

MEDICAL DEVICE SURVEILLANCE AND ASSESSMENT

ANNUAL REPORT 2022

MESSAGE FROM THE LEADERSHIP TEAM

This year marked a significant change in the expansion of our work beyond the National Implant Registries to Medical Device Surveillance and Assessment and a shift to leveraging existing KP HealthConnect data to answer clinical questions in multiple specialty areas.

Key 2022 accomplishments include:

- Recipient of the 2022 James A. Vohs Multiregional Award for National Total Joint Replacement Initiative
- Expanded inter-regional medical device surveillance to breast, hernia, cochlear, peripheral stent, urethral sling, deep brain stimulators, radial head arthroplasty, bovine shoulder patches, platelet-rich plasma, and transcarotid artery revascularization
- Monitoring >3.8 million devices to enhance quality and safety for >787,000 members
- Identified regional variations, clinical best practices, best performing implants, and risk factors to pre-operatively optimize patients who receive medical devices in existing registries and new surveillance initiatives
- Implemented a cross-specialty Medical Device Surveillance Committee scientific subcommittee to nationally prioritize and select the most impactful clinical research studies
- 28 peer-reviewed publications, 22 presentations, and 15 posters at national and international specialty conferences demonstrating the influence of our work on clinical practice within and beyond our organization
- Immediately identified patients with recalled devices for 16 medical device recalls affecting 15,451 patients in 9 specialties

We are excited to share these achievements with you. We want to thank everyone who supports and contributes to this important work enhancing patient safety and quality for our members and beyond.

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

MEDICAL DEVICE SURVEILLANCE COMMITTEE MEMBERS 2021-2022



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



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



Robin Cisneros
*Vice President, Planning and New
Clinical Technologies*



Barbara Crawford, MS, RN, NEA-BC
*Senior Vice President, National Health
Plan and Hospital Quality*



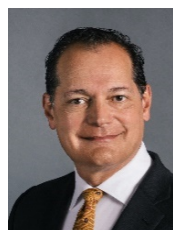
Sande Irwin, MD
*Otolaryngology/Head and Neck
Surgery, Vice Chair, National
Product Council, Chair, Core Group
Council, Co-chair, Northwest
Regional Product Council*



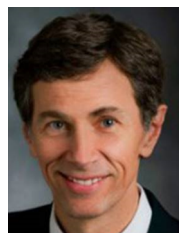
Jeffrey Klingman, MD
*Chair of Neurology, Assistant
Chief of Staff, Medical Services,
Walnut Creek Hospital*



Tracey McLean, MD
*Obstetrics/Gynecology, Regional
HPHC Core Team Lead*



Ronald A. Navarro, MD, FAAOS, FAOA
*Regional Coordinating Chief of Orthopedic
Surgery, SCPMG, Inter-Regional
Orthopaedic Chief, Lead, KP Shoulder
Arthroplasty Registry*



Scott Young, MD
*Senior Medical Director, Clinical
Quality and Safety, Executive
Director, The Care Management
Institute*

AWARDS AND RECOGNITION

National Total Joint Replacement Initiative receives the 2022 Vohs Multi-Regional Quality Award

We are proud to announce the NTJR initiative received the James A. Vohs Award. MDSA provided dashboard development, metrics monitoring, and research study analytical support for this initiative. It is an honor to receive this award recognizing programs that have a significant impact on patient safety and quality of care.

“This award represents so much collaborative work from so many constituencies that leaned in for the benefit of total joint arthroplasty patients to achieve a new paradigm and win with patient satisfaction and wonderful outcomes.”

Ronald A. Navarro, MD
Inter-Regional Orthopaedic Chief, Southern California
Permanente Medical Group, Pasadena, CA

INITIATIVE ACCOMPLISHMENTS



Home recovery
increased by 70%



80% decrease
in length of hospital stay



Safety and return to care rates
trended downward or remained stable



Higher patient satisfaction
for home recovery patients



Demonstrated significant
cost reduction estimated at
\$72 million in savings

[Link to Publication](#)

Cervical Spine Research Society recognizes the Spine Registry!

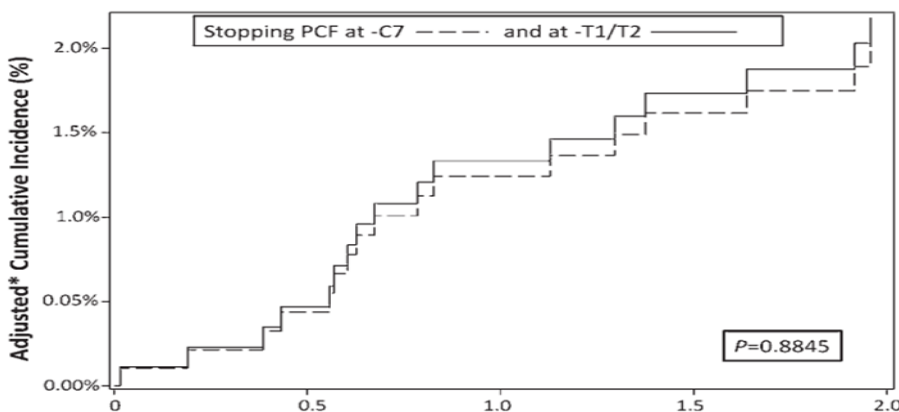


FIG. 2. Adjusted cumulative incidence of reoperations for nonunion in posterior cervical fusions stopping at C7 and those stopping at T1/T2.
* Adjusted for age at surgery and smoking.

This study was awarded first place in the most recent conference: *No Difference in Reoperation Rates for Operative Adjacent Segment Disease in Posterior Cervical Fusions Stopping at C7 Versus T1/T2.*

[Link to Publication](#)

BENCHMARKING STANDARDS OF CARE

Assessment of lifetime revision rates and post-operative outcomes indicate KP rates are similar or better when compared to those from existing programs and literature.

Specialty	Start Year	Procedure Volume	Lifetime Revision Rate
Total Knee Replacement	2001	303,844	3.0%
Total Hip Replacement	2001	170,520	3.2%
Spine	2009	92,352	1.0%
Hip Fracture	2009	71,087	1.6%
Anterior Cruciate Ligament Reconstruction	2005	63,976	4.2%
Mid-Urethral Sling	2009	38,733	1.4%
Shoulder Arthroplasty	2005	29,870	4.2%
Endovascular Aneurysm Repair	2010	7,936	6.5%
Cochlear Implant	2010	2,540	4.5%
Radial Head Arthroplasty	2009	1,899	3.2%

Specialty	Start Year	Procedure Volume	Post-op Outcome Rate*
Cardiac Device	2001	169,941	2.5% all-cause early explant
Hernia Repair	2015	105,326	3.4% reoperation
Breast Reconstruction	2010	73,831	8.7% return to OR
Deep Brain Stimulator	2010	3,923	2.2% lead revision
Peripheral Stents	2010	3,820	2.9% 1-year unplanned amputation
Transcarotid Artery Revascularization	2018	275	1.5% 30-day stroke rate
Bovine Shoulder Patch	2020	211	<2% return to OR
Platelet-Rich Plasma Injection	2020	200	0.5% subsequent PRP-related procedure

*Outcome time periods are lifetime unless otherwise noted.



Over 787,000 patients with enhanced implant surveillance



Reduced ED visits and readmission rates for hip fracture patients



Significantly reduced revision rates for shoulder arthroplasty patients



Shortened average length of stay for patients after hip, knee, and shoulder replacement



Increased utilization of rechargeable implantable pulse generators (IPG) for patients with deep brain stimulators



Decreased readmission and infection rates for total knee replacement patients

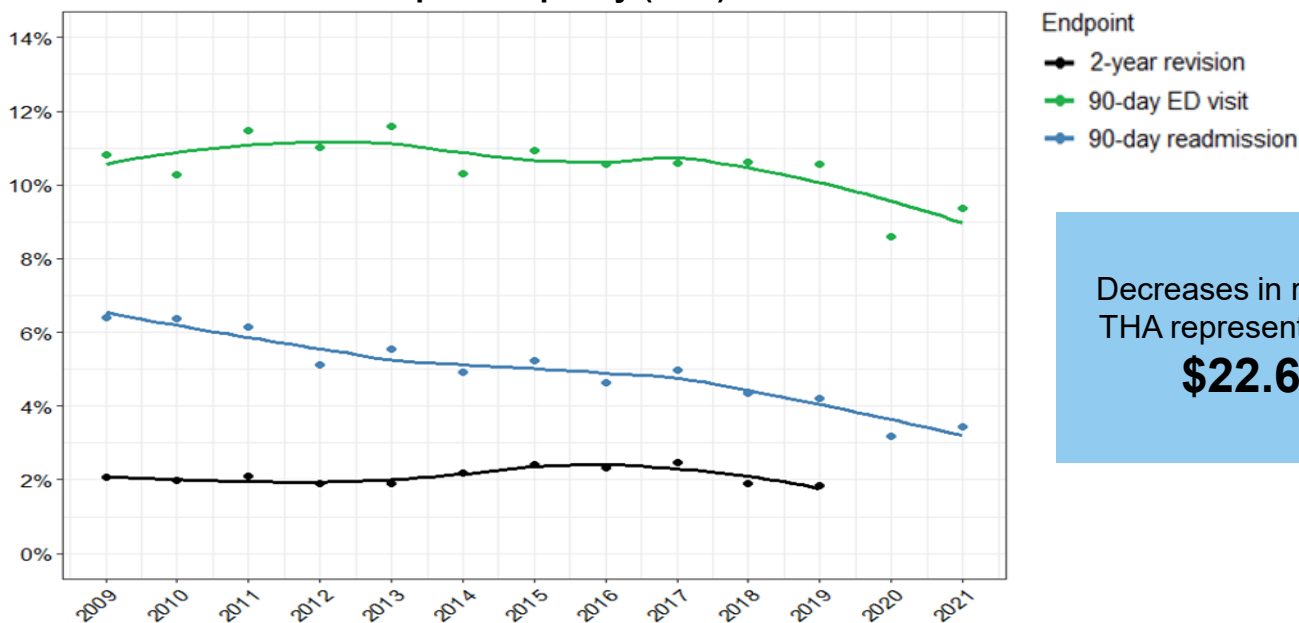


HIGHLIGHTING IMPROVEMENT OF CARE

Total Joint Replacement

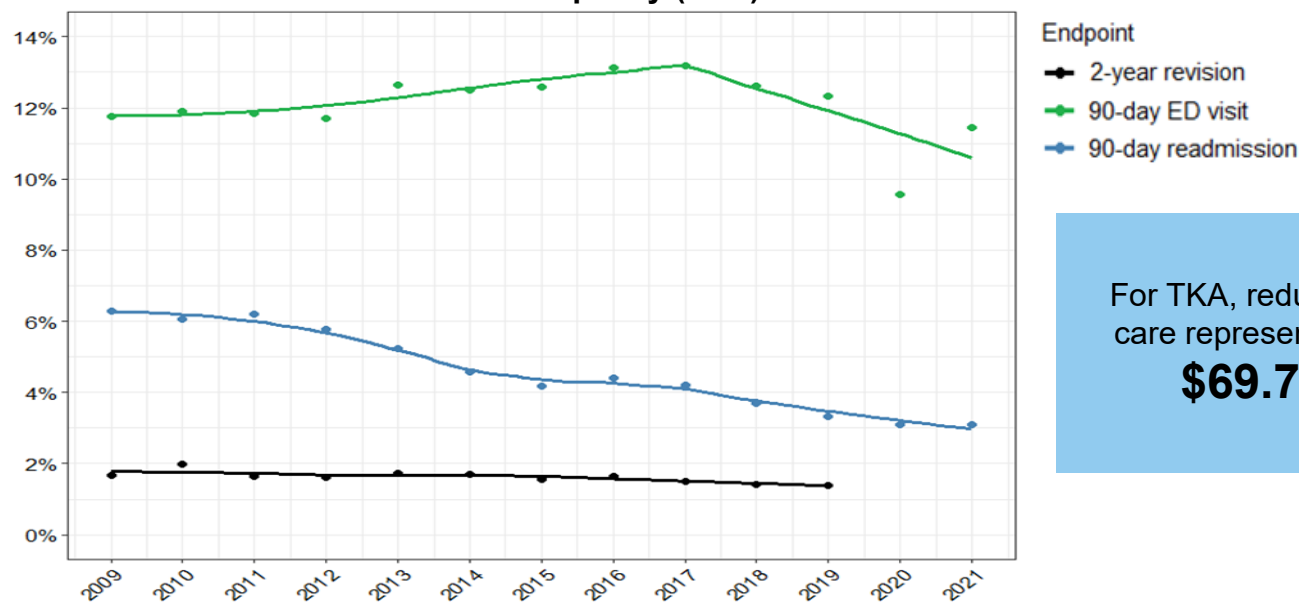
In 2014, SCPMG initiated a pre-operative primary elective total joint arthroplasty patient optimization and preparation program in which patients are medically optimized by their primary physician, a home safety evaluation is conducted, and patients identify a coach to help with post-operative care. Assessment of the program indicated improved outcomes and significant cost savings.

Total Hip Arthroplasty (THA)



Decreases in return to care after THA represent a cost savings of **\$22.6 million**

Total Knee Arthroplasty (TKA)



For TKA, reduction in return to care represented a savings of **\$69.7 million**

Forslund JM, Chan PH, Prentice HA, Purdy AC, Khatod M. "A pre-operative patient optimization program improves outcomes after primary elective total joint arthroplasty in a large US integrated healthcare system." Submitted to *J Am Acad Orthop Surg*, under review.

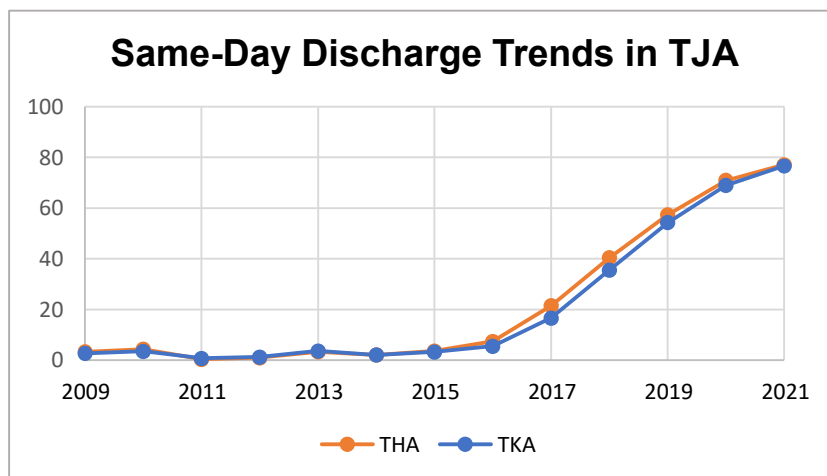
Association between same-day discharge total joint arthroplasty (TJA) and risk of 90-day adverse events in patients with ASA classification of ≥ 3 .

Same-day discharge TJA did not increase the risk of ED visits, unplanned readmissions, and complications compared with an inpatient stay for higher-risk patients.

These findings support expansion of indications for same-day discharge to include a more diverse selection of patients, provided that robust enhanced care protocols are in place to ensure patient safety and mitigate the risk of adverse events.

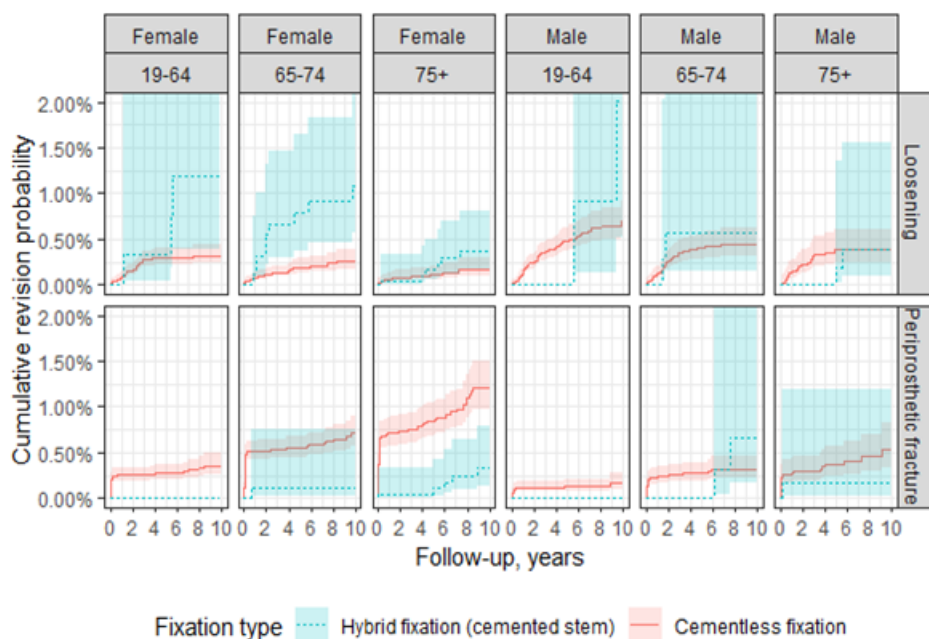
As a result, same-day surgery has been expanded to higher-risk patients.

**>75% increase
in same-day discharge
representing a cost savings of
>\$214 million**



[Link to Publication](#)

Cause-specific stem revision risk in primary elective total hip arthroplasty using cemented vs cementless femoral stem fixation in a US cohort.



Differences in cause-specific revision risks stem fixation method were related to patient age and gender.

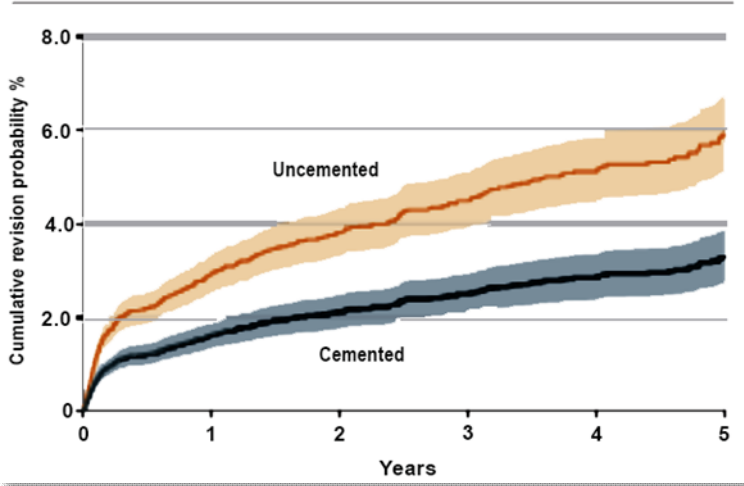
These findings support clinical decision-making for the use of cement fixation in specific patient populations.

[Link to Publication](#)

Hip Fracture Repair

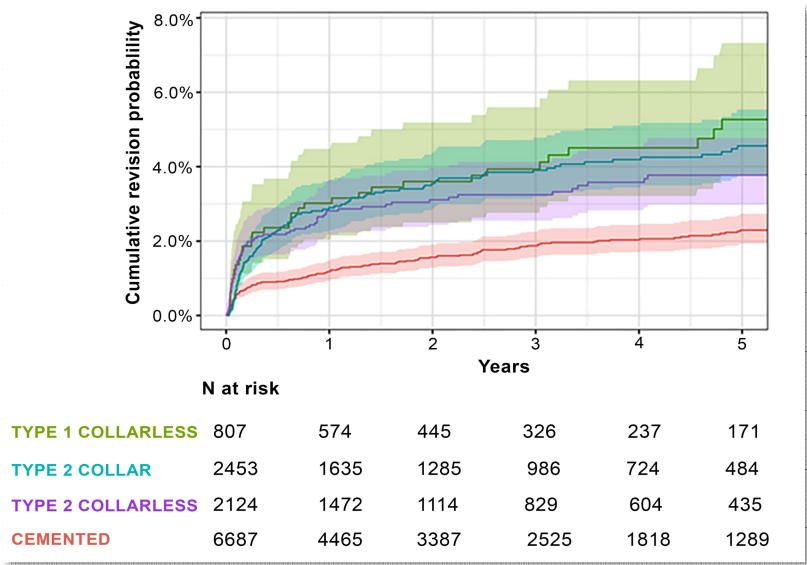
Uncemented fixation was associated with a higher risk for aseptic revision with no observed differences in mortality risk.

Figure. Cumulative Probability of Aseptic Revision Over Time, by Type of Femoral Fixation



[Link to Publication](#)

A second study found higher risk of aseptic revision for all the uncemented femoral stem designs compared with cemented fixation.

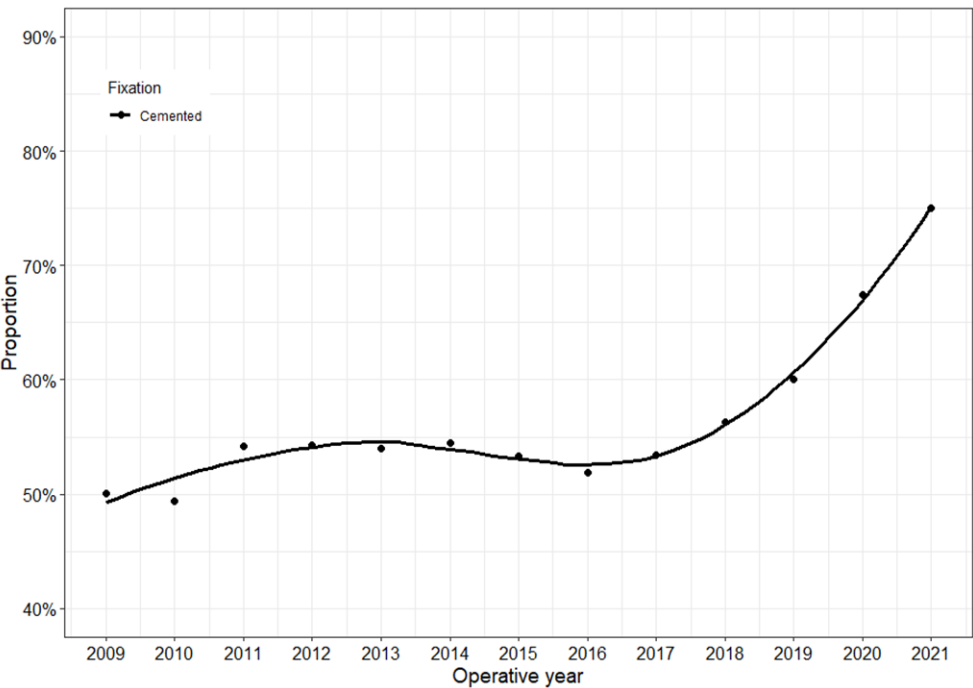


[Link to Publication](#)

These findings suggest using cemented fixation in the hemiarthroplasty treatment of displaced femoral neck fractures in the absence of contraindications.

The inter-regional orthopedic chiefs adopted cement fixation as a goal. Quarterly feedback from the registry resulted in changes in practice and cost savings.

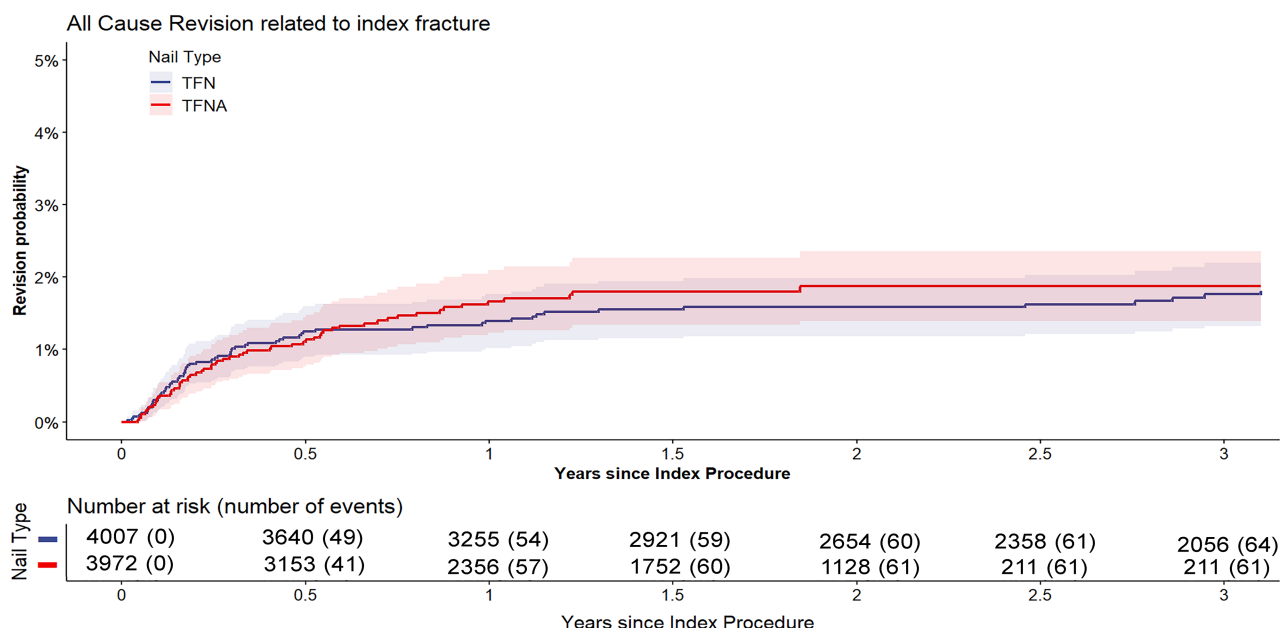
Improvement of Care: Increasing Trends of Cement Usage



45% increase
in cement usage

representing
a cost savings of
\$1 million

In a cohort of 7,979 after hip fracture fixation using DePuy Synthes Trochanteric Fixation Nail (TFN) or Trochanteric Fixation Nail Advanced (TFNA), TFNA had a higher risk of revision for nonunion.

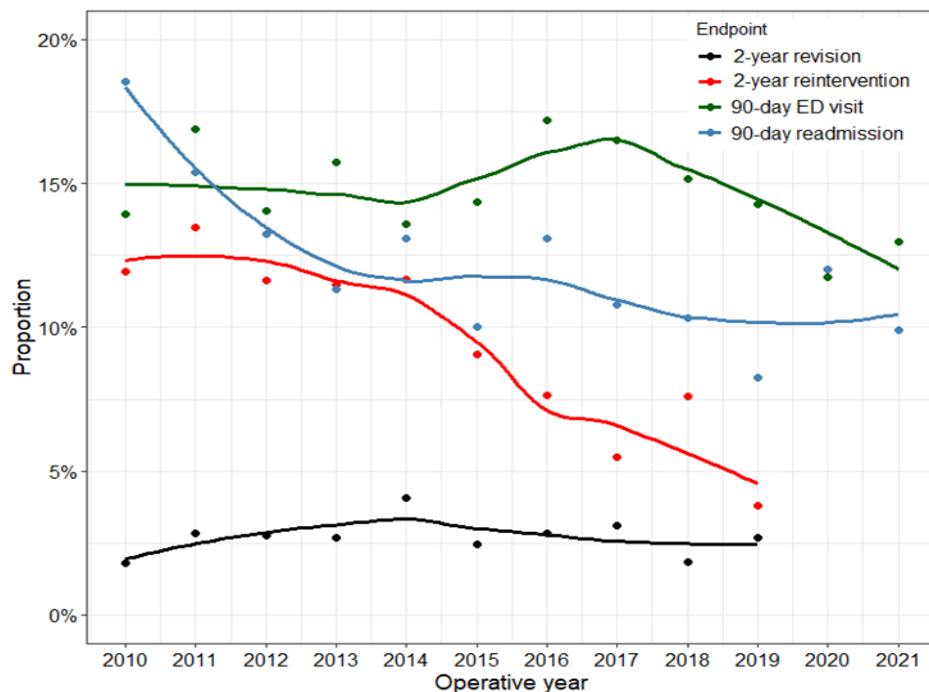


**Implant selection is an important component of surgical outcomes.
This study helps guide implant selection for hip fracture patients.**

[Link to Publication](#)

Endovascular Aortic Stent

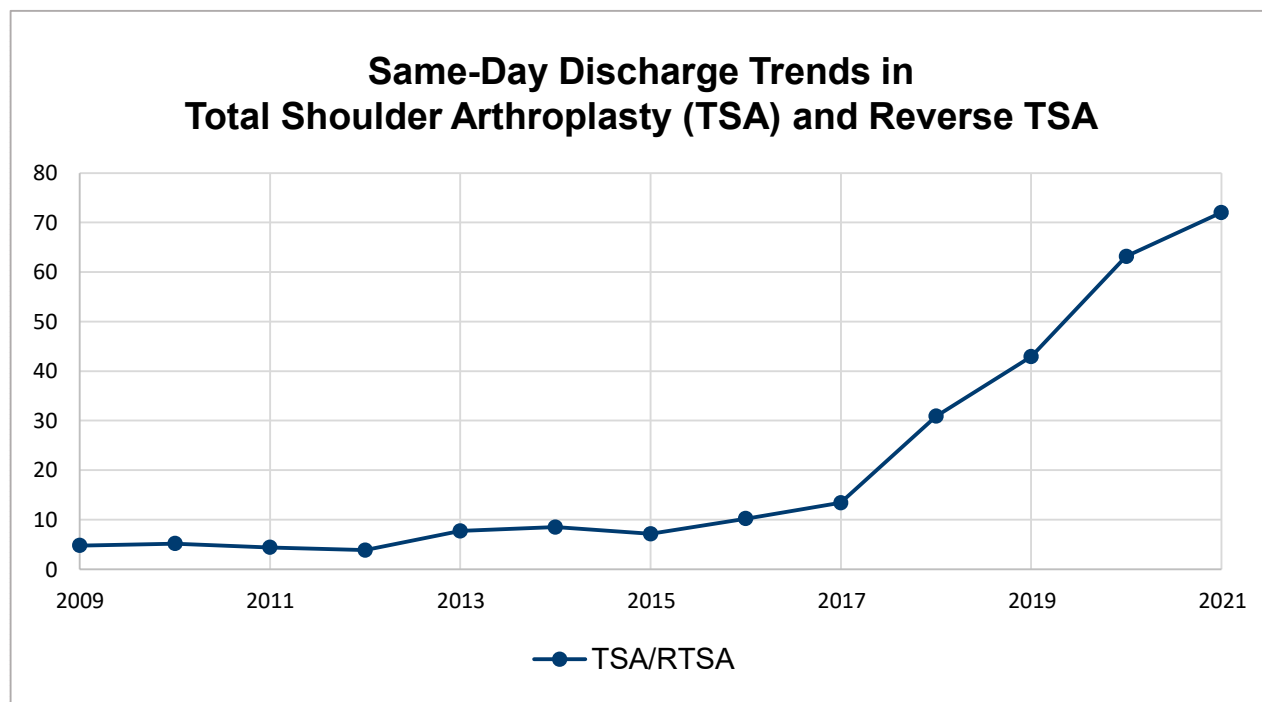
Trends in endovascular repair from 2010 to 2021 show complications decreased over time in >3800 patients. Improved graft durability, patient selection, and surgical technique have resulted in enhanced outcomes based on registry feedback to vascular physician leads.



Improved outcomes
represent a savings of
\$7 million

[Link to Publication](#)

Shoulder Arthroplasty



With adoption of same-day discharge, knowledge of underlying reasons for returns following shoulder arthroplasty is crucial to improve patient safety, satisfaction, and comfort.

Rates of same-day discharge
increased 67%

This increase represents
\$120 million
in cost savings.

Improvement of Care

- Pain and falls among the top reasons for early return to care in nearly 10,000 elective shoulder arthroplasties
- Unnecessary return to care for post-operative falls can be reduced with enhanced patient education

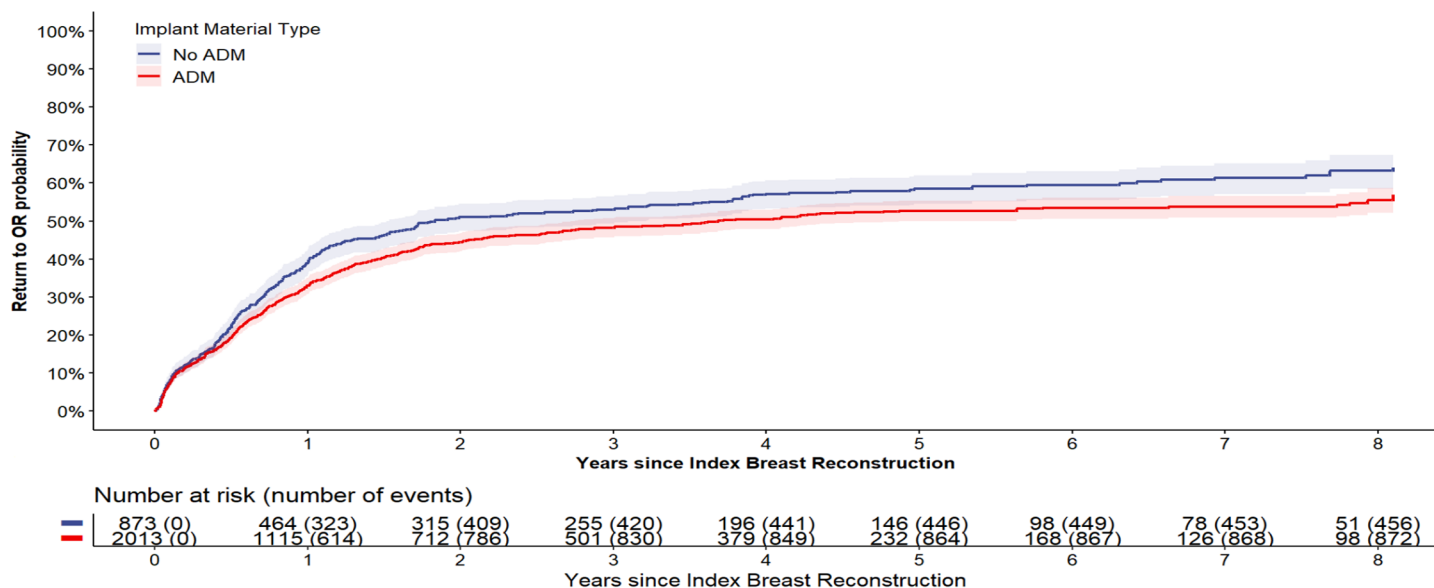
[Link to Publication](#)

ENHANCED DEVICE SURVEILLANCE

In 2020, we began surveillance of high-risk implants across multiple surgical specialties, evaluating overall risk assessments of implant, procedure, and patient characteristics.

Breast Reconstruction

Use of acellular dermal matrix (ADM), a costly addition to breast reconstruction, has significantly increased since 2010. ADM is marketed towards improving patient satisfaction, reducing complications and returns to the OR. In a study of >73,800 procedures ADM material versus non-ADM, no difference was observed in the risk of return to the OR following immediate direct-to-implant reconstruction, regardless of radiation status.



These findings are critical for implant selection and national contract decision-making.

Cochlear Implants



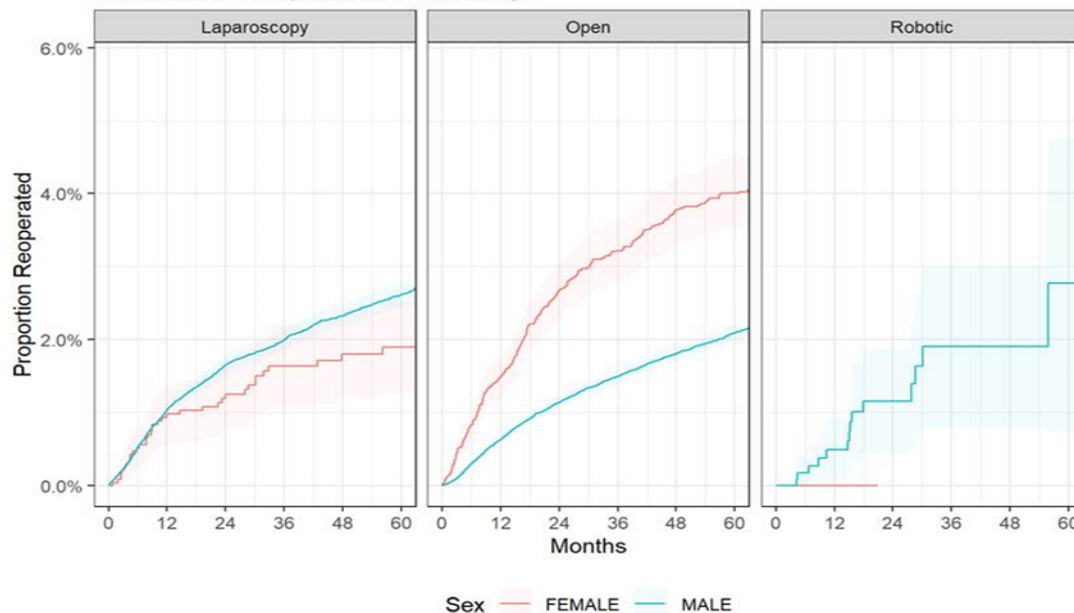
2,300 patients underwent primary cochlear implant placement between 2010 and 2021. Consistent with prior research, pediatric patients had higher rates of lifetime revision compared to adult patients.

Higher revision risk was observed in one manufacturer in the ≥ 18 patient age group due to recalled devices.

Hernia Repair

Inter-regional chiefs' group dissemination of findings of more than 105,000 repairs is influencing clinical practice program-wide.

- 10-year reoperation rates are <3.4%
- Reoperation risk is almost two-fold for patients with BMI>35
- Females have a higher risk for reoperation after open repair for inguinal hernia but lower risk after laparoscopic, compared to males



Mid-Urethral Slings

38,733 mid-urethral sling (MUS) procedures have been identified program-wide between 2009 and 2021.

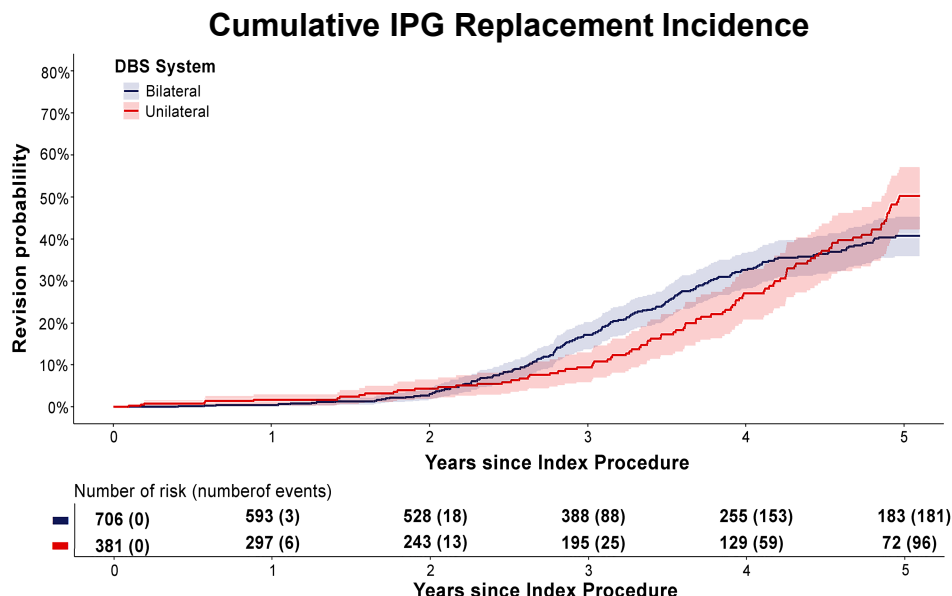
Overall reoperation rates for recurrent incontinence:

- MUS sling only and MUS sling plus hysterectomy or adnexal surgery; 7,706 patients; incidence rate 2.67%
- MUS sling plus all other procedures including prolapse; 25,087 patients; incidence rate 2.90%
- At 1 to 5 years, MUS plus other procedures including prolapse had higher reoperation rates for recurrent incontinence

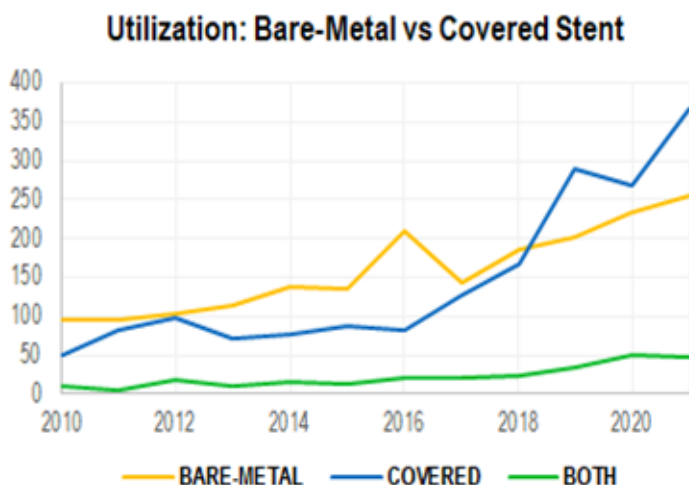
Deep Brain Stimulators

Assessment of deep brain stimulators identified regional clinical variation in implantation methods. In a descriptive study of a cohort of >1,000 patients, results indicated:

- Reduction in the overall percentage of medication prescribed post-operatively at 3 years: 48.2%
- Bilateral patients experienced more than 10% medication usage reduction compared to unilateral cranial systems



Peripheral Stents



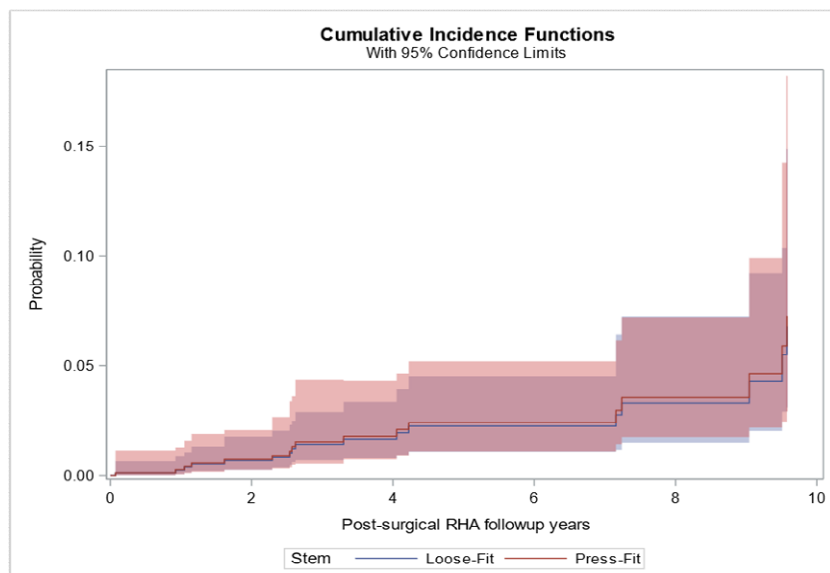
Chronic limb-threatening ischemia is associated with high rates of amputation and mortality. >1,400 of these high-risk patients who received a lower extremity stent were identified program-wide between 2010 and 2021.

Comparisons of utilization and outcomes for balloon-expanding, self-expanding, drug-eluting, bare-metal, and covered stents found an increased usage of covered over time. However, patients with less expensive bare-metal stents had lower rates of amputations and reinterventions.

Radial Head Arthroplasty

Press-fit versus loose-fit stems and risk for surgical outcomes following radial head arthroplasty.

1,620 patients underwent primary RHA between 2009 and 2021 in NCAL and SCAL. No difference was observed in risk of revision or reoperation with more than 4 years follow-up between implant stem types of press-fit or loose-fit. Findings from this study will assist in future contract decision-making.



NEW TECHNOLOGY ASSESSMENT

Enhanced surveillance of new technology is essential to assist with contract decision-making regarding patient safety, usage trends, and quality improvement.

Bovine Shoulder Patch

Bioinductive bovine shoulder patches are a new technology for the treatment of partial thickness rotator cuff tears. 116 patients in 3 regions across 21 medical centers over the last 18 months are currently monitored to assess safety.

3.4% returned to the OR for any shoulder procedure. Readmission and ED visit rates are suggesting this patch is safe in the short-term post-operative period.

Transcarotid Artery Revascularization

Transcarotid artery revascularization is a high-risk, minimally invasive procedure introduced as an alternative to open repair. The risk of stroke, death, readmission, ED visit, and length of stay following primary intervention were captured. >200 procedures are under enhanced surveillance from 2018 to 2021.

Post-operative stroke rates remain below reported benchmarks.

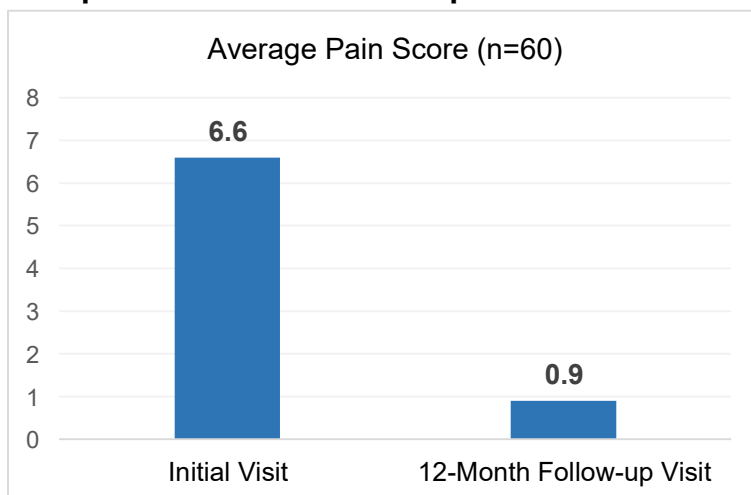
Platelet-Rich Plasma

Platelet-rich plasma (PRP) therapy is a biological regenerative treatment with potential clinical applications for tendinopathy. NCAL outcomes of PRP were evaluated in a pilot project.

One year after receiving the injection, patients reported improvement in their outcomes and pain scores and few patients proceeded to surgery for lateral epicondylitis.

Results from this pilot will be used for operational decision-making regarding coverage and expansion of the use of PRP in our organization.

Improvement in Patient-Reported Pain Scores



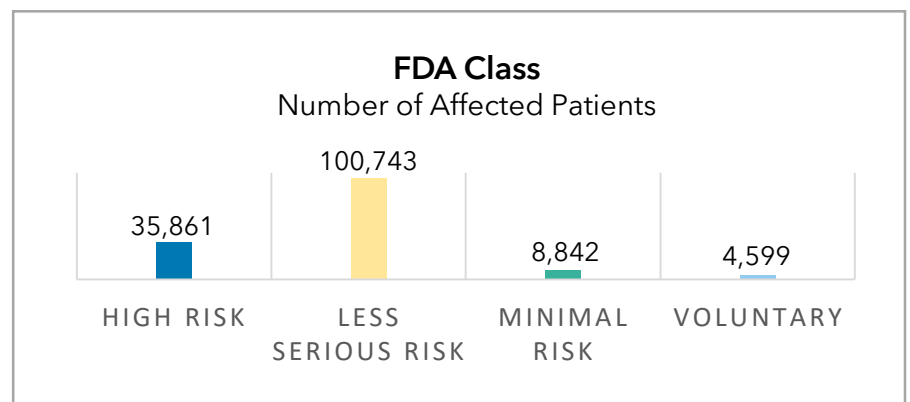
NATIONAL IMPLANT RECALL TRACKING

Our patient-specific recall system provides immediate identification and notification to clinical team program-wide. In 2022 alone, more than 15,000 patients were affected by a recall in 15 different clinical specialties.

Specialty	Number of Recalls	Affected Patients
Cardiac Implantable Electronic Device	39	92,867
Total Hip Arthroplasty	41	35,098
Total Knee Arthroplasty	26	8,169
Hip Fracture	5	6,556
Breast Reconstruction	1	2,937
Neurosurgery	7	1,122
Shoulder Arthroplasty	14	976
Spine	6	786
Endovascular Aneurysm Repair	4	776
Vascular Devices	7	249
Cardiology	6	214
Orthopedics: Screws, anchors & trauma	4	135
Anterior Cruciate Ligament Reconstruction	4	118
Gastroenterology	1	37
Ophthalmology	1	5
Total	167	150,045

Monitoring of implanted devices has improved patient safety and collaboration with:

- FDA
- Implant vendors
- National Recall Department
- Standards and Sourcing Team



ACKNOWLEDGMENTS

We would like to acknowledge the MDSA team's successful transition to the new operating model in just one year. As a result, implant surveillance has been enhanced for 787,000 patients in 18 specialties improving patient safety and care program-wide.

We would also like to thank and acknowledge our physicians, physician leads, inter-regional and regional chiefs' groups in identifying key clinical questions, providing clinical consultation and leadership and translating findings into clinical care. This work would not be possible without their support and leadership.