New research demonstrates benefits of national and international device registries

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An unprecedented collaboration among researchers from Kaiser Permanente, Weill Cornell Medical College, and worldwide registries demonstrates the importance of tracking medical devices' effectiveness and safety—specifically of hip and knee implants—after they are in use.

Most Americans will be exposed to a medical device during his or her life and tens of millions will receive an implantable device. However, public health and regulatory agencies in the U.S. and internationally acknowledge there are gaps both in the ability to track these devices and to provide the public the accurate, evidence-based information consumers need to improve their health and make informed care decisions.

In a series of research articles, sponsored by the Food and Drug Administration (FDA) and published today, researchers analyzed data from a collaboration among seven national and regional registries to examine the performance and safety of hip and knee implants. The registries are part of the International Consortium of Orthopedic Registries (ICOR), an initiative that aims to address major gaps in evidence related to implants, as well as demonstrate the importance of registries and international collaboration for evaluation performance and patient safety worldwide.

Their findings demonstrate the importance of registries and unique device identification (UDI) implementation for post-market surveillance of medical devices in the United States and worldwide. Post-market

surveillance is a collection of processes and activities the FDA uses to monitor the safety and effectiveness of medical devices once they are on the market.

"In orthopedics, large registries or networks of registries capture device information on a very detailed level and can become particularly important for active surveillance and post-market evaluation," said Art Sedrakyan, the principal investigator of the FDA contract and associate professor of healthcare policy and research at Weill Cornell Medical College. "Comparative studies of hip and knee devices illustrate the ability of a registry consortium to determine real-world evidence for various classes of devices and help surgeons and patients to make evidence-based choices."

"ICOR's achievements to date have enormous implications for medical device post-market surveillance system development in the United States and worldwide," said Liz Paxton, director of Kaiser Permanente's Surgical Outcomes and Analysis Unit of Clinical Analysis, San Diego, Calif. "Its ability to create an international, distributed research network in the field of medical devices opens a new door for evidence development and device-safety investigations. We are very excited about the potential of this critical work and its implications for patient safety and affordability in health care."

Researchers analyzed data from two U.S. registries (Kaiser Permanente and Health East), and registries in Australia, Spain (Catalonia), Italy (Emilia-Romagna), Sweden (Swedish Knee Arthroplasty Register), and Norway. ICOR's work provides an opportunity to collect real-world device data for performance in all settings and for all demographics, so important information can be identified and provided to surgeons and patients to determine the best implant for the patient.

Prior research found that almost no electronic health record system can

automatically and uniquely identify devices and link them to an individual patient's outcome data—but registries can. Similarly, very limited national data exists that can identify medical devices and link them to patient outcomes within claims systems, a process that can benefit from an aligned post-market surveillance system.

To enable these registries to share critical information while protecting patient privacy, researchers developed an innovative methodology. For this article supplement, researchers analyzed the health information of patients as a group, rather than their personal, protected health information—to communicate between registries and learn about individual devices and implants.

The FDA has made the development of device registries and the creation of a UDI system for medical devices a key priority. The FDA plans to develop a national medical device registry and will make recommendations for how to maximize the value of registries, along with providing guidelines on governance and other processes. Incorporating the UDI in electronic health records and medical device registry systems will help improve the efficiency and effectiveness of post-market surveillance activities.

"As an orthopedic surgeon, I have found that our registries have allowed me to help patients make more informed health care choices and they have enhanced the conversations I have with patients," said Thomas Barber, MD, associate physician-in-chief, The Permanente Medical Group, Inc., Oakland, Calif. "Based on the longitudinal data we can track and analyze, we are able to discuss the best implants and surgical techniques for patients based on their individual demographics, preferences, and lifestyles. Having robust registries at the national and international level furthers our understanding of how to optimize outcomes for patients."