Registries Revolutionize Care and Outcomes

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"No one could believe I'd had two knees replaced", says 61-year-old Jacquelyn Winn. In 2010, Winn traveled more than 2,800 miles across Japan to fulfill her dream of seeing Mt. Fuji. "I kept up with the activities and didn't need any extra breaks. We walked an average of 10 miles a day."

The decision to undergo joint replacement surgery is difficult and worrisome for patients like Winn. She suffered from osteoarthritis and tremendous knee pain for many years, which put her athleticism and world exploration on hold for a decade. "I'd been very active up to that point in my life. But ten years of pain put me on the sidelines. The pain was too much." Family and friends convinced her to talk to an orthopedic surgeon. After trying non-surgical interventions, doctor and patient decided together that surgery was the way to go. For Kaiser Permanente (KP) members and surgeons, decisions about implant choices are based on proven outcomes reported by Kaiser Permanente's Total Joint Replacement Registry (TJRR). The doctor showed samples of joints and explained what would work, how they would work, and what would best suit her individual needs. Winn's surgery was a success and eventually, she had both knees replaced.

What's Behind Kaiser Permanente's Achievement Award?

Kaiser Permanente, the largest nonprofit health plan and integrated healthcare delivery system in the United States, was the winner of ECRI Institute's 5th Annual Health Devices Achievement Award for its TJRR, along with its Cardiac Device Registry (CDR). The award honors excellence in health technology management. Beyond the benefits to patients, the registries can also help clinical engineering and purchasing departments in making decisions on device selection.

The joint registry is the nation's largest, allowing clinicians to analyze data on more than 100,000 joint replacement surgeries performed by more than 350 KP surgeons nationwide. Because of the TJRR, Kaiser Permanente is able to identify patients at risk for poor clinical outcomes, determine the most effective implant devices, track implant usage and cost, monitor and manage implant advisories or recalls, and better maintain overall quality assurance (QA).

Based on the success of the TJRR, Kaiser Permanente added orthopedic registries and implemented a Cardiac Device Registry (CDR). The other orthopedic registries address anterior cruciate ligament reconstruction, hip fracture, and shoulder and spine implants. The CDR tracks those patients who undergo implantation of an initial or replacement implantable cardiac defibrillator (ICD) or a pacemaker. The volume of the CDR database totals 52,000 defibrillators and pacemakers and 75,000 leads.

The goals of KP registries are:

- Identify and track patients with specified orthopedic or cardiac implants
- Respond immediately to patients with devices involved in recalls/advisories
- Provide active surveillance systems for unexpected or harmful events
- Monitor trends in device performance, safety, and overall QA
- Produce data to support best clinical practices
- Provide a framework for institutional review board (IRB)-approved research for peer reviewed journal

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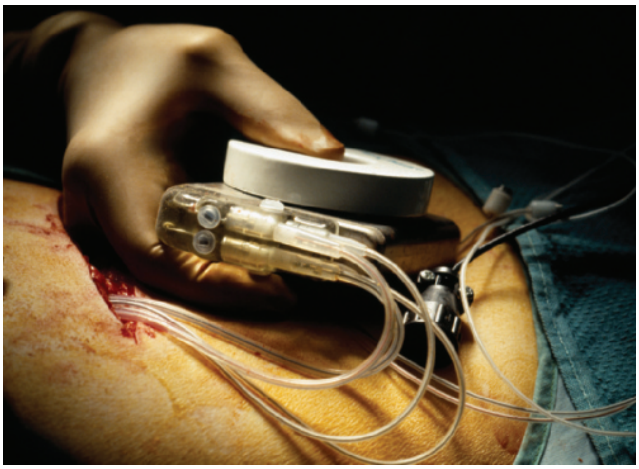
publications and/or national medical specialty conferences to share key findings

Motivation Behind TJRR Initiative

Within the United States, over 600,000 total hip and total knee replacements are performed each year.[1] By the year 2030, that number is projected to exceed 4 million. Once considered surgical breakthroughs, hip and knee replacements have become routine procedures. As the population ages and people expect to live longer and more active lives, demand for joint replacement is expected to grow. Annual hospital costs associated with these procedures are projected to exceed $40.8 billion by 2015.[2] The projected increases in total joint arthroplasty (TJA) demand and the associated costs are a looming disaster for our already overburdened U.S. healthcare system.



A patient is about to receive an automatic implantable cardio defibrillator (AICD) in a follow-up heart surgery.

One potential method to address this pending crisis is through comparative safety and clinical effectiveness research aimed at reducing the need for TJA revision surgery. Registry data supports clinical outcomes research to:

- Help surgeons and patients make informed decisions about which implant to use
- Identify patients for whom the risks and potential costs of failure make surgery unwise
- Evaluate the relative value of TJA over alternative treatments
- Assess effectiveness of one implant brand or design over another

"From the inception of our registries, our primary goal has been to monitor the performance of implant procedures and improve quality and outcomes through reduction in revisions and other failures," says Tadashi T. Funahashi, MD, chair of KP's Inter-regional Implant Registries Committee. "As the largest total joint Registry in the United States, we now have the database to leverage our findings and optimize outcomes."

Expansion to Cardiac Device Registry

During the past decade, there has been a steady increase in cardiac device implantation, in particular, in the rate of ICD implantation. In 2005, Medicare and the professional cardiology societies expanded the indications for ICD implantations to include primary prevention of sudden arrhythmic death in high risk patients.[3] That change resulted in expanded ICD utilization. The current annual volume of pacemaker implantation in the United States is estimated to be more than 200,000 initial pacemakers and 175,000 replacement devices.[4] Cost estimates per device range from $10,000 per unit for a pacemaker up to $50,000 for an ICD.

Unlike the TJRR efforts to reduce surgical revisions, patients with ICDs or pacemakers expect device replacement due to finite battery life of the pulse generator. The CDR monitors the timing of device explantation to report on premature battery failure, mechanical complications, infections or upgrades in device selection. This information is used by physicians, clinical technology assessment groups, clinical engineering and purchasing departments. "We can make better device selection, contracting and purchasing decisions, and use our patient care dollars more wisely and in the best interests of our patients," says Michael Lauer, CDR physician lead. "The registry provides us with an indispensable platform for longitudinal follow-up of patients and key clinical variables, including patient survival, cardiac ejection fraction, congestive heart failure status, and therapeutic benefits of these devices."

Methodology of Data Collection and Validation

The foundation of the TJRR is the use of standardized pre-operative, operative, and post-operative documentation forms which contain a number of key data elements. Data is collected at the time of care delivery, both in the clinic (by the surgeon and medical assistant) and in the operating room (by the registered nurse circulator and surgeon).The forms capture patient demographics, im-

plant characteristics, surgical techniques, and clinical outcomes. The forms are sent to the registry office for centralized data entry.

For the CDR, data collection occurs in the operating room. The manufacturers of implantable cardiac devices are required by the U.S. Federal and Drug Administration (FDA) to maintain databases of all implanted ICDs and pacemakers. The Kaiser Permanente registry has worked with these manufacturers to establish a system whereby each manufacturer submits monthly updates of new and replacement implants via electronic data transfer.

For both registries, additional data on elements such as utilization, mortality, diagnosis, complications, length of stay, and re-admission rates are pulled from a variety of administrative databases. A unique advantage for data gathering is the national implementation of the electronic medical record, Kaiser Permanente HealthConnect®, which facilitates behind-the-scenes data capture and extraction to supplement registry information. "Kaiser Permanente is in a unique position to leverage its integrated electronic health records in order to track joint replacements in a highly accurate manner. The KP Registry allows for seamless integration of clinical outcomes with quality assessment. In essence, we have the ability to accurately identify clinical outcomes and then apply them within our system to improve quality," says Monti Khatod, TJRR MD lead with Kaiser Permanente.

For reliable registry information and reports, data validation and quality control procedures are crucial. For the TJRR and CDR, quality control is completed in both an automated fashion using computer codes to flag data anomalies and by registry staff running quality check programs. Queries are run in the electronic medical record database using ICD-9 diagnosis codes to identify suspected complications. All suspected complications, such as infections, deep vein thrombosis, device malfunctions, are confirmed through chart review to determine if they meet pre-established criteria. Validated complications are reported to appropriate internal channels, such as infection control, the quality department, physician leaders, and operating room managers.

Registry Benefits

A critical element of the TJRR success has been the implementation of a dynamic feedback mechanism. When registry personnel identify clinical best practices, findings are shared with the surgeons and staff through chiefs of service and administrator meetings, website, individualized physician practice profiles, site visits, newsletters, e-mails, and national conference presentations. This feedback yields measurable objective improvements in care. The findings play an important role in counseling patients, identifying risk factors, tracking implanted devices during recalls, and assessing the comparative effectiveness of devices. The registries rely on the unique collaborative culture among the KP physicians, staff, and administrators.

> "In our organization, registries give an opportunity for the Clinical Technology Department to partner with physicians, outcomes leaders, purchasers, and others to analyze and improve care delivery."

The registries have resulted in significant improvement in safety, quality, and cost savings including:

- Immediate identification, monitoring, and notification of more than 2500 orthopedic and cardiac patients affected by 15 recalls or advisories in 2009 alone
- Improved TJRR infection surveillance reliability through use of a sophisticated electronic algorithm applied to registry data that replaced manual chart review of 17,000 total joint replacements per year
- Verification of a 2% higher total hip arthroplasty revision rate associated with smaller femoral size prevented 917 surgeries and saved millions of dollars from 2002 to present
- Addressing the trend of 10% higher failure rate for partial knee replacements prevented 16 revisions during 2005–2006
- Feedback to surgeons when one total knee technique was found to be associated with higher revision rates, resulting in a reduction in its use and monetary savings in prevention of revisions
- Comparative device performance evaluation influenced contract and purchasing decisions and led to the development of orthopedic device formulary. This formulary resulted in standardization of implant selection and substantial savings since its inception.
- Evidence-based findings of patient risk factors for

post-operative infections, hospital readmissions, deep-vein thrombosis, and other complications resulted in important changes for surgical indications and preoperative care

Prior to implementation of the TJRR and the CDR, Kaiser Permanente had limited knowledge of its surgical revision/re-operation/complication rates, had fragmented mechanisms in place to identify patients or inform surgeons during a recall situation, had inconsistent means to identify best practices, and no systematic ways to monitor implant performance or costs.

The work of the KP registries is a potent tool for longitudinal evaluation of device performance and safety. In our organization, registries give an opportunity for the Clinical Technology Department to partner with physicians, outcomes leaders, purchasers, and others to analyze and improve care delivery. Registries have allowed us to evaluate clinical indications for and outcomes of device implantation, to respond to recalls and advisories, and to contribute to purchasing initiatives and national quality improvement. ■

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