

Study finds medical device registries enhance patient safety and quality of care

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A detailed and standardized national registry of commonly used joint replacement devices would improve patient outcomes and create clinical and financial efficiencies, according to a Kaiser Permanente research study of 85,000 joint surgeries published in the November issue of the *Journal of Bone and Joint Surgery*.

Information on the more than 600,000 total knee and hip replacements performed annually in the United States could enhance [patient safety](#) and quality of care and provide a foundation for more in-depth research projects that will contribute to better outcomes as increasing numbers of replacements are performed in the future, researchers found.

This prospective study of 80,000 total joint replacement and 5,000 anterior cruciate ligament reconstruction procedures within Kaiser Permanente's national implant registries – the nation's largest registry of implants -- looked at patient demographics, implants and surgical techniques in relationship to outcomes for these procedures. This is the largest community-based research study of outcomes with total knees and hips and ACL reconstruction procedures, and one of few studies conducted with a registry that includes a level of detail to assess outcomes in the United States.

"Our findings demonstrate the critical impact of registries and the important role they play in counseling patients, identifying risk factors, tracking implanted devices during recalls and assessing comparative effectiveness of devices," said study lead author Elizabeth Paxton,

director of surgical outcomes and analysis at Kaiser Permanente.

Researchers found the three most common reasons for re-operations of ACL reconstruction of the knee were meniscus injury, stiffness and device removal. These risk factors and outcomes demonstrate how a registry can improve quality of care by providing feedback to physicians. Additionally, the orthopedic implant registries were used to track eight recalls and advisories during the study period, which were critical in immediately identifying and following up with patients that were impacted.

Since its inception in 2001, Kaiser Permanente's Total Joint Replacement Registry and subsequently the Anterior Cruciate Ligament Reconstruction Registry have helped health care providers identify clinical best practices, evaluate and monitor patient outcomes and risk factors associated with revision [surgeries](#), and assess the clinical effectiveness of implants. Kaiser Permanente is able to develop and utilize these data tools because of the information contained in Kaiser Permanente HealthConnect, the world's largest private sector electronic health record. The Kaiser Permanente TJRR now has more than 100,000 implants registered.

The United States does not have a national registry to track joint replacements to gauge implant effectiveness and patient risk. Sweden, Finland, Norway, Australia and Denmark have built large and successful national registries; those registries have had similar findings to those at Kaiser Permanente.

"The information we will obtain from our ACL registry will help us to identify those patient factors and surgical techniques that will lead to the best overall outcome," said Greg Maletis, MD, study co-author on the study and an orthopedic surgeon at Kaiser Permanente Baldwin Park (Calif.) Medical Center. "We will also be able to compare our results,

with the results of patients from other countries like Norway and Sweden who also have ACL registries."

Using integrated data systems and advanced statistical analyses, the registries collect patient demographics, implant characteristics, surgical techniques, and outcomes prospectively at the point of care. These data were supplemented with data from Kaiser Permanente HealthConnect, which enables all of the organization's more than 15,000 physicians to electronically access the medical records of Kaiser Permanente's 8.6 million members nationwide.

The study showed how registries can identify [risk factors](#) that can be applied to a larger population. For example, researchers found an increased rate of ACL reconstructions for specific demographics among men and women, and increased time between injury and surgery (six to 12 months) associated with an increased rate of additional knee injuries compared to surgery within three months of the original injury. This demonstrates the importance of addressing surgery needs early on to prevent subsequent injuries.

Provided by Kaiser Permanente

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