American Joint Replacement Registry

Fall 2013 Update

It starts with you.

And ends with benefits for your patients

AJRR American Joint Replacement Registry

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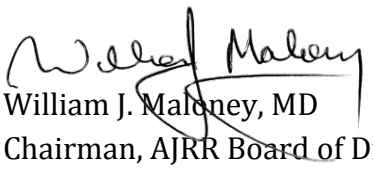
Foreword

The American Joint Replacement Registry (AJRR) is experiencing a remarkable 2013 (through October 31), achieving a number of important milestones. Our recruitment efforts have expanded with over 219 hospital participants in 47 states. These results far surpass our goal to have 180 hospital participants by the end of 2013. We also have increased the number of hospitals submitting data. At the start of 2013, only 48 hospitals were submitting. As of the end of October 2013, over 100 hospitals are submitting. One of our 2014 goals is to have over 50% of participating hospitals submitting data. Support from our community of stakeholders remains strong with ongoing support and strategic guidance for our development. Our corporate structure was also revised in 2013 with direct appointments to our Board of Directors coming from our five supporting entities. The composition of our board changed in 2013 with the addition of a representative from the American Hospital Association. We welcomed Kristin Murtos, MBA, President of Skokie Hospital in Skokie, Illinois, to our Board. Also, replacing Dr. Lewallen as Hip Society Representative was Dr. Daniel Berry, Chair of Orthopaedic Surgery at Mayo Clinic and past president of the American Academy of Orthopaedic Surgeons (AAOS). We will have many changes to our board in 2014 due to the departure of five original Directors. Drs. Thomas Barber, Kevin Bozic, Catherine MacLean, J. Wesley Mesko, and Patience White were integral to the development and launching of the AJRR. We wish them well and thank them for their tireless efforts on our behalf. One of our other important changes in 2013 was the addition of David Lewallen, MD, as Medical Director. Upon completion of his term as the first Chairman of the AJRR Board of Directors, Dr. Lewallen was named Medical Director, securing his ongoing role as one of the leaders advancing our national arthroplasty initiative. Final edits to our online data reporting and lookup tool have been made in 2013. This system will allow hospitals, surgeons, and our industry colleagues the ability to see their own data and to compare those results to national benchmarks. The subscription fees for hospitals to use this system were introduced in 2013 with collection starting in 2014, thus providing AJRR a new revenue stream. Collaborative efforts with domestic and international registry colleagues continued in 2013 and will hopefully expand in 2014. We also have enhanced our relationships with regulatory agencies and legislative offices through the AAOS Washington, DC office and the Physician Clinical Registry Coalition, a group of 20 clinical data registries working together to advance registry goals across disciplines. While AJRR has accomplished a great deal in 2013, more remains ahead as we continue our mission to improve arthroplasty care for patients.



William J. Maloney, MD
Chairman, AJRR Board of Directors

About the AJRR

The American Joint Replacement Registry is a not-for-profit 501(c)(3) organization for data collection and quality improvement initiatives for total hip and knee replacements. The AJRR is a collaborative effort supported by the American Academy of Orthopaedic Surgeons (AAOS), the American Association of Hip and Knee Surgeons (AAHKS), The Hip Society, The Knee Society, hospitals, health insurers, medical device manufacturers, patients and the public via our Public Advisory Board, and contributions from individual orthopaedic surgeons.

Mission

Foster a national center for data collection and research on total hip and knee replacement with far-reaching benefits to society including reduced morbidity and mortality, improved patient safety, improved quality of care and medical decision-making, reduced medical spending, and advances in orthopaedic science and bioengineering.

Vision

A national total joint registry dedicated to the improvement in arthroplasty patient care by data driven modifications in the behavior of collaborating providers, institutions, manufacturers, payers, and patients.

Governance and Structure

The American Joint Replacement Registry (AJRR) is unique compared to most of our domestic counterparts. When consideration was given to forming a national arthroplasty registry the surgeon leaders made a conscientious decision to be inclusive. Thus, they looked at what groups and organizations could make an impact and help direct the policy for a national arthroplasty registry. Currently, the AJRR leadership is appointed from the surgical community, industry, patient advocacy, hospital administration, and insurance sector. The thirteen member board of directors meets formally twice a year and by conference calls an additional two times.

As a mission was realized for the AJRR, a decision on how to fund the new venture was examined. The leadership at the time determined that all the stakeholders should share in the costs associated with administrative support, and design and implementation of a product that can collect the necessary data that makes the AJRR relevant. At this time, industry and insurance partners, with the support of numerous specialty societies bear the burden of supporting the efforts of the organization. The future plans for funding will evolve to the AJRR being supported almost fully by sales of software licensing to hospitals and individual practice groups (individual surgeons, too).

Board of Directors

In 2013, the Chairman of the AJRR Board of Directors is **William J. Maloney, MD**, of Stanford University, Stanford, CA, who is one of the AAOS representatives. Other 2013 Board members include:

AAOS representatives:

Thomas C. Barber, MD, Kaiser Permanente, Oakland, CA

J. Wesley Mesko, MD, Michigan Orthopaedic Center, Lansing, MI

E. Anthony Rankin, MD, Providence Hospital, Washington, DC

Orthopaedic specialty society representatives:

Daniel J. Berry, MD, Mayo Clinic, Rochester, MN (The Hip Society)

Kevin J. Bozic, MD, MBA, University of California, San Francisco, CA (AAHKS)

Terence J. Gioe, MD, University of Minnesota, Minneapolis, MN (The Knee Society)

Industry representatives:

Pamela L. Plouhar, PhD, DePuy Synthes, Inc., Warsaw, IN

Eric Rugo, MBA, Stryker, Inc., Mahwah, NJ

Payer representatives:

Catherine H. MacLean, MD, PhD, WellPoint, Inc., Thousand Oaks, CA

Steven H. Stern, MD, MBA, United Healthcare, Inc., Chicago, IL

American Hospital Association Representative

Kristen Murtos, MBA, Skokie Hospital, Skokie, IL

Public representative:

Patience H. White, MD, MA, Arthritis Foundation, Washington, DC

Public Advisory Board

AJRR has a Public Advisory Board (PAB). This group was established to provide input to the AJRR Board from a greater spectrum of patient and public advisory groups. They have been an integral part of the success of the AJRR thus far. The PAB seeks to improve the value of AJRR by ensuring a public voice in the registry's data collection, reporting, and utilization activities. The PAB members represent a variety of stakeholders, all with the interest of the patient at the forefront.

In 2013, the Chairman of the Public Advisory Board is **Patience H. White, MD, MA.** Dr. White is Vice President, Public Health Policy and Advocacy at the Arthritis Foundation and Professor of Medicine and Pediatrics at George Washington University School of Medicine and Health Sciences in Washington, DC. Other 2013 PAB members include:

John A. Canning, Jr., Chairman, Madison Dearborn Partners, LLC, Chicago, IL
Sally B. Hurme, JD, Project Advisor—Education & Outreach, AARP, Washington, DC
Colin Nelson, BA, Senior Research Associate, Informed Medical Decisions Foundation, Boston, MA
Martha Nolan, JD, Vice President, Public Policy, Society for Women's Health Research, Washington, DC
Margaret VanAmringe, MHS, Vice President for Public Policy and Government Relations, The Joint Commission, Oak Brook, IL
Robert P. Watkins, Esq., Attorney, Williams & Connolly, LLP, Washington, DC

AJRR Staff

Jeffrey P. Knezovich, CAE—Executive Director
David G. Lewallen, MD—Medical Director
Randolph R. Meinzer—Director of Information Technology
Caryn D. Etkin, PhD, MPH—Director of Analytics
Ahmad Fathi—IT Data Technician
September R. Cahue, MPH—Research Associate
Steve Hamada—Senior Software Engineer
Susan E. Hobson, MPH—Research Associate
Hannelore Venable— Administrative Assistant

Registry Funding Structure/Financial Support/Stakeholders

As mentioned previously, the AJRR is a not-for-profit 501(c)(3) organization. Currently the organization is supported by a multi-stakeholder model. The AJRR is a collaborative effort supported by AAOS, AAHKS, The Hip Society, The Knee Society, hospitals, health insurers*, and medical device manufacturers**.

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* 2013 health insurance contributors include: UnitedHealth Foundation and WellPoint.
** 2013 industry contributors include: Biomet, DePuy Synthes, DJO Surgical, Exactech, Smith & Nephew, Stryker, Wright, and Zimmer.

Executive Summary

The AJRR is making tremendous progress in 2013 toward the goal of becoming the first comprehensive national hip and knee orthopaedic implant registry in the United States. The AJRR has successfully developed and initiated the software required to operate a national registry. Members of the AJRR Board participate in numerous activities focused on encouraging incentives for registry participation with various entities including federal legislators, governmental agencies, The Joint Commission, and payers. In an effort to expand the services that the AJRR can provide to the public, the AJRR continues collaborative efforts with the International Society of Arthroplasty Registers (ISAR), the U.S. Food and Drug Administration (FDA), International Consortium of Orthopaedic Registries (ICOR), Centers for Medicare & Medicaid Services (CMS), ArthroplastyWatch, and Operation Walk USA. Throughout 2013, AJRR continued to prioritize the formal recruitment of institutions in order to achieve its goal to enroll 90% of all institutions conducting hip and knee replacements.

Achievements

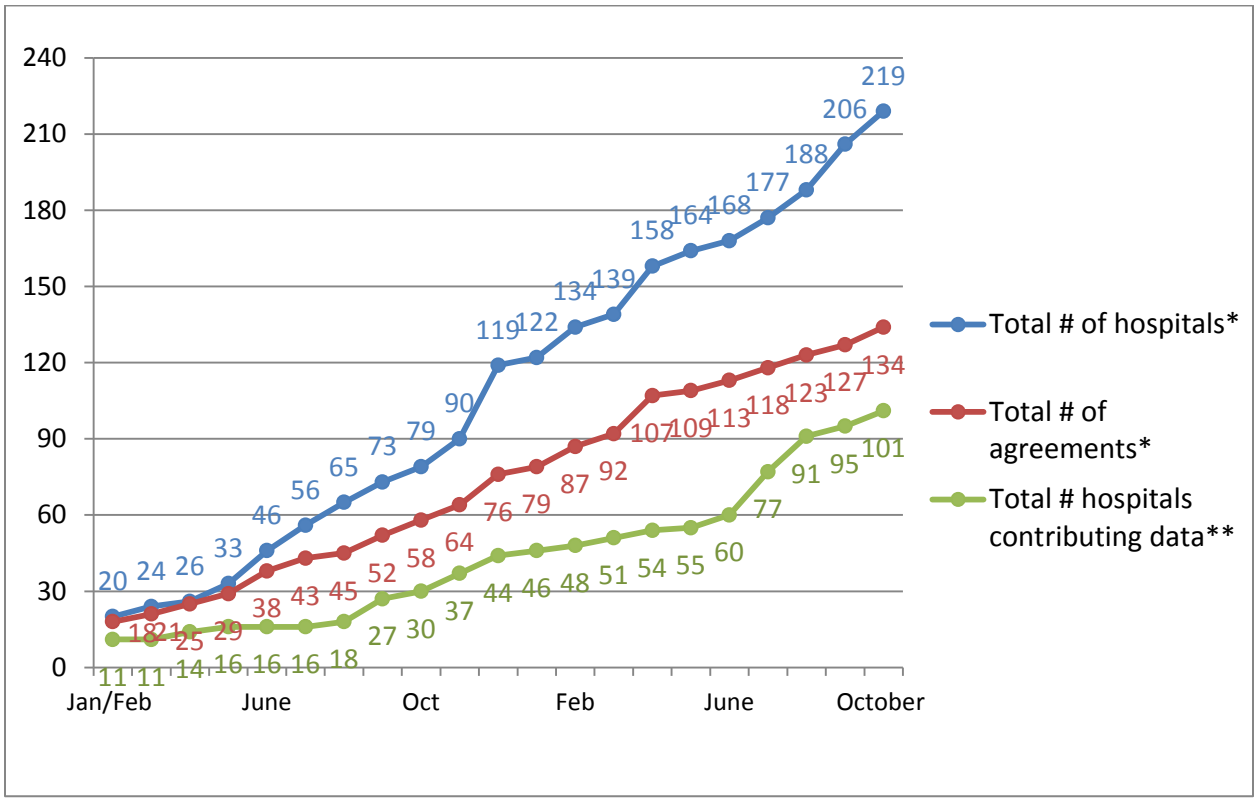
2013 Accomplishments

- Hired David G. Lewallen, MD, as first Medical Director
- Additional software personnel hired for a total of 9 staff members
- Substantial progress on completion of software development of Level II and Level III registry system
    - Level II and Level III pilot program began in fourth quarter
    - Full launch of Level II and Level III platforms will be in early 2014
- Launched development of component reference database
- Greatly expanded hospital recruitment efforts
- Added 100 hospitals for a total of 219 participants
- Leadership Planning Session conducted
- Participated in federal legislative and agency visits
- Restructured AJRR committee system
- Completed review and developed HIPAA compliance security documents
- Secured hospital sites in 47 of the 50 states
- Accepted data on over 63,000 hip and knee procedures since inception
    - Data as shown in this report reflects 52 hospitals

Enrollment

A major focus in 2013 was to increase the number of hospitals participating in the registry. Three staff members dedicate their time to enrolling new facilities and ensuring data is submitted in a timely fashion. In 2013, AJRR received 57 new Business Associate and Participation Agreements. As of the end of October, 219 hospitals enrolled to participate in the registry and AJRR had completed enrollment with at least 1 hospital in 47 states. Active discussions continue in the remaining three states, with the goal of having all 50 states represented in the registry early in 2014.

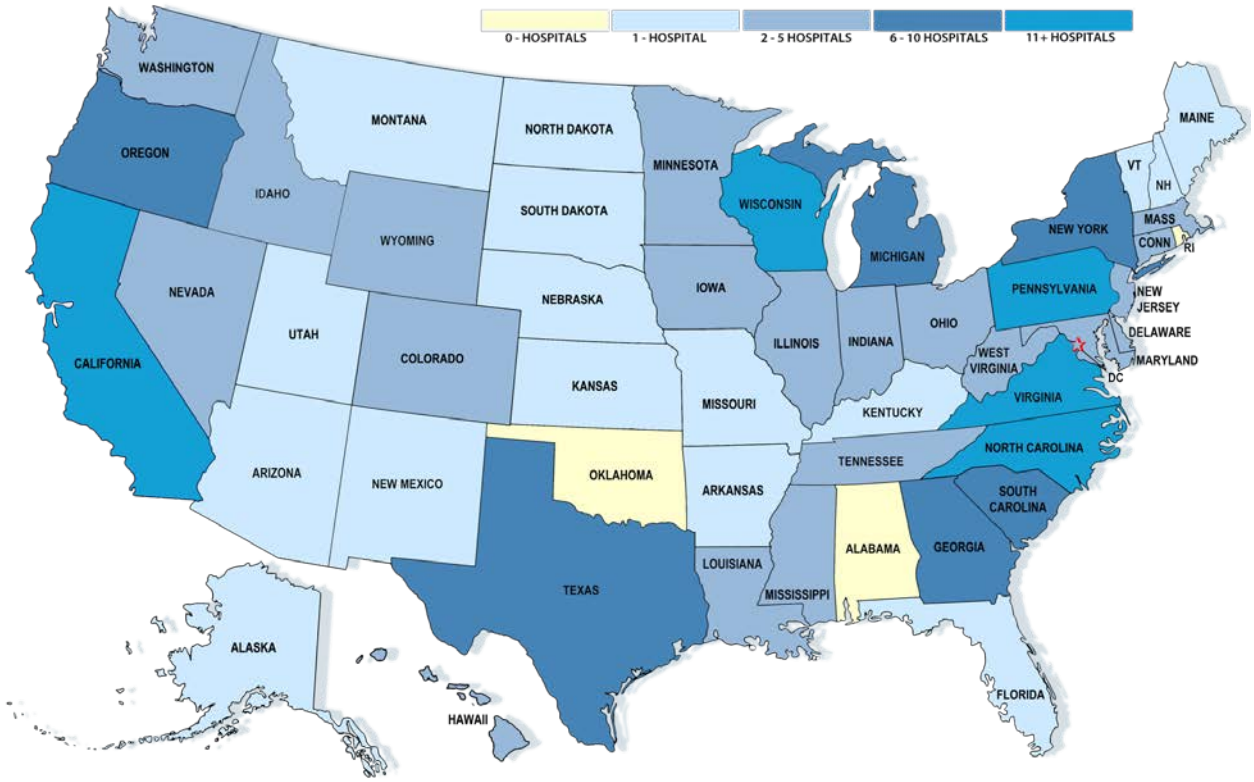
Figure 1. 2012-13 Enrollment



** Agreements frequently cover health systems with numerous locations, hence the discrepancy between agreements and hospitals.*

*** Some hospitals/systems with which AJRR has agreements are on hold with data submission due to EMR conversion.*

Figure 2. Geographic Distribution of AJRR Participants



Information Technology

In May 2013, the AJRR expanded the Information Technology department by hiring IT Data Technician Ahmad Fathi. Mr. Fathi works closely with our hospital participants on electronic transfer of Level I data to ensure that hospital data conforms to the AJRR Level I data specifications. The AJRR software tool provides a technology framework for which AJRR technical and analytics staff can add and delete data elements, build new forms, and adjust the technology to meet the changing registry requirements as our initiative evolves. The new platform also allows AJRR staff to create and modify reports for the various registry stakeholders.

Today, hospitals are submitting Level I data in two ways. With the first method, hospital staff enters data manually into the system using secure web forms. The second method utilizes electronic extracts containing Level I data submitted directly to the AJRR data systems. Electronic transfer typically requires assistance from hospital information technology specialists to extract the registry information from the hospital's electronic medical records (EMR). These specialists then aggregate the information into a multi-patient Excel or .csv file. Once the data is collected, the file is submitted to the AJRR through a secure transfer. At this time, over 90% of hospitals submit extracted data electronically rather than enter data manually into the registry. In late 2012, AJRR added technology

allowing sites to upload data extracts via a secure method that utilizes standard web browser technology (HTTPS). The secure web browser upload functionality focuses on those participating sites that have limited IT resources, as most hospital staff typically has access to web browsers on their standard desktop charting systems.

To facilitate electronic data transfers, the AJRR staff has focused on establishing relationships and business agreements with orthopaedic charting and EMR vendors. Vendor agreements and/or pre-defined AJRR reports from EMR vendors relieve the burden of creating custom reports on behalf of the participating hospital. The AJRR currently has agreements with three orthopaedic charting vendors, Ortech, Inc., Oberd, Inc., and InVivoLink, which include direct submission of data from the vendor to the AJRR on behalf of a participating hospital. AJRR IT staff has also been working with Epic and Cerner on predefined AJRR reporting modules. Epic released an AJRR reporting module which functions with their latest EMR and OpTime software release. Cerner is currently testing a report that it will make available to its users in the near future. The Cerner report requires their Millennium and SurgiNet systems. AJRR anticipates future shared efforts with other major EMR vendors in 2014.

Procedural Data Metrics

The AJRR has received data on over 63,000 procedures from contributing sites since launching our production registry database. Currently AJRR is collecting on average data on over 2,000 procedures per week, which represents approximately 10% of the procedures performed nationally. Included in this update report are basic metrics from approximately 22,000 procedures conducted by our participating sites in 2012. Each procedure imported into the AJRR registry is subject to additional data verification checks prior to inclusion in the final database. In many instances, the data requires minor error corrections. For example, component catalog numbers may be submitted with leading or trailing zeros suppressed or dashes removed from catalog numbers.

Data Completeness and Quality Improvement

The AJRR data systems verify incoming data by conducting conformance rules checks contained in the data system. One area of focus for 2013 was to improve the early submission process to ensure that all submitting sites conform to the AJRR specification. Subtle differences in the way hospitals chart ICD-9 procedure and diagnosis codes along with variability in the charting of component catalog numbers have been early problems resulting in variability in the AJRR data. The IT staff continues to verify the content of hospital data via comprehensive reviews of submitted procedural information to ensure that it adheres to our format and specifications. The submission process now includes a test submission, data review, and timely feedback to our participating sites in an effort to

remove possible sources of error before submission of patient information. A critical task for 2014 will be to define a data validation process that includes sampling patient charts to validate the data set.

Procedural Metrics

Data submitted to the AJRR in 2012 provides a unique sample of US surgical practice patterns relating to hip and knee arthroplasty. Of the 52 hospitals that reported to the AJRR in 2012, 21% have under 100 beds, while 37% have over 400 beds. With representation from 25 of 50 states, this experience does provide useful insight to national patterns of practice.

Highlights of the data gathered follows, and includes information on the national experience of the patient population undergoing arthroplasty; procedures performed; implant usage; fixation methods; and cause of early revisions within the first year.

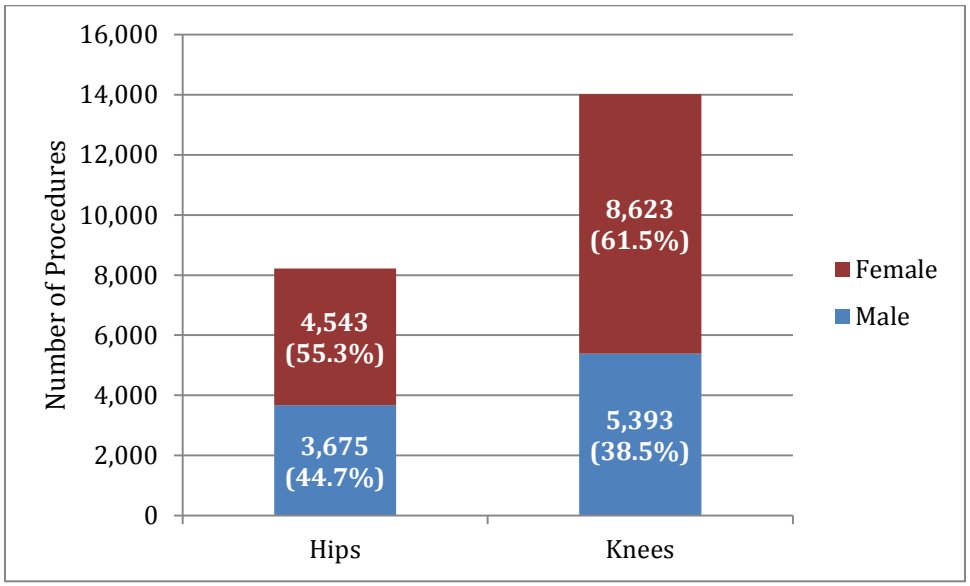
The analysis that follows reflects all reported procedures for calendar year 2012 (N=22,234) where a procedure had a hospital name, gender, diagnosis, and procedure code, unless otherwise indicated. Of the joints reported, knees outnumbered hip arthroplasty procedures and accounted for 63% of the total (Table 1). There were an additional n=948 procedures submitted to the database that were missing a combination of gender, procedure code, diagnosis code, and/or reflected miscellaneous procedures not relevant to this analysis. These 948 procedures were not included in the final analysis as displayed below, but are potentially subject to further validation efforts.

Table 1. Distribution of procedures by joint (N=22,234)

Distribution of procedures		%
Hips	8,218	37.0
Knees	14,016	63.0
Total	22,234	

Gender: Females outnumbered males for both hip and knee procedures with the disparity greater for knee procedures (Figure 3).

Figure 3. Distribution of total sample by joint type and gender (N=22,234)



Age: The distribution of patient ages at arthroplasty is shown for all hip (Figure 4) and knee (Figure 5) procedures submitted in 2012 and is widely distributed around a mean of 66 years for both. This points to the need for much more than Medicare data to fully assess practice patterns and implant performance in the US, since the nearly half of the arthroplasty patients recorded so far are under the traditional Medicare age of 65 years, and thus validates the need for a nationwide database collecting information on patients of all ages.

Figure 4. Age distribution of all hip procedures (N=8,218)

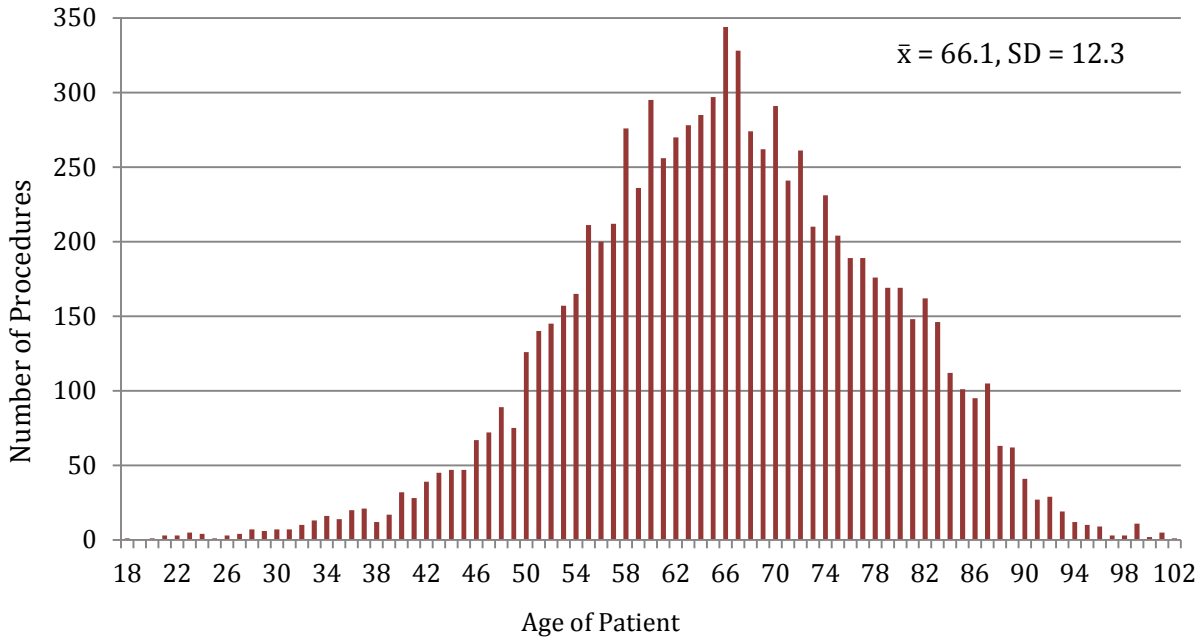
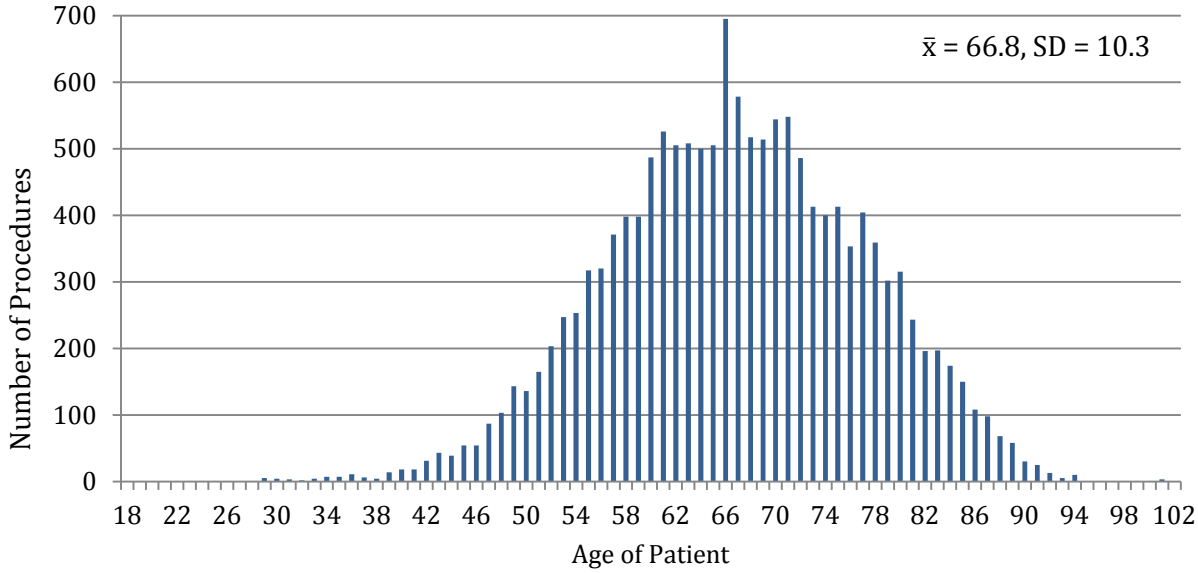


Figure 5. Age distribution of all knee procedures (N=14,016)



Diagnosis: Osteoarthritis is the predominant diagnosis leading to arthroplasty of both the hip and knee, with Rheumatoid Arthritis, a comparatively rare diagnosis currently in the US, likely related to the much improved medical management of inflammatory arthritis over the past decade (Figures 6 to 11).

Figure 6. Top 2 ICD-9 diagnosis codes for hip procedures (N=6,198)

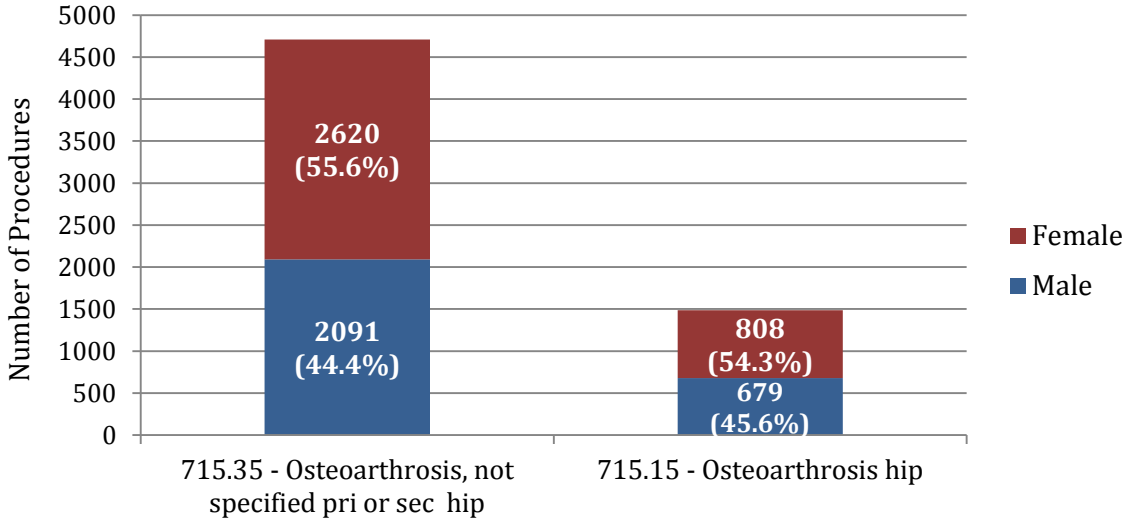


Figure 7: Other ICD-9 diagnosis codes for hip procedures (N=2,020 for Figures 7 and 8 combined)

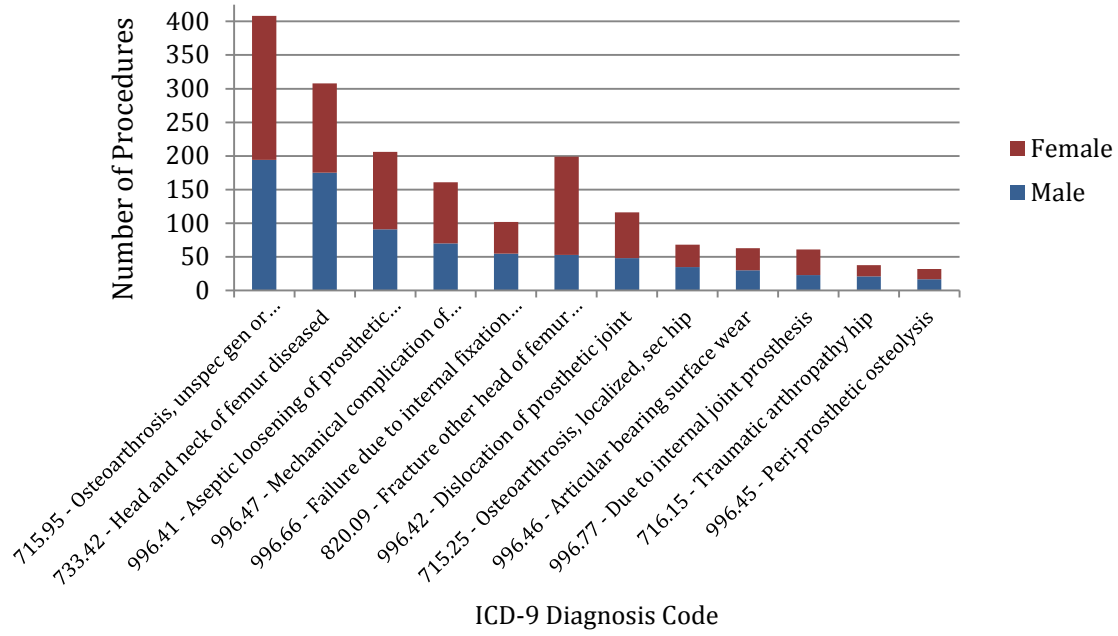


Figure 8.

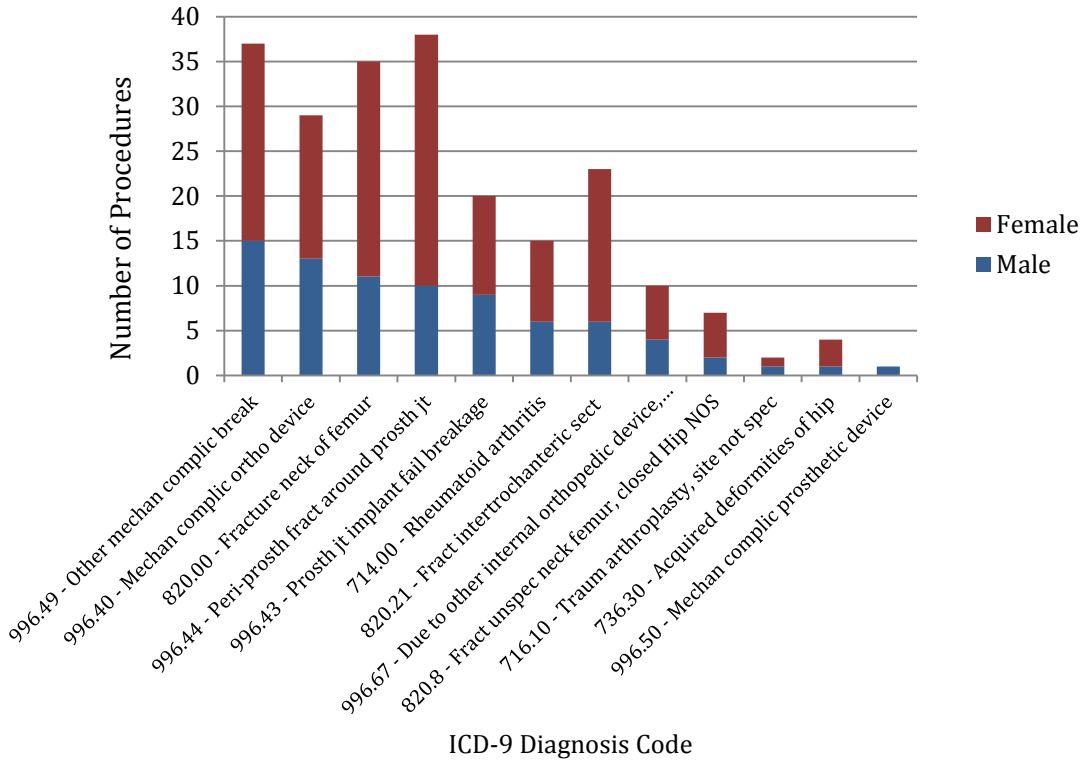


Figure 9. Top 2 ICD-9 diagnosis codes for knee procedures (N=11,810)

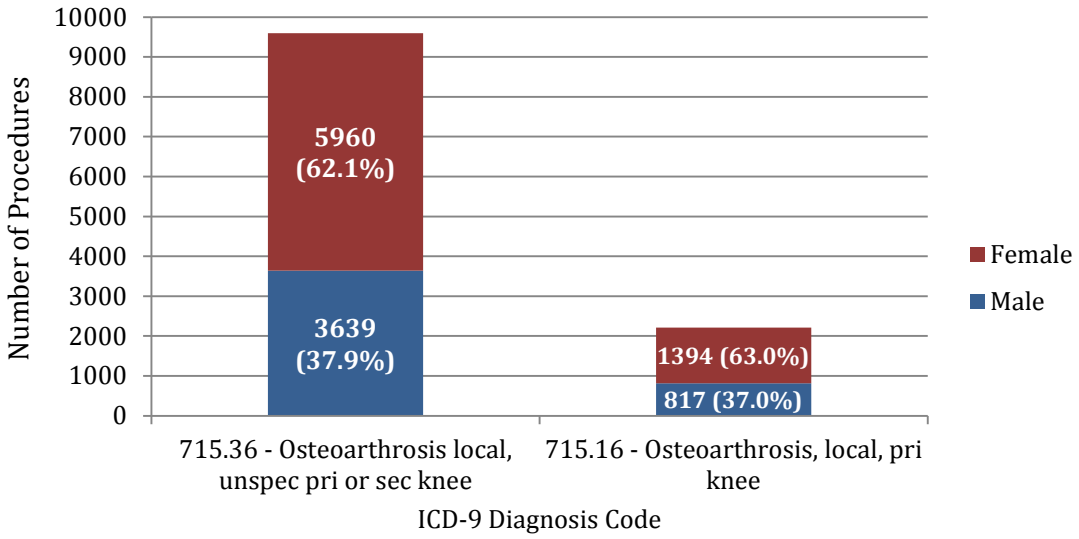


Figure 10. Additional ICD-9 diagnosis codes for knee procedures (N=2,206 for fig. 10 and 11 total)

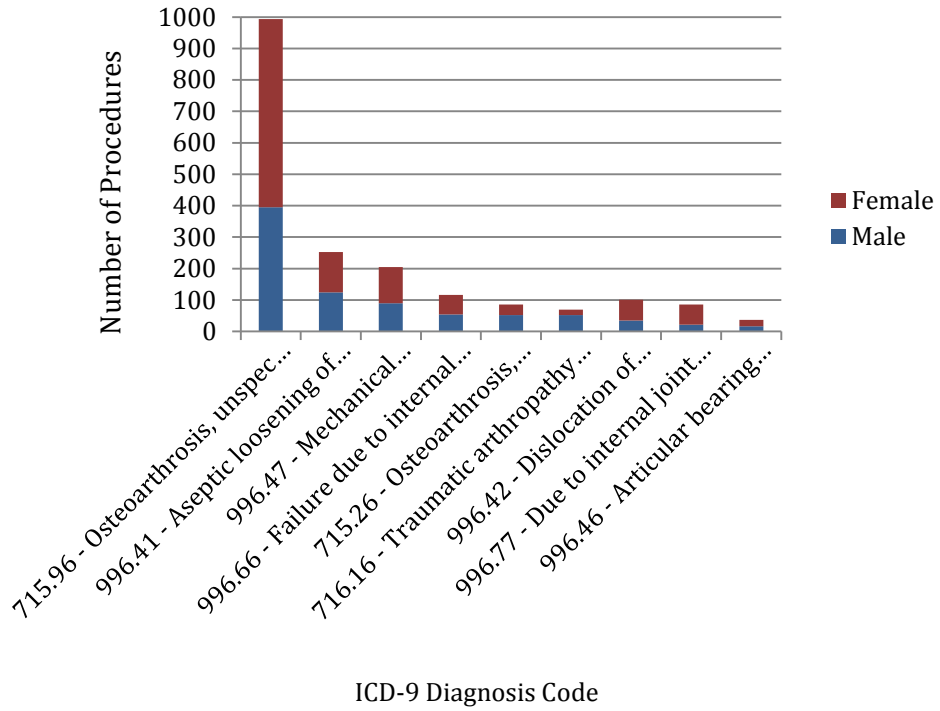
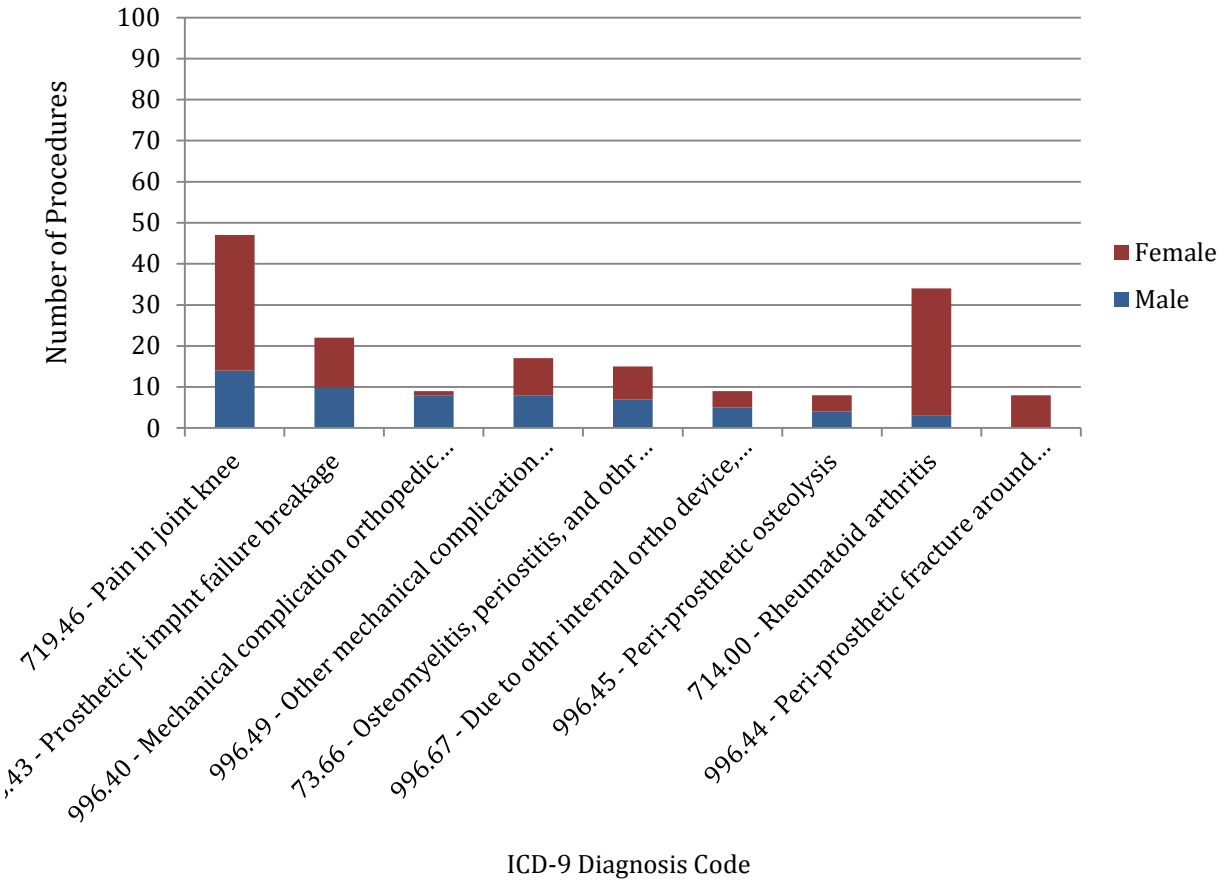


Figure 11.



THA and TKA Procedures: Inspection of the ICD-9 procedure codes for revision THA and TKA cases reveals a variety of specific procedures performed. For revision THA, acetabular revision (with or without revision of the femoral component) was the most common procedure performed, with isolated exchange of the polyethylene the next most common procedure, followed by conversion to THA (Figures 12 and 13).

Figure 12. All primary total hip arthroplasty (ICD-9 procedure code 81.51) (N=7,046)

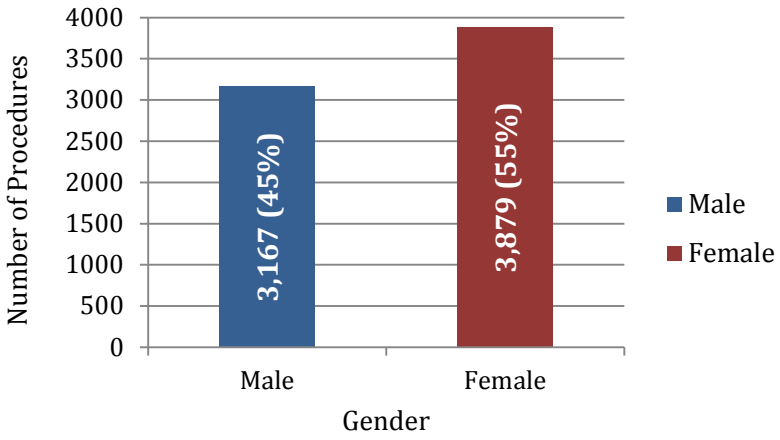
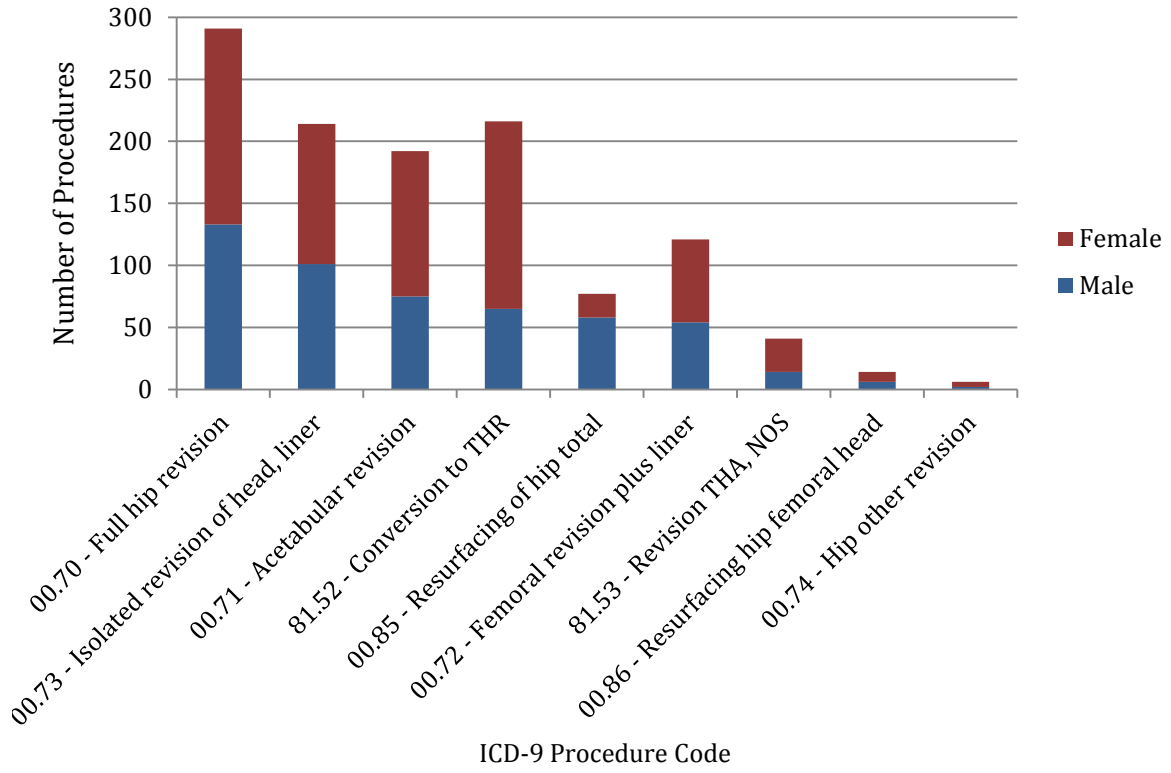


Figure 13. Other ICD-9 hip procedure codes (N=1,172)



For revision TKA procedures, by far the most common operation was revision of all components, followed by roughly equivalent number of procedures involving only exchange of the femoral component , isolated tibial component , or isolated polyethylene insert exchange.

Figure 14. All primary total knee arthroplasty (ICD-9 procedure code 81.54) (N=12,985)

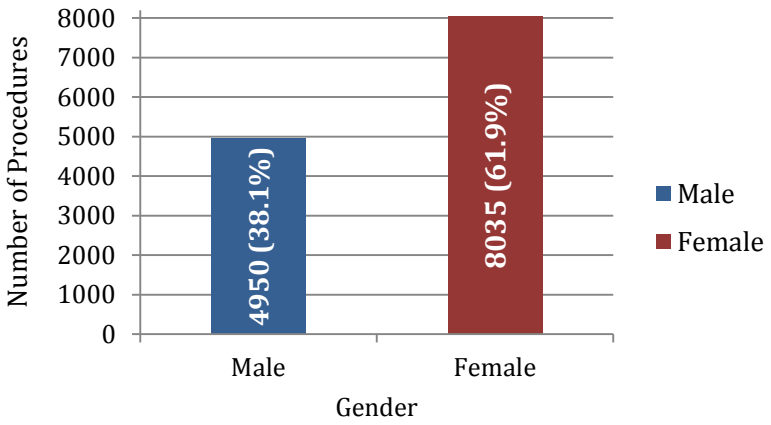
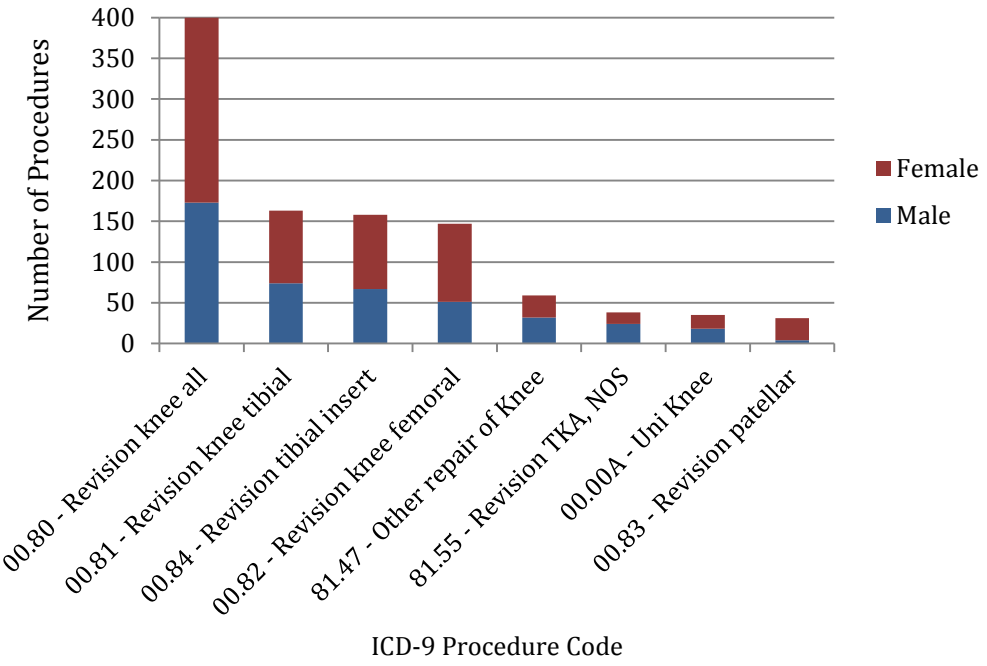


Figure 15. Other ICD-9 knee procedure codes (N=1,031)



Identification of early reoperations and revisions is of utmost importance to the AJRR. We were able to identify N=75 cases in which both the index and revision or reoperation procedures were performed in 2012; these include n=44 hips and n=31 knees. The following depicts the diagnosis codes for these early reoperations and revision procedures (Table 2).

Table 2. ICD-9 Diagnosis codes for early revisions

Early Revision ICD-9 Diagnosis Codes	Hip	Knee
996.66 - Failure due to internal fixation device *	14	14
996.42 - Dislocation of prosthetic joint	9	5
996.44 - Peri-prosthetic fracture around prosthetic joint	7	1
996.41 - Aseptic loosening of prosthetic joint	5	2
996.47 - Mechanical complication of prosthetic joint	5	2
715.35 - Osteoarthrosis, pri or sec hip	1	0
820.21 - Fracture intertrochanteric section	1	0
996.43 - Prosthetic joint implant failure breakage	1	0
996.67 - Due to other internal orthopedic device, implant and graft	1	2
715.36 - Osteoarthrosis local, pri or sec knee	0	1
716.16 - Traumatic arthropathy knee	0	1
73.66 - Osteomyelitis, periostitis, and other infections involving bone	0	1
996.77 - Due to internal joint prosthesis	0	2
Total number of early revisions	**44**	**31**

** AJRR recognizes that the diagnosis code "internal fixation device" does not accurately represent the reason for the revision. We will be working on further instructions to our participants and refinements of the dataset in the future.*

Component Database and 2012 Component Analysis

AJRR has been successful in cataloging over 35,000 orthopaedic implant components into the component reference data set. This reference set is based on components submitted to the registry over the last year. AJRR staff utilizes secondary sources, such as manufacturer websites, manufacturing catalogs, and existing component databases, as an additional reference when committing the components to the reference database. AJRR would like to acknowledge Stan Mendenhall from *Orthopaedic Network News* for graciously allowing the AJRR to access his component database when AJRR could not easily identify the components using standard web searches. Each reference component includes the manufacturer, catalog number, family name, and component type such as femoral stem or acetabular cup. In 2012, the AdvaMed Orthopaedic Sector provided further component reference data recommendations which will be incorporated into the AJRR component database project scheduled to begin in late 2013. These attributes include further detailed definitions of hip and knee component types, accessories, and materials. This information will allow AJRR to conduct richer data queries based on new attributes and assess performance of the devices as a system providing additional value to our stakeholders. These recommendations also included suggestions pertaining to the FDA's Unique Device Identification (UDI) Final Rule and will assist in ensuring that the AJRR component data remains consistent with any requirements imposed by the UDI ruling. AJRR would like to acknowledge the AdvaMed Orthopaedic Sector's efforts to assist the AJRR in this important endeavor and looks forward to their support on the 2013/2014 component reference data expansion project

Component Metrics

Implant fixation: Patterns of implant fixation for THA and TKA were very different. Fixation for THA procedures were predominantly uncemented (88%) and cemented or hybrid 12% (Table 3).

For TKA procedures, cemented fixation predominated (73%) but included over 1 in 4 cases performed uncemented. It will be interesting to see how this last number trends over the years ahead given the renewed interest in cementless fixation in TKA.

Table 3. Procedures using cement*

Metrics	n	%
Total procedures analyzed	22,234	
Procedures with cement as a component	11,293	50.8%
Total hip procedures	8,218	
Hip procedures using cement	1,015	12.3%
Total knee procedures	14,016	
Knee procedures using cement	10,266	73.2%

** Note that procedure count reflects all procedures that included a cement component.*

Figure 16. Leading ICD-9 Procedure codes for hip procedures utilizing cement (N=974)

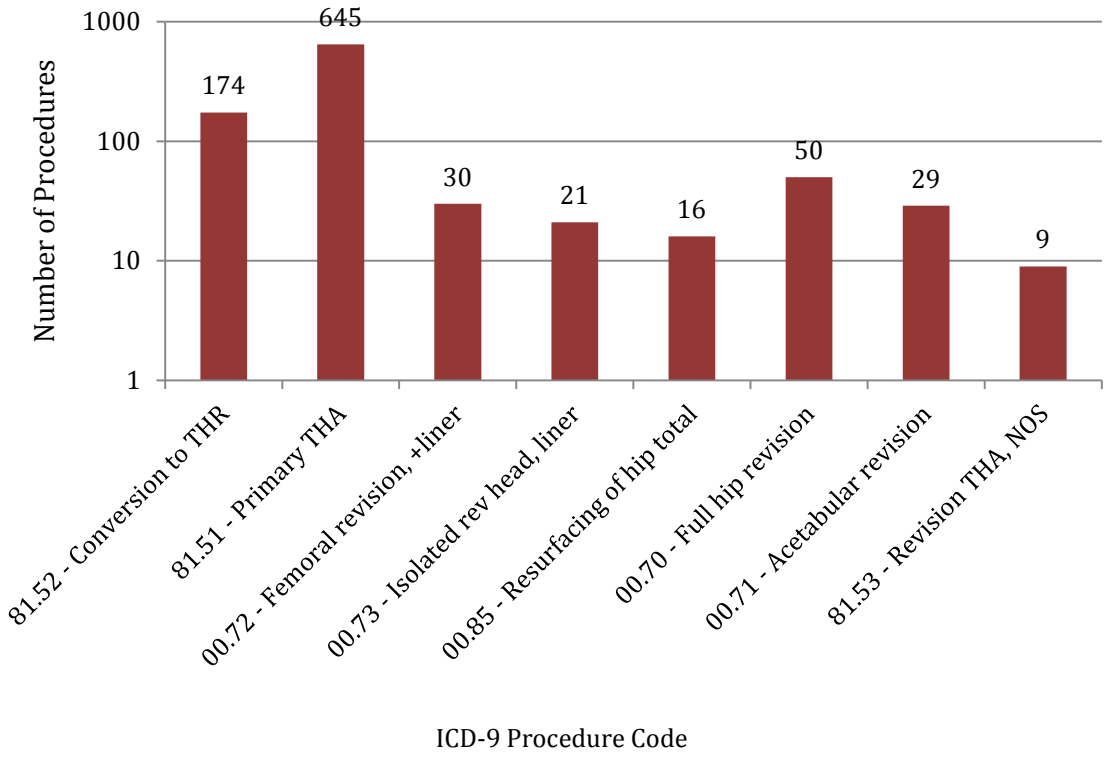
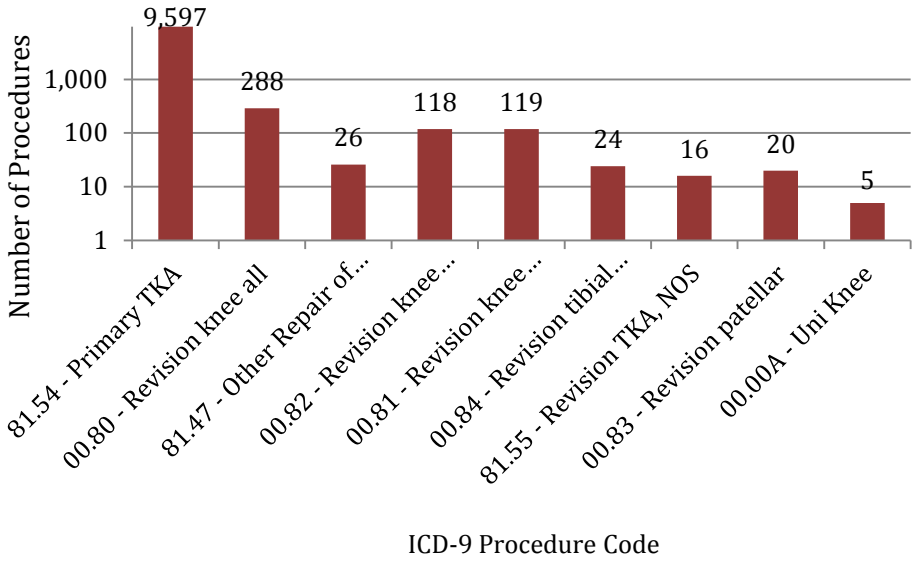


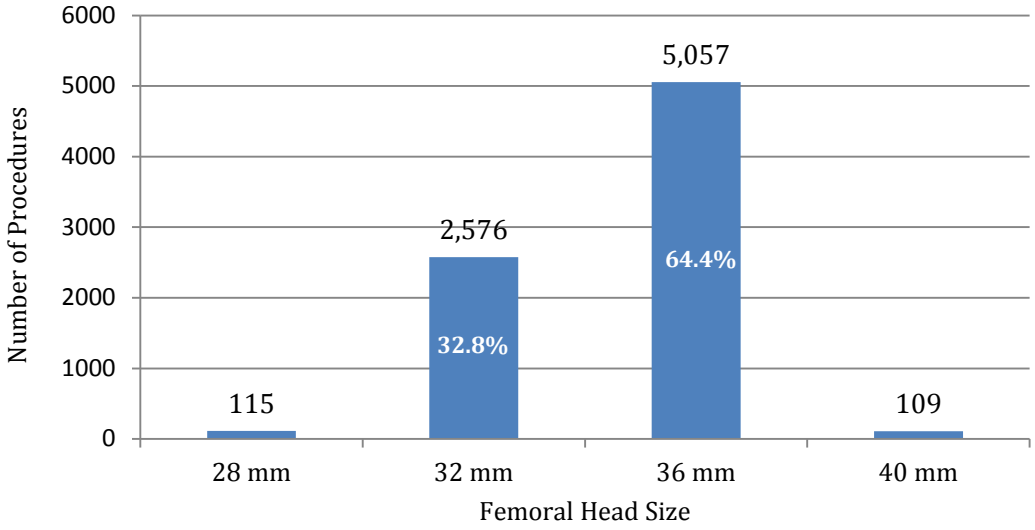
Figure 17. Leading ICD-9 Procedure codes for knee procedures utilizing cement (N=10,213)



Femoral Head Size in Hip Procedures

AJRR analyzed hip component database for the most commonly used femoral head sizes (N=7,857) as reported in Figure 17. The distribution of femoral head sizes used in hip procedures in 2012 are shown in Figure 18. There is a clear bias toward large sized heads of 36mm or greater.

Figure 18. Femoral head size among most frequently reported hip components (N=7,857)



Knee Implant Design and Articulation Choice

The knee analysis (N=6,190) included a review of implant design (either cruciate retaining or posterior stabilized) and the polyethylene material utilized (either ultra-high molecular weight polyethylene (UHMWPE) or highly cross linked polyethylene (HXLPE)) among the most commonly used tibial bearings (Figures 19 and 20). Posterior stabilized implants predominated and in 2012 around two thirds of all procedures performed utilized HXLPE, particularly when done with posterior standardized designs where over three out of four cases were done with HXLPE.

Figure 19. Implant design among most frequently reported tibial bearing components (N=6,190)

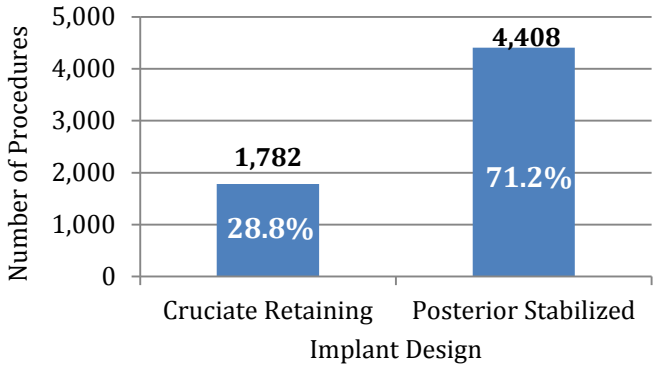
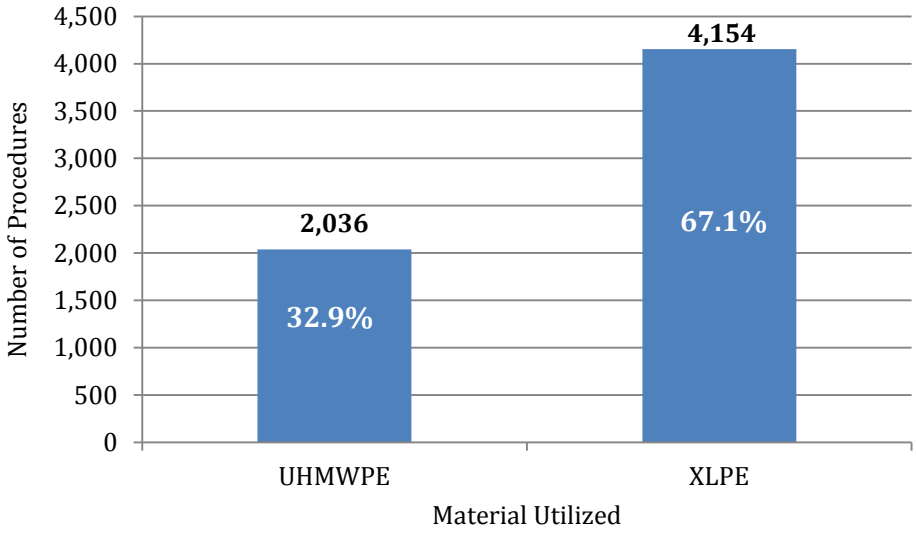


Figure 20. Material utilized among most frequently reported tibial bearing components (N=6,190)

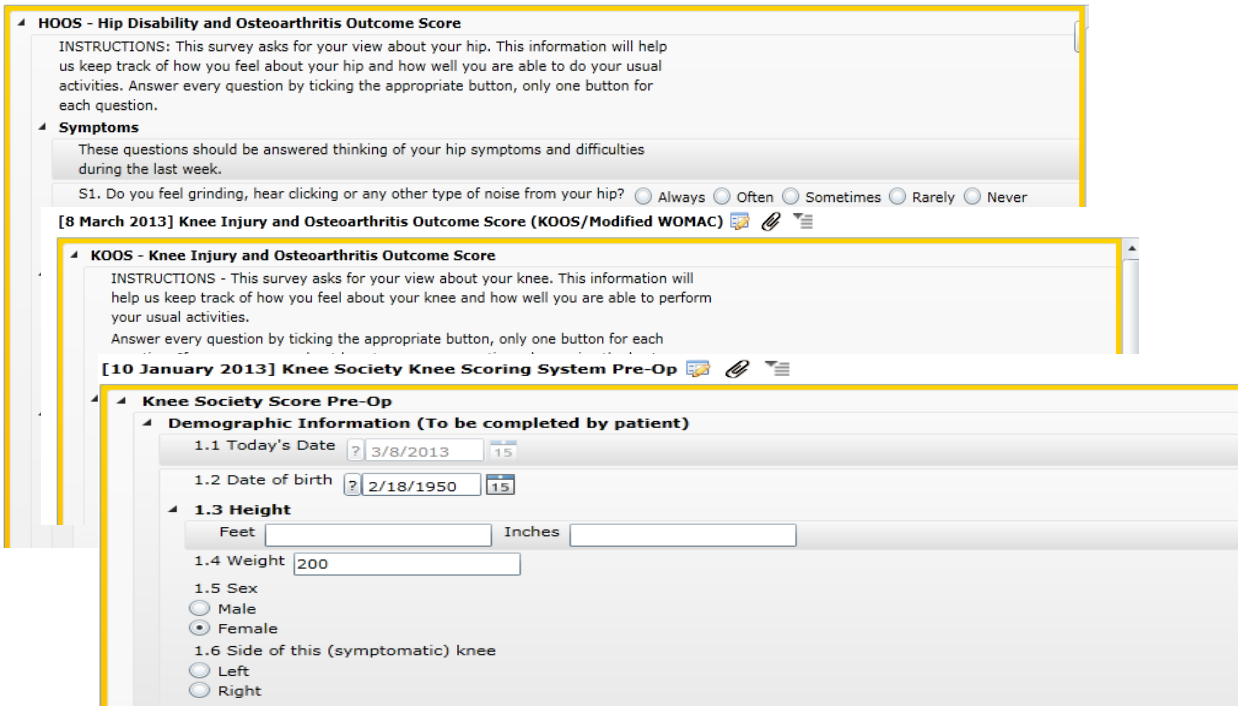


Level II and III Update and Data Reporting

In early 2013, the AJRR began developing the Level II and Level III data forms. The effort consists of adding forms and reports for Level II data which will include: pre-operative assessments with co-morbidities; expanded procedural information; Physician Quality Reporting System (PQRS) measures; and post-operative complications. Level III will reflect Patient-Reported Outcome Measures (PROMs) and will include the development of a patient portal, workflow manager, and the electronic forms for EuroQOL, Harris Hip Score, Hip Disability and Osteoarthritis Outcome Score (HOOS/Modified Western Ontario and McMaster Universities Arthritis Index [WOMAC]), Knee Injury and Osteoarthritis Outcome Score (KOOS/Modified WOMAC), Knee Society Knee Scoring System Pre-OP, Knee Society Knee Scoring System Post-OP, Medical Outcomes Study 36-Item Short Form Health Survey (SF-36), Oxford Hip Score, and Oxford Knee Score. See Figure 20 for sample data entry fields.

AJRR is also developing electronic reporting, including graphical dashboards, to provide to hospitals, physicians, manufacturers, and payers. AJRR began a pilot program in 2013 to identify automated methods to acquire Level II data and to test the features implemented to manage the PROMs process.

Figure 21: Sample PROM data entry fields



Business Planning and Funding

The management team consists of nine association professionals who advance the mission of the AJRR. The AJRR headquarters office remains in Rosemont, Illinois, in the office complex of the AAOS. Significant strides have been made to operate the Registry as a complete business undertaking. Initially, the AJRR concentrated on the development of a data collection system and the recruitment of hospitals. Those successes are now allowing the AJRR move into other areas of growth. This includes streamlining the data submission process to increase data acquisition and import of data into the system at a faster pace; emphasis on the recruitment of large volume institutions and hospital networks; ability to monitor and respond to proposed legislation that effects the growth of a national registry system; coordinated efforts with existing domestic hip and knee replacement registries; developing products that will be useful for individual needs (i.e. Maintenance of Certification (MOC) Part IV and PQRS); establishing participation fee procedures and cost; and preparing for the launch of Level II and Level III data submission. Each of these requires significant deliberation by the Board of Directors and the ability of the professional staff to implement and move the charge to fruition.

The capacity to fund these activities is always of concern. The AJRR is developing business plans and models that will have the Registry self-supporting through the sale of software

licenses, special report writing, and individual products that support MOC and PQRS. Until that time, the AJRR enjoys support from its industry partners, orthopaedic specialty societies, insurance foundations and contributions through the Orthopaedic Research and Education Foundation (OREF).

Strategic Alliances

AJRR continues to look to those specialty groups that can promote the AJRR or initiate programming that will benefit our participating hospitals. In addition, AJRR staff work with the AAOS Washington, DC office to carefully examine the socioeconomic and legislative issues affecting the emerging roles for National Registries and tracks and interacts regularly with appropriate regulatory agencies. This year, we prepared lengthy responses to two requests for information pertaining to the federal advancement of the "Qualified Clinical Data Registries". In addition, with the formation of the Physician Clinical Registry Coalition, the AJRR can now seek the support and utilize the experience of other specialty registries to advance our mission.

Incentives for Participation

Several of the AJRR activities focus on incentivizing hospital participation. The AJRR Board recognizes that hospitals involved with providing data to the AJRR incur expenses to enter data manually or to develop electronic methods to submit information. Additionally, hospitals may not have the staff or resources to address quality improvement initiatives, such as the AJRR, resulting in a de-prioritization of requests for assistance. The AJRR committees and workgroups are engaged in several activities focused on mitigation of hospital participation barriers.

Payers

The AJRR Board of Directors includes two members representing the payer community (Drs. MacLean and Stern). United Healthcare includes the AJRR as part of its Quality Program and gives points to hospitals for participation in AJRR. The inclusion of information on registry participation has stimulated numerous calls from hospitals on how they can participate in the AJRR. Early discussions on the possibility and appropriate timing of payer financial incentives for hospital participation are occurring and the AJRR will continue its efforts in these areas.

Influencers – The Joint Commission

The AJRR continues discussions with The Joint Commission, focusing on hospital recognition for participating and submitting data to the AJRR. Possibilities were discussed related to The Joint Commission Disease Specific Care Certification program in total hip and

knee arthroplasty in relation to general accreditation. After the first meeting, The Joint Commission agreed to host a teleconference introducing the AJRR to their constituents. The teleconference was held on November 29, 2012, and was attended by over 500 individuals. After the teleconference, numerous hospitals contacted the AJRR about enrollment. The AJRR Public Advisory Board membership includes a representative from The Joint Commission and we anticipate another successful teleconference in early December 2013.

Influencers – American Medical Association (AMA)

The AMA's Physician Consortium for Performance Improvement® (PCPI®) is a national, physician-led program dedicated to enhancing quality and patient safety. The ongoing mission of the PCPI is to align patient-centered care, performance measurement, and quality improvement.

In 2011, PCPI® began the process of creating the National Quality Registry Network (NQRN). The NQRN is a voluntary network of registry stewards and other stakeholders interested in advancing the development and use of registries to evaluate and improve patient outcomes. The AMA has taken the lead to complete an evaluation of registries on behalf of the NQRN regarding the operations and sustainability of existing registries. AJRR will attend the next NQRN meeting in late November 2013.

Influencers – The Pew Charitable Trusts

Over the past year, The Pew Charitable Trusts held multi-stakeholder meetings focused on how to advance the state of registries with medical device information; Dr. Lewallen participated in the series of convenings. The discussion included ways that FDA's UDI system—finalized in regulations issued at the end of September—could be useful for registry data collection. From these meetings, Pew will publish a report that will include recommendations for criteria to be used in determining if a device should be studied in a registry and transparency recommendations for making registry information available to clinicians and patients. Separately, Pew is also working to ensure that the UDI is taken up and utilized throughout the healthcare system to maximize the benefits to patients.

Influencers – Physician Clinical Registry Coalition

This coalition is a group of 20 medical society sponsored or physician-led clinical data registries working together to advocate for public policy changes that will promote and/or remove barriers to the development of registries.

Influencers – American Board of Orthopaedic Surgery (ABOS)

In October2012, AJRR leadership met with the ABOS to propose using the AJRR to collect and report data that would measure performance improvement for arthroplasty surgeons,

as a means of satisfying MOC Part IV practice improvement requirements. The ABOS requested AJRR submit a proposal that would assist in the collection of data that would qualify Diplomats for satisfactorily completing the requirements for MOC Part IV. We anticipate a positive response to our proposal.

Government

In September 2013, representatives from the AJRR met with governmental agencies including the FDA and CMS. These informational meetings were designed to provide staffers with background on our increasing activities and future release of data. All parts were interested on what types of data might be available and how this data will improve procedural outcomes. Developing an ongoing rapport with agency's staff will be important as we begin to collect data from patient surveys that measure satisfaction. Representatives of the AJRR Board of Directors and senior staff also met with key health staff from 4 Senate and 5 Representative offices.

There is also increasing interest in registries from the legislative side. As part of the 2012 so-called "Fiscal Cliff" legislation (H.R. 8--American Taxpayer Relief Act of 2012), the Comptroller General was instructed to conduct a study regarding registries and submit recommendations to Congress by November 15, 2013. The AJRR made comments on two federal requests for information pertaining to establishment of "Qualified Clinical Data Registries". Due to the partial government shutdown, the final rule date has been delayed.

Dr. Lewallen is also a member of the FDA's International Consortium of Orthopaedic Registries (ICOR) steering committee and focuses his work to ensure that the AJRR is involved with this important initiative. The AJRR continues discussions on how the registry may be able to contribute information to assist with product surveillance activities.

In 2007, a law was signed to establish a Unique Device Identification System to require; (a) the label of a device to bear a unique identifier; (b) the unique identifier to be able to identify the device through distribution and use; and (c) the unique identifier to include the lot or serial number if specified by FDA. Prior to the final rule, AJRR participated in several activities related to the request for comments on UDI, which were submitted in 2012. On September 20, the UDI final rule was distributed.

In addition, AJRR continues to work with The Knee Society, The Hip Society, and AAHKS to include performance measures being developed and approved for the CMS' PQRS initiative. These measures, as they become approved and available, will become part of the Level II quality dataset that will be used by surgeons to qualify for additional payment under PQRS.

Other Arthroplasty Registries

While AJRR is the first *national* joint replacement registry in the United States, several other arthroplasty registries exist in the United States, including the California Joint Replacement Registry (CJRR), The Virginia Joint Registry, and Michigan Arthroplasty Registry Collaborative Quality Initiative (MARCQI), and The Agency for Healthcare Research and Quality (AHRQ)-funded Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR), and various health care system and institutionally-based arthroplasty registries. Collaboration with such registries will enable rapid recruitment and resultant data acquisition. AJRR continues discussions with these organizations to minimize the burden of data submission and maximize the value of the information collected.

Affiliations

Several national and international initiatives relevant to AJRR began over the past few years, including the International Society of Arthroplasty Registries (ISAR) and the International Consortium of Orthopaedic Registries (ICOR).

International Society of Arthroplasty Registers (ISAR)

ISAR is a global consortium of joint replacement registries (http://www.isarhome.org). They facilitate the sharing of information to enhance the ability of participating countries to meet their own objectives. Additionally, ISAR assists in the development of collaborative activities and provide support to both established and developing registries such as AJRR. In June, AJRR Director of Analytics, Dr. Caryn Etkin, attended the Second Congress of International Society of Arthroplasty Registries and presented an update on AJRR progress. AJRR will be one of the sponsors of the Third Congress, to be held in Boston, Massachusetts, May 31 - June 2, 2014.

International Consortium of Orthopaedic Registers (ICOR)

ICOR was established by the FDA and rolled out during a workshop in May 2011. The intent of the workshop was to facilitate discussion among FDA and worldwide orthopedic registries that have orthopedic implant information in order to expand collaboration through a research network to pool the collective experience and data available worldwide. Dr. David Lewallen serves as a member of the ICOR steering committee. Initial ICOR projects currently underway include: a) development of a worldwide implant database; b) comparison of various bearings used in hip arthroplasty; and c) comparison of fixed and mobile bearings used in knee arthroplasty.

ArthroplastyWatch

ArthroplastyWatch is a Swedish-based information project, developed in 2011-12. The project is intended to collect data on arthroplasty safety issues from across the world and from a variety of sources. This information is then disseminated via a publicly available single site. Data are continually collected and monitored by a team of experts, such as Dr. Lewallen, who is a member of the ArthroplastyWatch Advisory Board.

Other Collaborative Efforts

Operation Walk USA

Last year marked the second annual Operation Walk USA event. On December 7, 2012, 105 surgeons performed total joint replacements on 200 under- or uninsured individuals in 29 states. Prior to Operation Walk USA, these individuals were unable to receive the care they desperately needed, and as such, many experienced substantial pain and disability. AJRR is proud to be a partner with this worthwhile organization. Our data collection software will be housing the basic demographic and procedural data collected on these patients so that the staff and surgeons of Operation Walk USA can track outcomes of these procedures over the coming years. We look forward to working with our colleagues on the 2013 Operation Walk USA event, which will be December 2 – 7, 2013.

DePaul University Master of Public Health Program

During the 2012-13 academic year, AJRR was a practicum site for a student from the DePaul University Master of Public Health (MPH) Program. Rylee Christensen focused her MPH capstone project on gaining an understanding of the needs of total joint replacement patients in order to enhance the patient education portal on AJRR's website. Her capstone paper contained recommendations for optimal presentation and dissemination of tailored educational materials, which will be incorporated in to our web-based materials. Throughout the 2013-14 academic year, AJRR is hosting another DePaul MPH student, Allison Stunard. Ms. Stunard will focus her work on the implementation of our Level II and Level III pilot study and subsequent launch of the final platforms.

2014 Goals

- Increase enrollment
- Finalize and launch Level II and Level III data collection
- Risk adjustment of AJRR results
- Expand staff
- Develop strategic alliances
- Dissemination of information
- Release licenses
- Implement business review plan

Enrollment

In 2014, AJRR will continue its primary focus on the recruitment of hospitals, with special attention paid to large health systems and health networks, hence eliminating the need for individual agreements with each hospital. We are also committed to continued enrollment of a diverse set of hospitals from large volume urban academic medical centers to smaller community-based hospitals. As seen in Appendix A, we have thus far been successful with those efforts. The AJRR also plans continued discussions with other registries such as the CJRR, The Virginia Joint Registry, MARCQI and FORCE-TJR to identify strategies to leverage joint recruitment efforts and participation agreements. It is the intent of the AJRR to have 360 hospital participants in 2014 and to have all 2013 participants submitting data by year-end.

Level II and III data collection

As discussed above, throughout 2013, a major goal of the AJRR Board of Directors was to examine the process to acquire Level II and Level III patient information [Appendix B]. In 2012, the AJRR Board of Directors approved the directive to prepare the software system to accept Level II and III data for 2013. In 2013, AJRR's IT staff completed a comprehensive plan to identify methods, tasks, resources, and schedules to begin acquisition of this information. The main focus of the effort was to ensure elimination of manual efforts at the site; mining of administrative claim forms for complications and co-morbidities; and patient involvement and interactions with outcome measurement vehicles. The AJRR production data system has features that accommodate the acquisition of both hospital and patient direct outcomes assessment. AJRR is currently conducting a pilot program to identify automated methods to acquire Level II data and to test the features implemented to manage the PROMs process.

Risk adjustment of AJRR results

Important efforts are underway through collaboration between AAHKS and FORCE-TJR research registry effort to develop a hip and knee arthroplasty specific risk adjustment tool. This can be validated and used to appropriately weight patient factors that influence arthroplasty outcomes. A widely accepted risk adjustment tool will be critical to future efforts at achieving transparency in public reporting of results.

Expansion of AJRR Staff

Already this year we have realized hospital data is being submitted at a swifter pace than in the past. To reduce the backlog of hospital submitted data, additional staff is being secured to accept and scrub hospital data. It is essential that a hospital's first data submission be reviewed for data point accuracies.

The workflow has been developed around five program planning areas, including Analytics, Information Technology, Policy, Governance, and Administrative. A senior staff member has been assigned to direct the activities and implement the policies of the Board of Directors that govern their area of concentration.

With the implementation of the fiscal 2014 budget significant dollars have been dedicated to expanding the staff. New roles and areas of concentration need to be added in order for the Registry to operate as a complete business operation. It is understood that as a growing and maturing organization changes may occur that will require modifications to the staffing plan.

Strategic Alliances

As our organization grows, we see numerous issues that affect the future of the registry. For instance, we will be looking to our specialty society colleagues for expertise in the area of measurement development. We hope to grow our relationship with The Joint Commission pertaining to the development of Disease Specific Care Certification for total joint replacement. Finally, we will continue working with our registry counterparts in the US and abroad to ensure that AJRR data is statistically sound, valid, and representative.

Dissemination of Information

Our intention is to conduct final data analysis on 2013 data throughout 2014 and distribute the final Annual Report in the fourth quarter of 2014. We will also be presenting more results from our 2013 data at the AAOS Annual Meeting in March, 2014.

Access to AJRR Demand Reporting and Electronic Dashboards System

Early in 2014, the AJRR will implement a licensing program, providing participating hospitals access to the AJRR demand reporting and electronic dashboard system. Licensed

hospitals will have the capability of running internal reports that benchmark quality outcomes to our national database. In addition, hospitals will be able to benchmark against like institutions, those in a geographic region or on some other scope. The average price for an individual hospital one-year license is approximately $3,000.00.

Business Operations Review

The AJRR Board of Directors hired the firm of Avalere Health, LLC to conduct a business operations review. The purpose of the review is to make sure AJRR is utilizing the resources available and to determine if the current direction and goals of the AJRR are obtainable. The review will also provide the Board of Directors with insight on how to appropriately plan and implement strategies for future successes.

How to enroll in the American Joint Replacement Registry

For more information regarding the AJRR, or to enroll your hospital please contact us at (847) 292-0531 or info@ajrr.net or visit our website at http://www.ajrr.net

Appendix A

2013 Participating Hospitals

Advocate Christ Medical Center
Allegheny General Hospital
Allen Memorial Hospital
Aspirus Wausau Hospital
Aurora Health Care
- *Aurora Medical Center Grafton*
- *Aurora Medical Center Washington County*
- *Aurora Sinai Medical Center*
- *Aurora St. Luke's Medical Center*

Ball Memorial Hospital
Bayhealth Medical Center
- *Bayhealth Kent General*
- *Bayhealth Milford Memorial*

Benefis Hospital
Beth Israel Deaconess Medical Center
Blessing Health System
Bronson Methodist Hospital
Cabell Huntington Hospital
Carolinas Healthcare
- *Carolinas Medical Center*
- *Carolinas Medical Center–Lincoln*

Catholic Health
- *Kenmore Mercy Hospital*
- *Mercy Hospital of Buffalo*
- *Sisters of Charity Hospital*
- *Sisters of Charity Hospital–St. Joseph Campus*

Central Peninsula General Hospital
Cheyenne Regional Medical Center
CJW Medical Center
Cleveland Clinic
Concord Hospital
Conway Medical Center
Cuyuna Regional Medical Center
Denver Health and Hospital Authority
Doylestown Hospital
Eisenhower Medical Center
Fletcher Allen Health Care
Franciscan St. Francis Health
George Washington University Hospital
Grant Medical Center
Hancock Regional Hospital
Hanover Hospital
Hawaii Pacific Health
- *Pali Momi Medical Center*
- *Straub Clinic and Hospital*
- *Wilcox Memorial Hospital*

HealthEast Care System
- *St. John's Hospital*
- *St. Joseph Hospital*
- *Woodwinds Hospital*

Hospital of Central Connecticut
Houston Medical Center
Indiana Orthopaedic Hospital
Inova Mount Vernon Hospital
Jordan Hospital
Kadlec Regional Medical Center
Lakeland Regional Health System
Lancaster General Hospital
Maine Medical Center
Marquette General Hospital
Massachusetts General Hospital
McLaren Health Care
- *McLaren-Greater Lansing*
- *McLaren Orthopedic Hospital*

MedStar Union Memorial Hospital
Memorial Hermann Health System
- *Memorial Hermann Memorial City Medical Center*
- *Memorial Hermann Southwest Hospital*

Memorial Medical Center (IL)
Memorial Medical Center (MI)
Mercy Health System
- *Mercy Fitzgerald Hospital*
- *Mercy Philadelphia Hospital*
- *Mercy Suburban Hospital*
- *Nazareth Hospital*

Methodist Hospital (KY)
Mission Hospital (NC)
Morristown Medical Center
Mount Carmel New Albany
Mountain States Health Alliance
- *Indian Path Medical Center Hospital*
- *Johnson City Medical Center Hospital*
- *Johnston Memorial Hospital*

MountainView Regional Medical Center
Nix Health
North Mississippi Medical Center
NorthBay HealthCare
- *NorthBay Medical Center*
- *NorthBay VacaValley Hospital*

Northern Hospital of Surry County
NorthShore University HealthSystem
- *Evanston Hospital*
- *Glenbrook Hospital*
- *Highland Park Hospital*
- *Skokie Hospital*

Northwestern Memorial Hospital
Novant Health
- *Novant Health Brunswick Medical Center*
- *Novant Health Charlotte Orthopaedic Hospital*
- *Novant Health Forsyth Medical Center*
- *Novant Health Franklin Medical Center*
- *Novant Health Gaffney Medical Center*
- *Novant Health Huntersville Medical Center*
- *Novant Health Kernersville Medical Center*
- *Novant Health Matthews Medical Center*
- *Novant Health Prince William Medical Center*
- *Novant Health Rowan Medical Center*
- *Novant Health Thomasville Medical Center*

NYU Hospital for Joint Diseases
OASIS Hospital
Ochsner Clinic Foundation
- *Ochsner Baptist*
- *Ochsner Medical Center*
- *Ochsner Medical Center–Kenner*
- *Ochsner Medical Center–West Bank*

OrthoCarolina Research Institute
OrthoColorado Hospital
OSS Orthopaedic Hospital
Orthopaedic Hospital of Wisconsin
Palmetto Health
- *Baptist Easley Hospital*
- *Palmetto Health Baptist*
- *Palmetto Health Richland*

Park Ridge Health
Penn Presbyterian Medical Center
Penn State Milton S. Hershey Medical Center
Pennsylvania Hospital
PinnacleHealth Hospitals
- *Community General Osteopathic Hospital*
- *Harrisburg Hospital*

Pomona Valley Hospital Medical Center
Providence Health & Services
- *Providence Holy Cross Medical Center*
- *Providence Hood River Memorial Hospital*
- *Providence Little Company of Mary San Pedro*
- *Providence Little Company of Mary Torrance*
- *Providence Medford Medical Center*
- *Providence Milwaukie Hospital*
- *Providence Newberg Hospital*
- *Providence Portland Medical Center*
- *Providence Saint Joseph Medical Center*
- *Providence Seaside Hospital*
- *Providence St. Peter Hospital*
- *Providence St. Vincent Medical Center*
- *Providence Tarzana Medical Center*
- *Providence Willamette Falls Medical Center*

Quincy Medical Center
Reading Hospital
Redmond Regional Medical Center
Renown Regional Medical Center
Roper St. Francis Healthcare
- *Bon Secours St. Francis Hospital*
- *Roper Hospital*
- *Roper St. Francis Mount Pleasant Hospital*

Rush University Medical Center
Saint Alphonsus Health System
- *Saint Alphonsus Medical Center– Baker City*

- *Saint Alphonsus Regional Medical Center*
- *Saint Alphonsus Medical Center– Nampa*
- *Saint Alphonsus Medical Center–Ontario*

Saint Elizabeth Regional Medical Center (NE)
Saint Mary's Regional Medical Center (NV)
San Antonio Community Hospital
Sanford Health

- *Sanford Medical Center–Fargo*
- *Sanford USD Medical Center*

Schneck Medical Center
Scott & White Memorial Hospital
Sentara Healthcare

- *Martha Jefferson Hospital*
- *Rockingham Memorial Hospital*
- *Sentara CarePlex Hospital*
- *Sentara Leigh Hospital*
- *Sentara Norfolk Hospital*
- *Sentara Northern Virginia Medical Center*
- *Sentara Obici Hospital*
- *Sentara Princess Anne Hospital*
- *Sentara Virginia Beach General Hospital*
- *Sentara Williamsburg Regional Medical Center*

Sharp Healthcare

- *Sharp Chula Vista Medical Center*
- *Sharp Coronado Hospital*
- *Sharp Grossmont Hospital*
- *Sharp Memorial Hospital*

Sibley Memorial Hospital
Southeast Georgia Health System
Sparrow Hospital
Spencer Hospital
St. Dominic Hospital (MS)
St. Francis Hospital & Medical Center (CT)
St. Helena Hospital (CA)
St. John's Medical Center (WY)
St. Luke's Hospital (MO)
St. Mary's Hospital and Regional Medical Center (CO)
St. Peter's Hospital (NY)
St. Vincent's HealthCare (FL)
University of Texas Southwestern Medical

- *St. Vincent's Medical Center Riverside*
- *St. Vincent's Medical Center Southside*
- *St. Vincent's Clay County*

St. Vincent Infirmary Medical Center (AR)
St. Vincent's Medical Center (CT)
Stanford Hospital & Clinics
Steward Holy Family Hospital
Swedish Health Services

- *Ballard Campus*
- *First Hill Campus*
- *Issaquah Campus*

Texas Health Presbyterian Hospital–Plano
Texas Spine and Joint Hospital
ThedaCare

- *Theda Clark Medical Center*
- *Appleton Medical Center*
- *New London Family Medical Center*
- *Riverside Medical Center*
- *Shawano Medical Center*

The Ohio State University–Wexner Medical Center
The Valley Hospital
Thomas Jefferson University Hospitals
Torrance Memorial Medical Center
Unity Hospital
University of California, Los Angeles Medical Center

- *University of California Medical Center, Santa Monica*
- *Ronald Reagan UCLA Medical Center*

University of California San Francisco Medical Center
University of Iowa Hospitals and Clinics
University of Michigan Health System
University of Pennsylvania Health System

- *Hospital of the University of Pennsylvania*
- *Penn Presbyterian Medical Center*
- *Pennsylvania Hospital*

University of Utah Hospital
University of Wisconsin Hospitals and Clinics

Center

Valley Medical Center

Virginia Hospital Center

Virginia Mason Medical Center

WellSpan Health

- *WellSpan Gettysburg Hospital*
- *WellSpan Surgery and Rehabilitation Hospital*
- *WellSpan York Hospital*

Wellstar Health System

- *WellStar Cobb Hospital*
- *WellStar Douglas Hospital*
- *WellStar Kennestone Hospital*
- *WellStar Paulding Hospital*

Wesley Medical Center

Western Maryland Health System

William Beaumont Hospital

Winthrop-University Hospital

West Virginia University Healthcare

Ruby Memorial Hospital

Appendix B

Core Data Elements

LEVEL ONE

- Patient
  - Name (Last, First)
  - Date of birth
  - Social Security Number
  - Diagnosis (ICD-9)
  - Gender
  - Ethnicity
- Hospital
  - Name
  - National Provider Identifier (NPI)
  - Address
- Surgeon
  - Name
  - National Provider Identifier (NPI)
- Procedure
  - Type (ICD-9)
  - Date of surgery
  - Laterality
  - Implants

Coming soon: Expanded procedural information

  - Surgical Approach
  - Computer assistance
  - Procedure Start / Stop times
  - Expanded diagnosis codes

LEVEL TWO

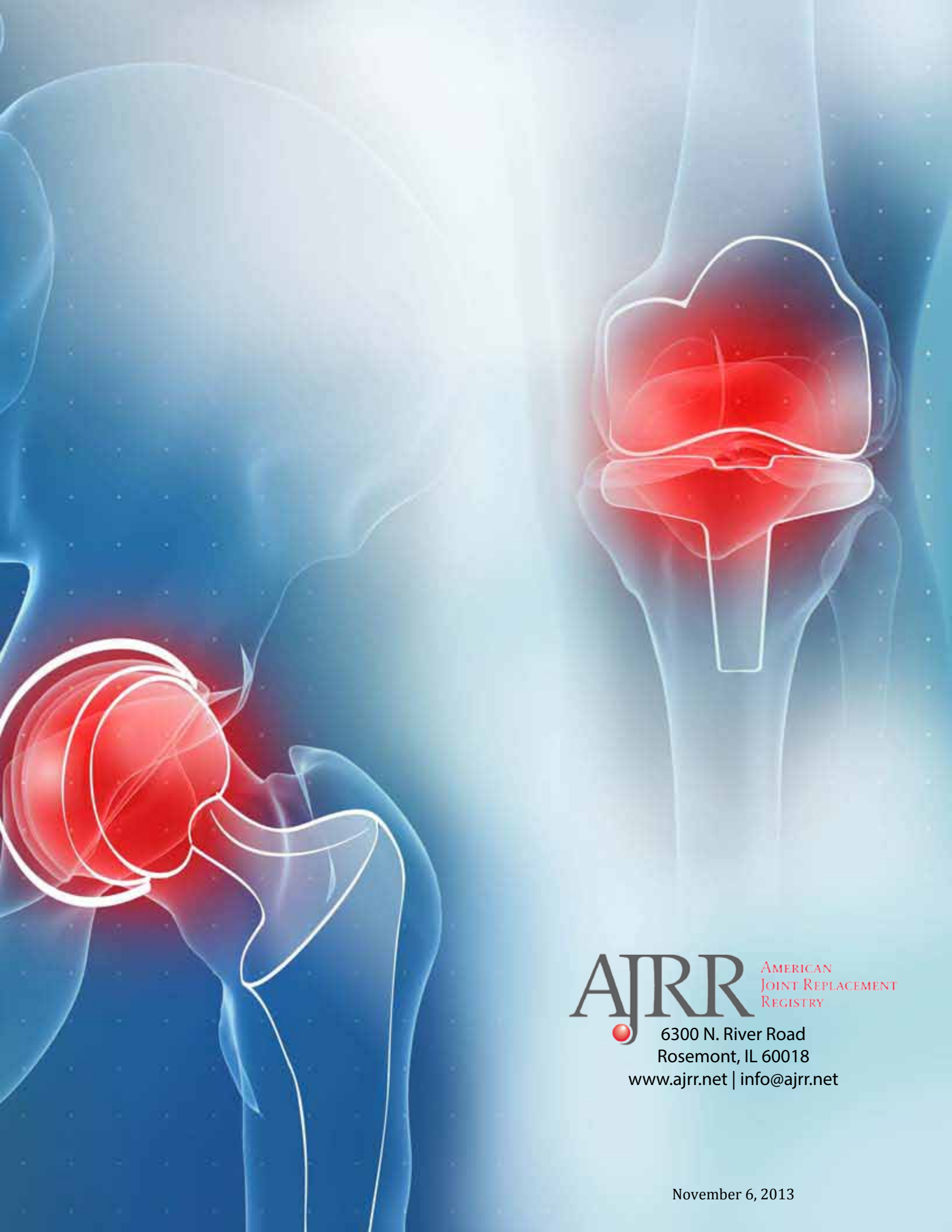
- Pre-Operative Assessment
- Patient risk factors/co-morbidities (ICD-9)
- PQRS and Other Metrics
  - Prophylaxis
  - Length of stay
  - American Society of Anesthesiologists (ASA) score
  - HIP and KNEE Metrics
- Operative and post-operative complications

LEVEL THREE

- Medical Outcomes Study 36-Item Short Form Health Survey (SF-36)
- Hip disability and Osteoarthritis Outcome Score (HOOS)
- Knee injury and Osteoarthritis Outcome Score (KOOS)
- Western Ontario and McMaster Universities Arthritis Index (WOMAC)
- Oxford Hip and Knee Scores
- Knee Society Knee Scoring System
- Harris Hip Score

LEVEL FOUR

- Radiographic Images



AJRR
American Joint Replacement Registry

6300 N. River Road
Rosemont, IL 60018
www.ajrr.net | info@ajrr.net

November 6, 2013