of outcomes tracking and outpatient initiatives to regional chief's goals, since the start of the registry, we have observed the following changes for patients undergoing primary total knee arthroplasty:

2384% increase in high viscosity cement to 72.3% in 2020.	**751% increase** in aspirin reported for deep vein thrombosis prophylaxis to 88.3% in 2020.
54% decrease in 90-day mortality to 0.2% in 2020, equivalent to 384 deaths prevented.	**51% decrease** in 90-day readmissions to 3.1% in 2020, preventing 3,469 readmissions.
32% decrease in 2-year revision rates following the peak in 2006 to 1.4% in 2018, preventing 271 revisions.	**33% decrease** in 90-day deep surgical site infections to 0.2% in 2020; 44 infections prevented since a peak in 2010.
50% decrease in cobalt chromium on polyethylene to 51.9% in 2020.	**19% decrease** in 90-day emergency department visits to 9.6% in 2020.

A national total joint home recovery program was implemented in 2016. Dashboard monitoring of same day discharge with quality metrics and clinical studies from the Total Joint Replacement Registry reported same-day discharge to be safe, with no differences observed in adverse 90-day events. Similar findings were reported for patients with comorbidities who historically may not have been considered candidates for same-day discharge. Patients also reported higher satisfaction with home recovery. Since the program was implemented, there has been a:

2105% increase in same-day discharge to 70.6% all primary total hip arthroplasties in 2020.

2562% increase in same-day discharge to 69% of all primary total knee arthroplasties in 2020.

Hospital bed days are one of the costliest components of total joint replacement. By successfully expanding a home recovery program using registry data, there was **a cost savings of over $146 million** while increasing patient satisfaction and enhancing the quality of care.

To address the US opioid epidemic, registry studies identified rates of postoperative total hip and knee opioid use, risk factors for prolonged opioid use, prescribers of opioids, and **a higher revision risk associated with prolonged postoperative opioid.** Findings were shared with the interregional chiefs' group and with physicians program wide. Reduction in opioid prescriptions was established as an interregional chiefs' goal, **leading to a 30% reduction in postoperative opioid use.**

Koplan KE, Paxton EW, Bellow J, Rabrenovich V, Convissar J, Wang MC, Grimsrud CD, Navarro RA. "Same-day joint replacement care: Achieving the quadruple aim" *NEJM Catalyst*, 2021; 2(2).

Reddy NC, Prentice HA, Paxton EW, Hinman AD, Lin AG, Navarro RA. "Association between same-day discharge total joint arthroplasty and risk of 90-day adverse events in patients with ASA classification of ≥3." *J Bone Joint Surg Am*, 2021; 103(21): 2032-44.

Reddy NC, Prentice HA, Paxton EW, Hinman AD, Navarro RA. "Frequency and timing of complications and catastrophic events following same-day discharge compared to inpatient total hip arthroplasty." *J Arthroplasty*, 2021; 36(7S): S264-71.

Wang MC, Chan PH, Paxton EW, Bellows J, Koplan K, Rabrenovich V, Convissar J, Reddy NC, Grimsrud CD, Navarro RA. "Factors influencing patient satisfaction with care and surgical outcomes for total hip and knee replacement." *Perm J*, 2021; 25(4).

Prentice HA, Inacio MCS, Singh A, Namba RS, Paxton EW. "Preoperative risk factors for opioid utilization after total hip arthroplasty." *J Bone Joint Surg Am*, 2019; 101(18): 1670-8.

Namba RS, Paxton EW, Inacio MCS. "Opioid prescribers to total joint arthroplasty patients before and after surgery: The majority are not orthopedists." *J Arthroplasty*, 2018; 33(10): 3118-24.

Namba RS, Singh A, Paxton EW, Inacio MCS. "Patient factors associated with prolonged postoperative opioid use after total knee arthroplasty." J Arthroplasty, 2018; 33(8): 2449-54.

Namba RS, Inacio MCS, Pratt NL, Graves SE, Roughead EE, Paxton EW. "Persistent opioid use following total knee arthroplasty: A signal for close surveillance." *J Arthroplasty*, 2018; 33(2): 331-6.

Namba RS, Inacio MC, Pratt NL, Graves SE, Roughead EE, Craig Cheetham T, Paxton EW. "Postoperative opioid use as an early indication of total hip arthroplasty failure." *Acta Orthop*, 2016; 87(Suppl 1): 37-43.

Anterior Cruciate Ligament Reconstruction Registry

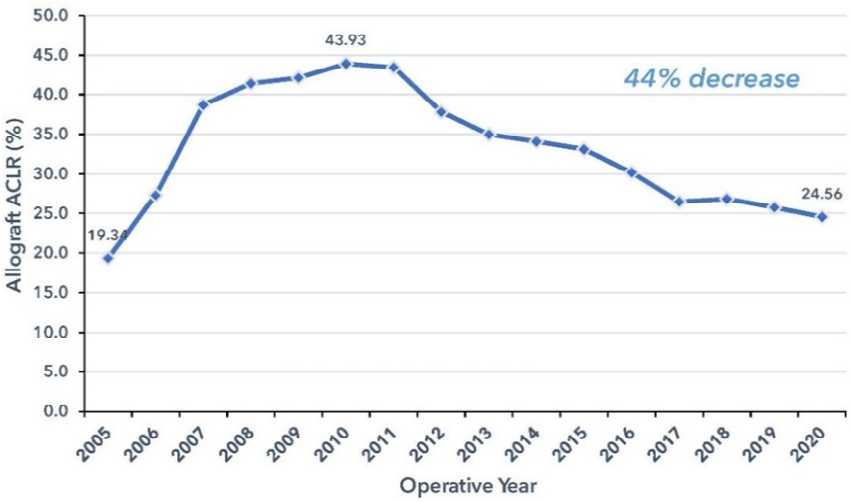
Since its inception in 2005, feedback to surgeons on clinical best practices, surgeon profiles, risk calculators, and medical center specific reports, resulted in the following changes in practice:

18% decrease
in 2-year revision rates to 1.9% in 2018.

77% decrease
in 90-day readmission to 0.2% in 2020, preventing 164 readmissions.

20% decrease
in 90-day emergency department (ED) visits to 4.9% in 2020 preventing 142 ED visits.

Studies using data from the ACLR Registry found allograft utilization to be associated with a higher revision risk following primary ACLR. This risk was more pronounced for chemically processed or irradiated allografts and for ACLR in patients <22 years of age. The orthopedic chiefs implemented reduction of allograft use in primary ACLR as an interregional goal. Data was shared at chief's meetings, region champions meetings, and disseminated to front line physicians. Since implementation, there has been a:



44% decrease
in allograft utilization from peak utilization in 2010 (Figure).

79% decrease
in allografts identified as higher risk to 2.5% in 2020.

87% decrease
in allograft ACLR in members <22 years to 3.2% in 2020.

Due to dissemination of registry findings and partnership with the orthopedic chiefs, we have observed:

Prevention of more than 1,200 revision surgeries
within the first 2 years of the ACLR procedure, enhancing the quality of care for our members.

This translates to a **savings of over $21 million program-wide.**

Maletis GB, Funahashi TT, Inacio MCS, Paxton LW. "Optimizing anterior cruciate ligament reconstruction: Individualizing the decision-making process using data from the Kaiser Permanente ACLR Registry: 2018 OREF award paper." *J Orthop Res*, 2021; (Epub ahead of print).

Maletis GB, Chen J, Inacio MC, Funahashi TT. "Age-related risk factors for revision anterior cruciate ligament reconstruction: A cohort study of 21,304 patients from the Kaiser Permanente Anterior Cruciate Ligament Registry." *Am J Sports Med*, 2015; 44 (2): 331-336.

Tejwani SG, Chen J, Funahashi TT, Maletis GB, Love R. "Revision risk after allograft anterior cruciate ligament reconstruction: Association with graft processing techniques, patient characteristics, and graft type." *Am J Sports Med*, 2015; 43 (11): 2696-2705.

Maletis GB, Inacio MC, Desmond JL, Funahashi TT. "Reconstruction of the anterior cruciate ligament: Association of graft choice with increased risk of early revision." *Bone Joint J*, 2013; 95-B (5): 623-628.

Hip Fracture Registry

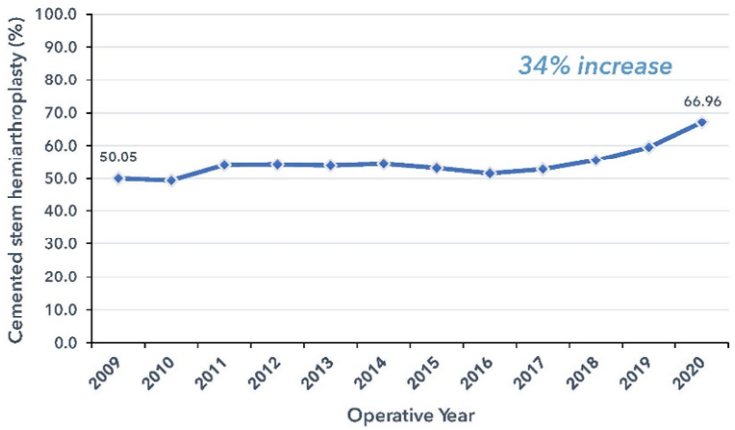
Since the implementation of the registry, using a collaborative approach between operational practice and clinical research findings, the following improvements have been observed for patients undergoing hip fracture repair:

48% decrease in 90-day deep surgical site infections to 0.3% in 2020, preventing 104 infections.	**33% decrease** in 90-day readmissions to 14.8% in 2020, preventing 2,840 readmissions.
29% decrease in 2-year revision rates to 3.3% in 2018, preventing 608 revision surgeries.	**21% decrease** in-hospital length of stay to an average of 4 days in 2020.
20% decrease in the number of prescriptions for postoperative opioids dispensed.	**16% decrease** in 90-day mortality to 11.0% in 2020.
8% increase in number of patients going from admission to operating room within 48 hours to 92.9% in 2020.	

Recent findings from the Hip Fracture Registry reported a higher revision risk following uncemented hemiarthroplasty for the treatment of hip fracture. Historically cement usage was consistent at 50-55%.

Based upon dissemination of registry findings and collaborating with the inter-regional chiefs, cement fixation has now increased to 67% in 2020 (Figure).

This practice change translates to a **26% increase** in two years.



Increasing utilization of cement fixation has led to:

A prevention of 31 revision surgeries within the first 2 years of hemiarthroplasty, enhancing the quality of care and value for our members.

This prevention translates to a **savings of over $2.1 million program-wide.**

Okike K, Chan PH, Prentice HA, Paxton EW, Burri RA. "Association between uncemented vs cemented hemiarthroplasty and revision surgery among patients with hip fracture." *JAMA*, 2020; 323(11): 1077-84.

Okike K, Chan PH, Navarro RA, Khatod M, Paxton EW, Prentice HA. "Hip fracture surgery volumes among individuals 65 years and older during the COVID-19 pandemic," *JAMA*, 2022; 327(4): 387-388.

Shoulder Arthroplasty Registry

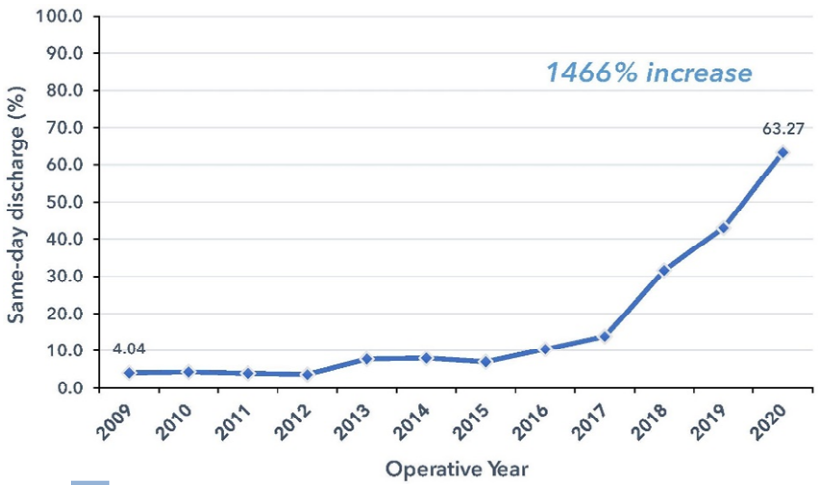
Dissemination of study findings has supplemented changes in clinical practice. Since 2005, for patients undergoing primary shoulder arthroplasty, we have observed:

1775% increase in the use of reverse total shoulder arthroplasty to 91% of all arthroplasty treated proximal humerus fractures in 2020.	
45% decrease in 2-year revision rates to 2.0% in 2018, preventing 179 revisions.	**52% decrease** in 90-day readmission to 3.9% in 2020, preventing 703 readmissions.
33% decrease in the number of prescriptions for postoperative opioids dispensed.	**20% decrease** in 1-year deep surgical site infections to 0.4% in 2020, preventing 39 infections.

Using data from the registry, no differences were observed in 90-day postoperative adverse events for patients who were successfully discharged on the same-day as their shoulder arthroplasty procedure when compared to those who had an inpatient stay. Similar observations were made in a study of surgically treated proximal humerus fractures during the pandemic.

In 2020, **same-day discharge for primary shoulder arthroplasty increased 63%** program wide (Figure).

This includes:
65% of all elective procedures and
46% of all procedures for proximal humerus fractures.



Significant differences in cost have been published for outpatient versus inpatient shoulder arthroplasty. By successfully expanding a home recovery program based on safety studies from the registry resulted in **cost savings of over $91 million** while enhancing the quality of care provided to our members.

Richards J, Inacio MCS, Beckett MP, Navarro RA, Singh A, Dillon MT, Sodl JF, and Yian EH. "Patient and Procedure-specific Risk Factors for Deep Infection After Primary Shoulder Arthroplasty," *Clinical Orthopaedics and Related Research*, 2014; 2809-15.

Kramer JD, Chan PH, Prentice HA, Hatch J, Dillon MT, Navarro RA. "Same-day discharge is not inferior to longer length of in-hospital stay for 90-day readmissions following shoulder arthroplasty." *J Shoulder Elbow Surg*, 2020; 29: 898-905.

Dillon MT, Chan PC, Prentice HA, Royse KE, Paxton EW, Okike K, Khatod M, Navarro RA. "The effect of a statewide COVID-19 shelter-in-place order on shoulder arthroplasty for proximal humerus fracture volume and length of stay." *Semin Arthroplasty*, 2021; 31(2): 339-45.

Spine Registry

The development of a standardized feedback mechanism for both instrumented and non-instrumented spine procedures for leadership and surgeons has resulted in:

39% decrease of in-hospital length of stay to a mean of 3 days in 2020.	**12% decrease** in 2-year reoperation rates to 7.6% in 2018, preventing 951 reoperations.
12% decrease in 90-day mortality 1.5% in 2020, Preventing 380 deaths.	**26% decrease** in 90-day readmissions to 8.2% in 2020, preventing 1,738 readmissions.

BMP-2 is a compound developed to enhance bone fusion but is significantly more expensive than the current standard of care. Based upon findings from the Spine Registry, no statistically significant differences were observed in 2-year operative nonunion rates following fusion procedures with and without BMP-2. Medical centers with high BMP-2 were notified and usage guidelines were created.

As a result, there has been **a decline in use of BMP-2 to fewer than 30% of lumbar fusion procedures** representing a 52% decrease.

There has also been a **44% decrease in BMP-2 use** for all spine procedures to 33.5% in 2020.

By reducing usage of this high-cost device our organization has **saved over $106 million** while continuing to provide high quality care to our members.

Guppy K, Paxton E, Harris J, Alvarez J, Bernbeck J. "Does bone morphogenetic protein change the operative nonunion rates in spine fusions?" *Spine (Phila Pa 1976)*, 2014; 39 (22): 1831-1839.

Stent Graft Registry

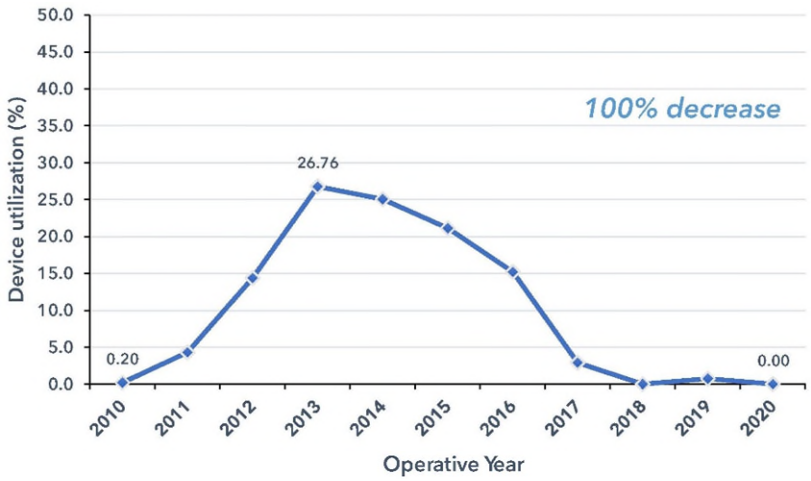
In 2010, a safety net to capture long-term outcomes for the high-risk abdominal endovascular aneurysm repair (EVAR) procedure was developed. With enhanced reporting metrics and data sharing using the registry, there has been a:

54% decrease in 2-year endograft revision surgeries following peak incidence in 2014 to 2.0% in 2018, preventing 32 revisions.	**48% decrease** in 2-year secondary reinterventions (not including revision surgery) to 5.4% in 2018, preventing 135 reinterventions.
33% decrease in 90-day mortality following peak incidence in 2012 to 3.0% in 2020, preventing 58 deaths.	**36% decrease** in 90-day readmissions to 11.8% in 2020, preventing 337 readmissions.

In 2016, the inter-regional vascular chiefs made the decision to halt use of specific endovascular AAA systems based upon alarming rates of revision identified in the Endovascular Stent Graft Registry and in conjunction with a safety advisory from the US Food and Drug Administration (FDA). In late 2018, the FDA announced a formal recall.

The FDA has since also issued two Safety Communications, in December 2020 and January 2022, which were in part **based on findings from the registry**.

Since 2013, **utilization decreased 100%** for this specific endovascular device in 2020.



Ceasing use of this device has translated to:

A prevention of 21 revision surgeries and 22 secondary reinterventions within the first 2 years of the EVAR procedure, enhancing the quality of care and safety for our members.

Equating to a **savings of over $1.4 million program-wide.**

Chang RW, Rothenberg KA, Harris JE, Gologorsky RC, Hsu JH, Rehring TF, Hajarizadeh H, Nelken NA, Paxton EW, Prentice HA. "Midterm outcomes for 605 patients receiving Endologix AFX or AFX2 Endovascular AAA Systems in an integrated healthcare system." *J Vasc Surg*, 2021; 73(3): 856-66.

Cardiac Device Registry

Remote monitoring is the standard of care for patients with cardiac implantable electronic devices (CIED). Using data in the Cardiac Device Registry, and in collaboration with vendors, quarterly patient-specific reports were generated and disseminated to medical centers to encourage increased adoption of remote monitoring.

In 2017, **73% of members had enhanced surveillance of their devices.**

With a teamwork approach, including Leadership, the Health And Value Creation Initiative (HAVC), chief's groups, and front-line device nurses, **89% of members are now being monitored.**

40% increase
in rates of remote monitoring

3,000 members have enhanced monitoring of their cardiac care in our organization, representing a significant shift in obtaining real-time clinical feedback just prior to the global pandemic. Remote monitoring has **the potential to increase patient satisfaction, reduce clinic visits, and increase longevity.**

The Cardiac Device Registry has empowered Kaiser Permanente physicians to make patient-centric, value-based purchasing decisions and serves as a foundation for quality improvement and research studies.

Examples of specific product decisions for CIED patients includes:

- Leadless pacemakers
- MRI compatible leads
- Pacemakers with poor battery longevity
- Plasma blades

Monitoring Medical Devices Expands Horizons of Medical Excellence in Integrated Care

By Janet Byron, The Permanente Federation

Permanente physicians deploy surveillance of surgical implants for evidence-based medicine

For the past 2 decades, Permanente physicians have played an integral role in leading the Kaiser Permanente National Implant Registries to track and evaluate millions of medical devices implanted in members. When linked with patient health records, the registries for orthopedic, vascular, and cardiac devices have provided a powerful tool for monitoring devices after surgery and evaluating their effectiveness.

Now, through the implementation of operational efficiencies, the scope of National Implant Registries is expanding to encompass a wider range of medical devices and surgeries.

"Our medical device surveillance and assessment results in groundbreaking quality improvements across our organization, and we have published industry-transforming studies that have helped identify devices that are safer for our patients, across the nation, and the world," says Nancy Gin, MD, FACP, The Permanente Federation's executive vice president for quality and chief quality officer. "Expanding to other high-risk devices will further enhance quality and safety."

Millions of Americans now have medical devices – such as cardiac pacemakers, replacement joints, pins and screws, or breast implants – somewhere in their bodies. The burgeoning U.S. medical device industry is valued at hundreds of billions of dollars, with thousands of companies developing and releasing new products.

Although most medical devices improve lives, some patients may suffer significant pain, injury, and death. Over the past 10 years, some 1.73 million injuries and 83,000 deaths have been linked to medical devices and 26,700 devices have been recalled in the United States.

"A lot of medical devices enter into the market with little to no clinical evidence on patient safety and product performance," says Liz Paxton, PhD, MA, director of Medical Device Surveillance and Assessment for the National Implant Registries. "Kaiser Permanente, with our large patient population, comprehensive electronic medical records, and high-quality surgical teams, is the perfect environment to evaluate these devices."

Transforming registries for broader device surveillance

With funding from Kaiser Foundation Health Plan and Hospitals and a new partnership with The Permanente Federation, the National Implant Registries is transforming and expanding to encompass a broader range of medical services; it will now be known as Medical Surveillance and Assessment.

Several pilot projects demonstrate the importance of integrating data and assessment into clinical care in new areas, says Nolan Chang, MD, executive vice president of strategy, corporate development, and finance for The Permanente Federation and chair of the newly formed Medical Device Surveillance Committee.

"We are excited about these opportunities to further enhance quality of care and patient safety for more members with other implantable devices and lead the nation in medical device surveillance."

New surveillance activities that have been launched recently include monitoring of breast reconstruction, hernia repairs, and transcarotid artery revascularization.

"Having data from all Kaiser Permanente regions for this relatively rare procedure will allow us to better understand long-term risks related to the surgery," says Robert Chang, MD, vascular surgeon with The Permanente Medical Group and principal investigator of the endovascular stent graft registry.

Likewise, Ronald Navarro, MD, interregional chief of Orthopedic Surgery for The Permanente Federation and champion of the shoulder replacement surgery registry, and other Permanente physicians are involved with a new surveillance effort to monitor outcomes related to a new bovine patch used as an adjunct to complex rotator-cuff repairs.

"While we felt that this biological technology was promising, no one had years of follow up in a large system such as ours," Dr. Navarro says. "Having access to real world, real-time data allows us to monitor patient reoperations and return to care to ensure this product is safe and has high value for our patients."

Driving evidence-based medicine

Kaiser Permanente's National Implant Registries have been critical not only for patient safety, but also as a driver of evidence-based medicine. Physicians use information gathered in these specialized registries to guide device purchasing decisions, quickly notify patients about recalls, identify best practices and care disparities, and publish peer-reviewed, industry-leading research on device safety and efficacy.

According to the National Implant Registries, Kaiser Permanente monitored 3.26 million implants across all regions through 2019 in 8 registries. Research conducted with this rich data yielded 209 peer-reviewed publications and over 400 presentations at national symposiums. More than 110,000 Kaiser Permanente members currently receive enhanced surveillance of their implants in response to 102 product recalls.

The cardiac device registry, for example, provides surveillance for patients with 100,000 pacemakers, 35,000 implantable cardioverter defibrillators, and 14,000 cardiac resynchronization therapy treatments across Kaiser Permanente. Nigel Gupta, MD, director of regional cardiac electrophysiology services with the Southern California Permanente Medical Group, is a physician champion of the cardiac device registry.

"Having all this clinical data in a central location allows an easy way to track patient outcomes on multiple levels," Dr. Gupta says. "In the event of a recall, we are not dependent on the vendors for an accurate and timely list of who may be affected. And the registry has progressed to the next level by providing additional information on how we can maximize the use of the devices to get maximum benefit for our patients."

Dr. Navarro says the registries allow Permanente physicians to ask research questions that can ultimately influence care.

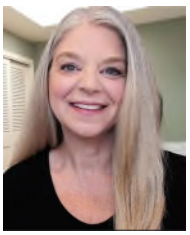
"For example," he says, "in our research we asked, 'Is it safe to send a patient home the same day as a shoulder arthroplasty?' And the answer, we found, was, 'Yes, it is.'"

Note: This article originally appeared on permanente.org

INTRODUCING THE MEDICAL DEVICE SURVEILLANCE COMMITTEE

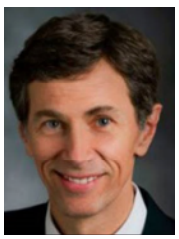
With the transformation of our work to surveillance of additional medical devices in other specialties, a new governance structure was created: the Medical Devices Surveillance Committee (MDSC). This committee is responsible for overseeing medical device surveillance for Kaiser Permanente program-wide. We are fortunate to have representatives from the Medical Group and Health Plan Quality, the Interregional New Technologies Committee (INTC), the National Product Council (NPC), and Orthopedics on the committee.

Nolan Chang, MD
Chair, MDSC and INTC
Executive Vice President, Strategy, Corporate Development, and Finance, The Permanente Federation; Regional Medical Director of Business Management, Southern California Permanente Medical Group



Robin Cisneros
Sponsor, MDSC and INTC
Vice President, Planning and New Clinical Technologies, The Permanente Federation

Liz Paxton, PhD, MA
Director, Medical Device Surveillance and Assessment Southern California Permanente Medical Group



Scott Young, MD
Executive Director and Senior Medical Director, Care Management Institute, Associate Executive Medical Director, The Permanente Federation

Jeff Klingman, MD
INTC, Representative
Chair of Neurology, Assistant Chief of Staff, Medical Services, The Permanente Medical Group

Sande Irwin, MD
Otolaryngology/Head and Neck Surgery, Vice Chair, National Product Council, Chair, Core Group Council Northwest Permanente, P.C.

Margaret Mentakis, MD, FACS
TPMG Technology Leader KPHC Procedural and Perioperative Services The Permanente Medical Group

Carol Keohane, MS, RN
Vice President, Quality, Safety, Experience and Health System Performance Improvement The Permanente Federation

Ronald A. Navarro, MD, FAAOS, FAOA
Regional Coordinating Chief of Orthopedic Surgery, Southern California Permanente Medical Group
Inter-Regional Chief of Orthopaedic Surgery, The Permanente Foundation
Board Member, KP Insurance Corporation
Lead, Kaiser Permanente Shoulder Arthroplasty Registry

MEDICAL DEVICE SURVEILLANCE COMMITTEE
RESPONSIBILITIES AND SELECTION CRITERIA

The MDSC is responsible for strategically guiding interregional medical device surveillance and evidence-based medicine across multiple specialties and shaping the future of medical device surveillance at Kaiser Permanente to improve patient outcomes system-wide.

In a short period of time, the MDSC has created a team charter, developed criteria for selection of high-risk interregional device surveillance, prioritized existing projects, and selected new medical device surveillance initiatives.

Once a research request form is submitted to the MDSC, with a well-defined clinical question for current and future research opportunities, the selection process begins. Selection criteria for new surveillance initiatives are based upon the following categories to fully assess overall risk:

- FDA risk classification
- History of recalls
- Procedure volume
- Risk of adverse events
- Risk of reoperation/revision
- Aligned with strategic clinical areas of focus

After selection, the MDSC team begins collaborating with the selected regional clinical leadership teams and identified investigators to address the selected clinical question using existing data found within our electronic health records.

Key findings from each project will be packaged by the MDSC team into a final product and disseminated to relevant stakeholders across Kaiser Permanente to help improve clinical decision-making, increase value, and mitigate risk for our patients.

Findings may also be shared externally via academic conference and/or peer-reviewed publication to further accomplish Kaiser Permanente's mission of improving the health of our patients and our communities.

A study protocol, including a statistical analysis plan, is developed for each clinical question selected as a project. Analyses performed may include benchmarking, outlier identification, comparative analysis, and non-inferiority/superiority analysis.

NATIONAL IMPLANT SURVEILLANCE INITIATIVES

Optimizing patient outcomes is a goal of our healthcare organization. Selecting the appropriate surgical procedure, approach, and implant type could be challenging without real-time outcome reporting. In 2020, we began the surveillance of high-risk implants across multiple surgical specialties, evaluating overall risk assessments of both implant and procedure characteristics.

The first devices identified for enhanced monitoring and outcome assessment included breast reconstruction procedures after a cancer diagnosis and high-volume inguinal hernia repair procedures. The United States Food and Drug Association (FDA) risk categorization and volumes of national recalls were used to assist in the identification of these devices.

Partnering with our clinical teams and the National Product Council, analysis was performed across Kaiser Permanente regions, outliers were identified, and dissemination of findings was completed to support clinical decision making. Abstracts were written to answer hypothesis-driven clinical questions to support further dissemination of findings to the broader health community.

In 2021, five high-risk procedures were selected for evaluation. Using our electronic health record as our data source, surgical reintervention, major and minor complications and risk of adverse events were evaluated. This included:

Cochlear Implants
Head and Neck Surgery

Deep Brain Stimulators
Neurology

Intraocular Lenses
Ophthalmology

Urethral Slings
Urogynecology / Urology

Lower Extremity Peripheral Stents
Vascular Surgery

NATIONAL IMPLANT SURVEILLANCE INITIATIVES

After breast reconstruction and hernia repair procedures were identified as high-risk implants short and long-term outcomes, return-to-care metrics including ED visits, revision, reoperation, and readmissions were assessed. Dashboards were developed to support hypothesis-driven questions and clinical decision-making. Abstracts were created and accepted to international medical conferences. Key clinical findings were shared with the NPC, regional chiefs' groups, and other key stakeholders.

KEY CLINICAL FINDINGS

HERNIA REPAIR

A description of 131,629 inguinal hernia repair patients

- Most patients were male (92.3%) and White (64.9%) and had an ASA classification of 1 or 2 (79.8%)
- Majority of patients had a same-day discharge (95.4%)
- 5.3% of patients had a 30-day ED visit and 1.1% had a 30-day readmission
- Incidence of reoperation at 5- and 10-years of follow-up was 2.38% and 3.42%, respectively

Reoperation risk factors following inguinal hernia repair

- Modifiable patient risk factors associated with reoperation following inguinal hernia repair include obesity, diabetes, chronic pulmonary disease, drug abuse, and peripheral vascular disease
- The association for reoperation risk strengthened with increasing BMI, with BMI>35 showing an almost two-fold higher risk than BMI ≤25 kg/m^2

Female sex and risk of ipsilateral reoperation following inguinal hernia repair

- Higher reoperation risk after open repair of inguinal hernia for females but a lower risk after laparoscopic repair
- Of those who had a reoperation, 10.3% of females and 0.6% of males had a femoral hernia repair

"Given our large surgical volume, over 17,000 abdominal wall hernias a year, the KP integrated health care system is in a great position to contribute to the body of literature to help determine the most appropriate techniques and mesh implants that result in the best outcomes for our patients, not just as a measure of recurrence rates, but also for patient satisfaction, quality of life scores, and post-op pain measurements."

Elliott Brill, MD
TPMG, Santa Clara, General Surgery

BREAST RECONSTRUCTION

Comparative analysis of immediate versus delayed breast reconstruction

- 23% increased odds of 7-day return in the immediate reconstruction group compared to delayed, with further analysis needed to assess additional follow up periods.
- 14% increased risk of return to OR in patients with IBR compared to delayed

No difference in risk of complications using Acellular Dermal Matrix (ADM) material versus non-ADM materials

- ADM usage has increased 90% since 2010 at KP as it is marketed towards improving patient satisfaction and reducing complications that could lead to a return to the OR.
- We found no difference in 1-year OR return adjusting for patient factors overall and after accounting for radiation.

"Working with this team on data for breast reconstruction has been of tremendous incalculable value. The meetings with the surgeons established critical questions that would help us plan for safer and optimized care delivery while minimizing waste and identifying variations in practice that may be costly and non-productive. We believe it will greatly improve patient outcomes and enhance the safety of our chosen pathways in breast reconstruction."

Cissy Tan, MD
SCPMG, San Diego, Plastic Surgery

NATIONAL IMPLANT SURVEILLANCE INITIATIVES

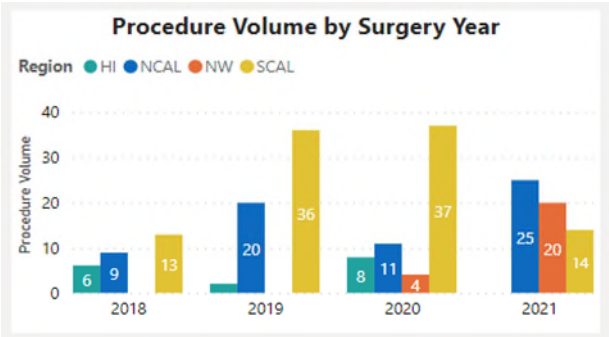
NEW TECHNOLOGY ASSESSMENT

In 2021, we expanded to include assessment of new surgical technologies. In collaboration with the National Product Council (NPC) leadership and the Standards and Sourcing Teams (SST), opportunities to identify new procedural technology and new device innovations were identified for evaluation. Two procedures are currently under assessment including the Transcarotid Artery Revascularization procedure and the bioinductive bovine patch for rotator cuff repair.

By extracting existing data we created a platform for real-world benchmarking assessment and prompt identification of post-operative complications. This generated a dashboard tool for clinicians to monitor and evaluate Kaiser Permanente member outcomes to ensure industry standards and regulatory requirements fell within the anticipated range.

Transcarotid Artery Revascularization

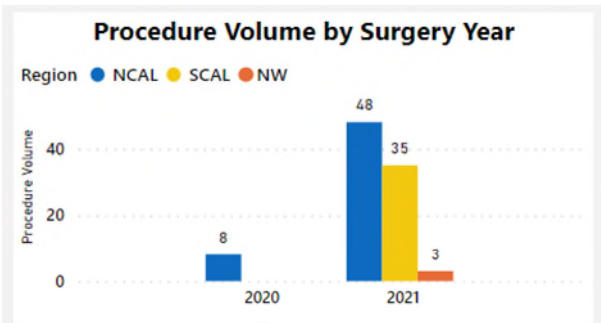
The Transcarotid Artery Revascularization procedures were selected to assess the risk of stroke, death, readmission, ED visits, and length of stay following primary intervention. Currently >200 procedures are under enhanced surveillance program-wide.



30-Day Outcomes	Rate (%)
Stroke	2.4%
Readmission	4.8%
ED Visit	7.3%

Bioinductive Bovine Patches

New-to-market bioinductive bovine patches for partial thickness rotator cuff tears were also selected to assess the risk of revision, readmission, and ED visits following implantation. This assessment including >90 procedures has yielded low rates of adverse events to date.



Outcomes	Rate (%)
Lifetime Revision	1.0%
Readmission – 90-Day	0.0%
ED Visit – 90-Day	0.0%

This new technology assessment creates a foundation for additional procedural and implant specific evaluations allowing for greater combined learning throughout Kaiser Permanente in the areas of quality, patient safety and regulatory requirements.

NATIONAL RECALL TRACKING

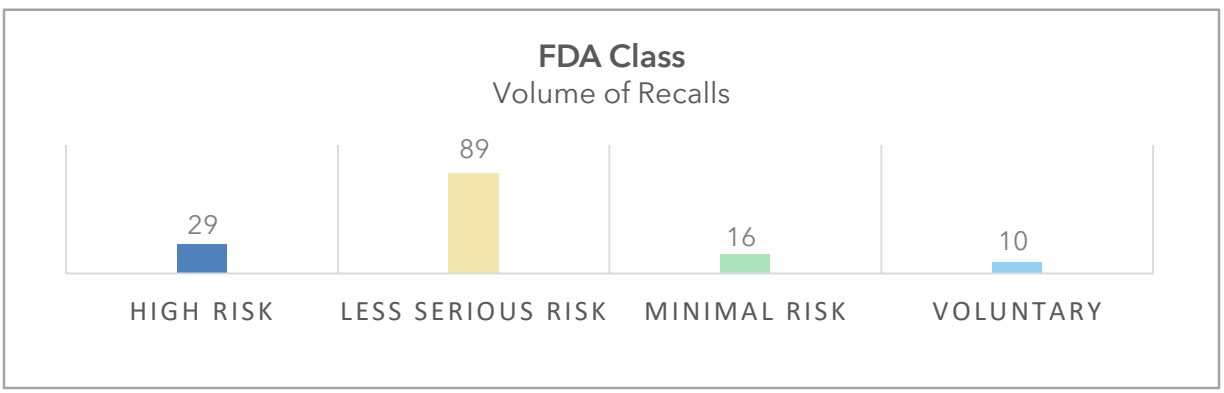
The tracking of national recalls within our National Implant Registries has been performed since 2001. Working with the FDA, vendors, and the Kaiser Permanente National Recall Department we have identified 125 implant recalls, across eight registries, affecting 130,744 patients. These national recalls include >130,000 total implants ranging from voluntary or minimal risk to high-risk recalls requiring implant removal.

Starting in 2020, national implant tracking expanded outside of the National Implant Registries to include all implanted devices used throughout Kaiser Permanente. In the first year of expanded recall tracking an additional 19 implant recalls were identified in the areas of: neurostimulators, venous and thoracic stent grafts, deep brain stimulators, ORIF plating systems, and breast implants.

To date, this combined recall tracking system has captured 144 total recalls, affecting 134,554 patients within Kaiser Permanente allowing for enhanced monitoring of patient safety and lifetime surveillance.

RECALL SUMMARY

Specialty	Recalls	Cases	Patients
Expansion of Recall Surveillance	19 (13.2%)	4,335 (3.2%)	3,810 (2.8%)
Registry	125 (86.8%)	132,961 (96.8%)	130,744 (97.2%)
ACLR	3 (2.1%)	116 (0.1%)	116 (0.1%)
Cardiac Device	36 (25.0%)	91,377 (66.6%)	92,073 (68.4%)
Endovascular	2 (1.4%)	747 (0.5%)	747 (0.6%)
Hip Fracture	5 (3.5%)	6,556 (4.8%)	6,556 (4.9%)
Shoulder	12 (8.3%)	1,004 (0.7%)	974 (0.7%)
Spine	4 (2.8%)	850 (0.6%)	778 (0.6%)
Total Hip	38 (26.4%)	28,077 (20.4%)	25,729 (19.1%)
Total Knee	25 (17.4%)	4,234 (3.1%)	3,771 (2.8%)
Total	144 (100.0%)	137,296 (100.0%)	134,554 (100.0%)



MEDICAL DEVICE SURVEILLANCE AND ASSESSMENT TEAM

We would like to acknowledge the significant work done by the MDSA team. Their ability to expand outside of the Implant Registries while taking on the Surveillance Initiatives and Recall Identification roles without the addition of increased resources is a testament to their passion for the work that they do and dedication to the mission of Kaiser Permanente.

This team includes management, administrative assistants, biostatisticians/research scientists, database administrators, data consultants/programmers, project managers, and research associates who work in concert each year to help produce and disseminate quality outcomes reporting, data analytics, and key clinical research findings throughout Kaiser Permanente.