

## Introducing Our New Staff!

The American Joint Replacement Registry is excited that we now have eight full time staff members. How we have grown! Just one year ago, we only had two full time employees. Recent acquisitions of key directors and a researcher will help us to broaden our reach in our national scale efforts.

**David Lewallen, MD, Chairman of the AJRR Board of Directors** is pleased with our expansion efforts. "AJRR has seen tremendous growth over the past year since concluding our pilot trial, and beginning official operations in August, 2011. We have collected data on over 30,000 arthroplasty procedures and enrolled over 70 participating hospitals, growing staff to keep pace with the rapidly expanding activities. With key individuals now in place, including Executive Director Jeff Knezovich, and three outstanding Directors for Information Technology, Research, and the recently added Strategic Initiatives, I am confident that AJRR is well positioned to accelerate our ability to capture 90% of the nearly 1 million hip and knee arthroplasties performed each year in the US."



Jeffrey Knezovich, CAE, became AJRR's first Executive Director on August 1, 2012. Prior to coming to AJRR, Jeff was founder and Chief Executive Officer of the association management firm

Sentergroup, Inc. located in Chicago. There he oversaw the growth of the firm and developed associations under management. His experience in operations modeling and creating strategic plans will be a great asset to the AJRR.

Before starting Sentergroup, Jeff worked for Smith Bucklin and Associates, the world's largest association management firm. During Jeff's tenure, clients included the American Academy of Cosmetic Surgery (AACS), Southern Thoracic Surgical Association, Society of Thoracic Surgeons and American Society of Podiatric Orthopaedics. His other healthcare association management experi-

ence has included work with the Cook County Medical Society and the American College of Surgeons. In addition, for the last 18 years he has concurrently served as the AACS Executive Vice President.



Pamella Leiter, MSA, OTR/L, joined the AJRR on August 27th as Director of Policy and Strategic Alliances.

Pam graduated from the University of Illinois with a B.S. in Occupational Therapy and the University of Notre Dame with an M.S. in not-for-profit administration. She has worked as an occupational therapist and a hospital administrator. She also owned an outcomes measurement company called Formations in Health Care, Inc. which focused on developing valid measures for inpatient and outpatient rehabilitation and sub-acute care, enrolling providers of these services and comparing the providers' outcomes to that of the database of providers via quarterly report. This company was sold and went public as Caredata.com. Later Pam worked at the American College of Surgeons as the Manager of the Surgeon Specific Registry. This registry, designed for general surgeons, has 20 procedures with about 5 negative occurrences per procedure and is accepted by the American Board of Surgeons and CMS. Pam is looking forward to building enrollment in the AJRR through gaining regulatory acceptance of the AJRR as a standard for hip and knee surgery and building strategic alliances and partnerships.



September Cahue, MPH, is the newest Research Associate with the AJRR. September joined the AJRR on September 17th. She comes to us after 14 years at Northwestern University Feinberg School of Medicine in Chicago where she was the Project Coordinator for the NIH-funded Mechanical Factors in Arthritis of the Knee (MAK) Study in the Division of Rheumatology. September has a B.S. in Biology from the University of Michigan and an M.P.H. in Community Health Sciences from the University of Illinois at Chicago.

### The AJRR Welcomes Its Newest Participants!

- Bayhealth Medical Center
- Benefis Hospital
- Cabell Huntington Hospital
- Lakeland Regional Medical Center
- OSS Orthopaedic Hospital
- Providence Health and Services
- Roper Hospital
- Southeast Georgia Health System
- UCLA

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## AJRR Board of Directors

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of the Standard Business Associate/Data Use Agreement so that sites must give 48 hours to AJRR to review and comment on any breach notification, but AJRR does not have the right to approve the notice. However, the site must also agree that it will not identify AJRR in the notification without AJRR's consent.

*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.*



### Info Tech 101

By Randolph Meinzer

### AJRR Level I Data Requirements

Currently, the AJRR is collecting Level I data which includes patient demographics, physician and hospital identifiers, and procedural elements, to track implant survivorship nationally.

In more detail, Level I data includes:

- Patient identifiers, including Protected Health Information (PHI), which allow AJRR to track patients who receive revision procedures at hospitals that did not conduct the primary procedure. Hospital and physician identifiers are also included in Level I data to enable AJRR to provide tailored reports.
- ICD9 primary procedure and diagnosis codes enable AJRR to aggregate and report national benchmarks for comparisons. We will be able to accept ICD10 coding when implemented.
- Implant manufacturer, catalog and lot numbers facilitate the monitoring of implant performance nationally and locally.

Currently, the AJRR can accept Level I data via a secure web form or via an electronic transfer of data extracted by the hospital.

### AJRR Level II and III Data Requirements

In August of 2012 the AJRR Board of Directors agreed to begin development of software platforms for Level II and Level III data submission. Level II data will include

patient co-morbidities, Physician Quality Reporting System (PQRS) measures, surgical approaches, prophylaxis, and American Society of Anesthesiologists (ASA) scores. These elements will be used for risk adjustment of the data. Level III data will include patient-reported outcomes instruments that assess health-related quality of life and physical function. AJRR Level III forms will be available as a service for hospitals that wish to assess covariates and outcomes at a deeper level. AJRR expects to begin testing of the Level II and III systems in the fourth quarter of 2012 with full implementation scheduled to begin early in the second quarter of 2013.

Our Winter newsletter will outline in greater detail the Level II data elements.

For more detailed information on AJRR's data collection efforts, please visit [www.ajrr.net](http://www.ajrr.net).



## Legal Corner

By Robert Portman, JD



### Do the indemnification provisions of the AJRR standard participation agreement apply to state institutions?

Most states have laws that do not permit state agencies or institutions to agree to indemnify parties with which the agency or institution contracts. Recognizing this fact, the AJRR standard participation agreement has alternative language for state institutions that are precluded by state law from agreeing to contractual indemnification provisions. Under the alternative language, each party agrees to take full responsibility for its own acts or omissions with respect to the agreement, but neither indemnifies the other. The limitation of liability provisions remain the same.

### Our hospital is not comfortable with allowing AJRR having the right to review and approve breach notification notices to patients as we believe this will interfere with our obligations under HIPAA.

This was a concern raised by several sites. In response, the AJRR has changed the breach notification language in Section 5(c)

## The AJRR Proudly Recognizes These Contributors for their Support

- American Association of Hip and Knee Surgeons (AAHKS)
- American Academy of Orthopaedic Surgeons (AAOS)
- Aesculap Implant Systems
- Biomet
- Blue Cross Blue Shield Association
- Consensus Orthopedics
- DePuy Orthopedics, Inc.
- DJO Surgical
- Exactech
- The Hip Society
- The Knee Society
- Smith & Nephew
- Stryker
- UnitedHealth Foundation
- Wellpoint
- Wright
- Zimmer

# Thank You to the AJRR Champions!

One of the first efforts undertaken by the AJRR was a pilot study to test the feasibility of implementing a total joint registry on a national scale. Between Fall, 2010 and Summer, 2011 eight institutions participated in this pilot program. During that time, AJRR collected data on over 3,600 procedures and refined the procedures for the completion of legal agreements and streamlined the process for data submission. We would like to thank the Champions at each of our pilot sites who not only made the program a success, but who are integral to the success of the registry today. These sites continue to participate in data submission and are also an invaluable resource to us as we expand.

Thank you to the following individuals:

**Courtland G. Lewis, MD;**  
**Stephanie Caminiti, APRN, MS;**  
**Ifeoma Inneh; Deb Smith;**  
**Katina Diakouloukas and Nicholas Milton**  
Connecticut Joint Replacement Institute at St. Francis Care in Hartford, CT

**James D. Slover, MD and**  
**Cara-Lee Fontaine, MHA, CCRC**  
NYU Hospital for Joint Diseases in New York, NY

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**Angela Opsahl, RN, MSN, CPHQ;**  
**Ann Bumb, RN, BS, CPHS, CPHRM, NE-BC**  
**and Shelley Voelz RN, BSN, CPHQ, FNAHQ**  
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**Kevin J. Bozic, MD and**  
**Steven Takemoto, PhD**  
University of California, San Francisco Medical Center in San Francisco, CA

**Javad Parvizi, MD and Bethany Worobey, MS**  
Rothman Institute and Thomas Jefferson University Hospitals in Philadelphia, PA

## Publications of Interest

Griffiths EJ, Stevenson D, Porteous MJ. **Cost savings of using a cemented total hip replacement: An analysis of the National Joint Registry data.** J Bone Joint Surg Br August 2012 94-B:1032-1035. doi: 10.1302/0301-620X.94B8.28717

Jameson SS, Baker PN, Charman SC, Deehan DJ, Reed MR, Gregg PJ, Van der Meulen JH. **The effect of aspirin and low-molecular-weight heparin on venous thromboembolism after knee replacement: A non-randomised comparison using National Joint Registry Data.** J Bone Joint Surg Br July 2012 94-B:914-918 doi: 10.1302/0301-620X.94B7.29129

Lalmohamed A, Vestergaard P, Klop C, Grove EL, de Boer A, Leufkens HGM, van Staa TP, de Vries F. **Timing of Acute Myocardial Infarction in Patients Undergoing Total Hip or Knee Replacement** Arch Intern Med September 2012 172(16) 1229-1235. doi:10.1001/archinternmed.2012.2713

## FDA News

On September 6, 2012, the FDA Center for Devices and Radiological Health (CDRH) made available for public comment a report entitled "Strengthening Our National System for Medical Device Postmarket Surveillance." The report provides an overview of the FDA and US medical device postmarket systems and discusses ways to enhance these systems. The report and forum for comment can be seen [here](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm?source=govdelivery):

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm301912.htm?source=govdelivery>

In conjunction with the release of the report, AJRR was invited to a series of CDRH meetings in Greenbelt, MD. The meetings began on September 10 with "Strengthening the National Medical Device Postmarket Surveillance System". The second meeting, "Partnership for Building Global Medical Device Epidemiology and Surveillance Capabilities: MDEpiNet 2012 Annual Meeting", was held September 11, with David Lewallen, MD Chair of the AJRR Board of Directors representing the AJRR. The last meeting, "Leveraging Registries With Medical Device Data for Postmarket Surveillance and Evidence Appraisal Throughout the Total Product Life Cycle", was September 12-13. AJRR was represented by E. Anthony Rankin, MD, AJRR Board member and Chair of the AJRR Legal and Regulatory Committee. We are grateful for the opportunity to participate in such important initiatives.

## Upcoming Events

AJRR will have a booth at these upcoming meetings. Stop by and visit us at:

- **Advances in Arthroplasty**  
Cambridge, Massachusetts  
October 2 - 5, 2012
- **AAHKS Annual Meeting**  
Dallas, Texas  
November 2 - 4, 2012
- **Current Concepts in Joint Replacement**  
Orlando, Florida  
December 12 - 15, 2012
- **AAOS Annual Meeting**  
Chicago, Illinois  
March 19 - 23, 2013

## AJRR Staff

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**Pamella Leiter, MSA, OTR/L**  
Director of Policy and Strategic Alliances

**Randolph Meinzer**  
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**Hannelore Venable**  
Administrative Assistant

Support the AJRR via donations to the Orthopaedic Research and Education Foundation. Scanning this QR code will take you directly to the AJRR donation page.



<http://www.oref.org/site/PageServer?pagename=ajrr>



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