Unprecedented international effort to improve safety of orthopedic devices

December 21 2011

Responding to a need for better post-market surveillance of orthopedic devices, the U.S. Food and Drug Administration (FDA) established the International Consortium of Orthopaedic Registries (ICOR) in October 2010.

As outlined in a Dec. 21 special online supplement in the Journal of Bone and Joint Surgery, ICOR is in the process of developing a collaborative process for improving the safety of orthopedic devices using outcomes registries from the U.S. and other countries. The combined ICOR registries may include data on millions of orthopedic surgical procedures and all implantable devices on the market.

More than 700,000 joint replacement devices are implanted in patients in the U.S. every year, and this volume is projected to increase twofold for hip-joint replacements and sevenfold for knee-joint replacements, to a total of more than 3 million annually, in the 20 years.

While there have been dramatic advancements in orthopedics, including new devices and improved surgical techniques, the value of many of these devices has not been established using large studies in real-world settings. The FDA chair of the meeting Dr. Danica Marinac-Dabic and ICOR meeting co-leads Dr. Art Sedrakyan (NewYork-Presbyterian/Weill Cornell and Hospital for Special Surgery) and Elizabeth Paxton, M.A., (Kaiser Permanente) believe that the consortium will help ameliorate this problem.

Unlike drugs, devices have a different path of approval that may not require conduct of clinical trials in the United States. Furthermore, adverse outcomes reporting for devices is voluntary, and the resulting data are often incomplete or inaccurate. While there is currently an effort by the American Academy of Orthopedic Surgeons to develop a large national registry, the midterm follow up will likely take several years or more, says Dr. Sedrakyan, who coordinated the supplement for ICOR and is directing the Patient-Centered Comparative Effectiveness Program. He is associate professor of public health at Weill Cornell Medical College.

For the time being, the most reliable data on devices come from large registries in the U.S. such the Kaiser Permanente Implant Registries and international registries such as those in Australia, the U.K. and Scandinavian countries that track 100 percent of device implants in those countries. While these data are complete, each registry takes a unique approach to monitoring safety.

As a result, ICOR is bringing together orthopedic surgeons, scientists and other stakeholders to establish a unified method for analyzing and reporting multinational registry data. "The result will allow us to find important differences among implants -- and thus provide important evidence to inform decision-making by physicians, hospitals and patients," say ICOR researchers.

"This collaboration provides a unique opportunity to improve patient safety worldwide by identifying the best implants for our patients," says Ms. Paxton, supplement co-author and director of Kaiser Permanente's Implant Registries, which has more than 130,000 implants registered in it.

The Journal of Bone and Joint Surgery supplement summarizes the inaugural ICOR meeting held May 9 and 10 at the headquarters of the

FDA in Silver Spring, Md. A total of 14 papers (including a summary paper) report on a variety of the meeting's topics such as implant safety and methodology. Conference invitees included 73 stakeholders from 29 registries representing 14 nations. In addition, more than 25 non-registry stakeholders represented the medical device industry, the Agency for Healthcare Research and Quality, the National Institutes of Health, Centers for Medicare & Medicaid Services, academia, device regulatory agencies, device cataloging experts, insurers and other payers. The Hospital for Special Surgery was an important partner in organizing the meeting.

Provided by New York- Presbyterian Hospital