AJRR Participation Is On the Rise!

Welcome everyone to the first official newsletter of the American Joint Replacement Registry.

It is our goal to send The Register out on a quarterly basis and our hope that you will find it informative.

Each quarter the newsletter will have regular sections. “Legal Corner,” will answer one frequently asked question relating to the AJRR Participation and Business Associate agreements. “Info Tech 101” will offer helpful information about the data submission process. “Research Realm” will offer current topics in orthopaedics, news about international registries, and publications of interest.

Each issue will also profile a “Champion of the Quarter.” This staff or surgeon champion is highlighted for their work with registries and efforts in getting the AJRR implemented at their hospital.

We would also like to keep everyone informed about our webinars, which give prospective sites the opportunity to learn more about AJRR’s legal process and raise questions unique to their institution.

Since its inception in 2009, the AJRR has collected over 27,000 procedures from its current list of participants. What began as a group of 11 pilot sites has matured to over 40 participating hospitals and we are still growing. We would like to acknowledge all of our participants by listing them here.

Thank you and enjoy!

AJRR Hosts Its Second Legal Webinar

AJRR hosted its second Legal Webinar on Wednesday, May 30, 2012. The presenter was Robert M. Portman, JD of Powers Pyles Sutter & Verville.

This and other legal webinars to be hosted in the future are intended to address the numerous questions about our legal agreements and other non-technical aspects of participation. During the webinars, Mr. Portman will discuss the terms of both the Business Associate/Data Use Agreement and the Participation Agreement. He will also review AJRR’s IRB Waivers of Consent and HIPAA compliance. At the completion of his presentation, we will always provide ample opportunity for questions from participants.

For those who were unable to participate in our most recent webinar, you may review the content online here until September 6, 2012; or copy and paste the following hyperlink into your browser.

http://event.on24.com/r.htm?e=480471&s=1&k=968C41459A7196BFA0BA9D8F2C706982
Legal Corner
By Robert Portman, JD

Why doesn’t the AJRR allow redlining of their agreements, accept side agreements/ amendments, or sign individual hospital Business Associate Agreements?

AJRR is working with hundreds of hospitals across the country on this initiative. It is not feasible for the AJRR, as a small 501(c)(3) organization, to have individualized legal agreements with each participating hospital or system. We have a universal set of agreements (Participation Agreement and Business Associate/ Data Use Agreement), for all participating hospitals and hospital systems. The AJRR staff are happy to discuss your questions and concerns and welcome the feedback. Each year, the AJRR staff and I will review the agreements and comments and concerns raised by hospitals and make any revisions we deem necessary to meet the needs of potential or current participants and that are appropriate to apply to the standard agreement. We will give participating hospitals adequate time to review the proposed global changes to the agreements and provide feedback. After that, we will circulate updated standard agreements or amendments.

Of note, the AJRR will take into consideration items not in agreement with a particular hospital’s state law. For example, if a state’s law has a shorter breach notification period, we are willing to make changes for the purposes of complying with that state’s law.

If you would like more information on our legal agreements, we have a recorded legal webinar that you may find helpful. Please contact the AJRR Staff at info@ajrr.net, to request the archived link.

Robert M. Portman is a principal in the law firm of Powers Pyles Sutter & Verville PC in Washington, DC. Mr. Portman concentrates his practice in health and association law, focusing on healthcare regulation, administrative law, antitrust, litigation, and transactions. He represents a wide range of non-profit healthcare organizations including professional societies, trade associations, and certification bodies, as well as numerous individual physicians and healthcare providers. Mr. Portman holds a BA, summa cum laude and Phi Beta Kappa, from Northwestern University and a JD, magna cum laude, from Harvard.

He also earned a Masters in Public Policy degree from Harvard’s Kennedy School of Government.

AJRR staff are always available to work with your local IT team and staff to address training, security, technology and implementation questions. We hope to ensure a seamless transition for your site into participation in the AJRR.

Info Tech 101
By Randolph Meinzer

As the AJRR IT Director, I would like to welcome you to the registry. AJRR staff are focused on making your data submission efforts simple. One of our main goals is to minimize the time you need to spend in the submission process.

Once the necessary contracts are signed, the AJRR will begin the process of setting up our technology to implement your preferred method of data submission. This process begins with a conference call between AJRR IT staff and your hospital to finalize the method for data transfer and answer any questions on the technical implementation. Regardless of the approach, the AJRR requires all participating hospitals to complete a preliminary form that defines the hospital (i.e., name, address, NPI, bed size, etc.), its orthopaedic surgeons, and individuals who will access the system. Once this form is completed, the AJRR will set up the enabling features for your site.

Start here to participate in the
AAOS 2013 Annual Meeting
Tuesday through Saturday
March 19-23
Chicago, Illinois
Research Realm

We are pleased to report active collaboration with arthroplasty registries from around the world. The 1st Congress of the International Society of Arthroplasty Registers (ISAR) was held May 20-22 in Bergen, Norway. Over 160 orthopaedic surgeons and researchers representing 20 countries presented updates on the development of national and regional registries along with cutting-edge research from these registries. AJRR Director of Research, Dr. Caryn Etkin, presented an update on the development and implementation of AJRR. Chairman of the AJRR Board of Directors Dr. David Lewallen moderated a session which presented findings from the International Consortium of Orthopaedic Registries (ICOR), an organization in which AJRR participates. Finally, AJRR Board member Dr. Terence Gioe discussed the influence of registries on surgeon behavior. Data for Dr. Gioe’s presentation came from the HealthEast Joint Replacement Registry, the first community-based joint registry in the US.

FDA News

On July 3, 2012 the U.S. Food and Drug Administration (FDA) announced that medical devices utilized in the US will be required to carry a unique device identifier, or UDI. Such a system has the ability to facilitate the timely reporting on adverse events.

In general, the UDI would include a unique numeric/ alphanumeric code specific to a device model along with the production information for a device. Information will be available in a public UDI database with no patient identifiers.

According to the FDA, a UDI system can provide multiple benefits, such as:

- Reducing medical errors by precise identification and characteristics of devices.
- Providing a consistent way to enter information about devices in electronic systems.
- Offering a standardized identifier to more effectively manage medical device recalls.

Click here to read the full press release, or copy and paste the following hyperlink into your web browser.

Publications of Interest


Rising JP, Reynolds IS, Sedrakyan A. Delays and difficulties in assessing metal-on-metal hip implants. NEJM June 20, 2012; DOI: 10.1056/NEJMtp1206794

Champion of the Quarter

Gina Bissett is the Manager for Clinical Research at Lancaster General Hospital (LGH), where she is responsible for coordinating and overseeing performance improvement projects in the Department of Peri-operative Services. She is a member of the Institutional Review Board (IRB) and served as the founding Managing Editor for the Journal of Lancaster General Hospital (JLGH). Shortly after the opening of the LGH Ortho Center, she developed and successfully implemented the LGH Total Joint Registry. This Registry currently enrolls approximately 2,000 total hip and knee arthroplasties performed each year at LGH.

Gina has more than 25 years of experience in orthopaedic outcomes. She started her career in orthopaedics at The Johns Hopkins Hospital in Baltimore. Prior to coming to Lancaster, she was the Assistant Director of Clinical Research for the Rothman Institute at Thomas Jefferson University in Philadelphia. As a consultant for both industry and academia, Gina designed and integrated data collection systems using automated data scanning technology. She holds a Bachelors degree in Healthcare Management from Immaculata University.

Gina has remained committed to the early goals of AAOS for establishing a national registry, and is enthusiastic about AJRR’s efforts to accomplish those goals.

AJRR Staff

Caryn D. Etkin, PhD, MPH
Research Director

Steven Hamada
Senior Software Engineer

Susan Hobson, MPH
Research Associate

Randolph Meinzer
Informational Technology Director

Hannelore Venable
Administrative Assistant