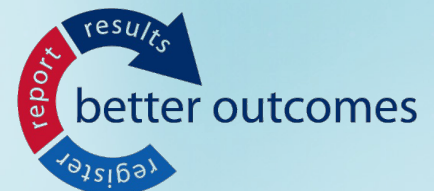


**The American  
Joint Replacement Registry  
Annual Report  
2011**

**It starts with you**  
And ends with benefits  
for your patients





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## 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, government agencies such as the Centers for Medicare & Medicaid Services (CMS) and the Agency for Healthcare Research and Quality (AHRQ), consumers, and medical device manufacturers.

The Chairman of the AJRR Board of Directors is David G. Lewallen, MD of Mayo Clinic who represents The Hip Society. Other 2011 Board members include:

### AAOS representatives:

Thomas C. Barber, MD, Kaiser Permanente  
 William J. Maloney, MD, Stanford University  
 J. Wesley Mesko, MD, Michigan Orthopaedic Center  
 E. Anthony Rankin, MD, Providence Hospital

### Orthopaedic specialty society representatives:

Kevin J. Bozic, MD, MBA, University of California, San Francisco (AAHKS)  
 Terence J. Goe, MD, University of Minnesota Medical School (The Knee Society)

### Industry representatives:

Cheryl Blanchard, PhD, Zimmer, Inc.  
 Robert E. Durgin, JD, Biomet, Inc.

### Payer representatives:

Catherine MacLean, MD, PhD, WellPoint, Inc.  
 Steven H. Stern, MD, MBA, United Healthcare

### Public representative:

Patience White, MD, MA, Arthritis Foundation

A hospital representative has yet to be appointed.

## Executive Summary

The AJRR made tremendous progress in 2011 toward the goal of becoming the first comprehensive national hip and knee orthopaedic implant registry in the United States. The AJRR has successfully completed a pilot registry program focused on refining the participation recruitment process, updating and standardizing participation agreements, and identifying methods for acquiring procedural information. Members of the AJRR Board participated in numerous activities focused on encouraging incentives for registry participation with various entities including governmental agencies, The Joint Commission and payers. In an effort to expand the services that the AJRR can provide to the public, the AJRR obtained membership to the International Society of Arthroplasty Registers (ISAR) and the International Consortium of Registries (ICOR). Finally the AJRR has transitioned into a formal recruitment effort focused on our goal to recruit 90% of all hospitals conducting hip and knee implant procedures by the end of 2015.

## Achievements

### AJRR Pilot Program

In late 2010 the AJRR initiated a data submission pilot program engaging fifteen volunteer sites throughout the United States. The volunteer sites were representative of large, small, research and community hospitals. In total eight institutions representing eleven hospitals provided procedural information to the AJRR. The goals of the pilot program included: feedback and refinement of the AJRR recruitment process, identification of data submission methods, review and feedback on participation and business agreements, and development of the various hospital functions involved with the recruitment process and their specific roles.

The AJRR Board decided to end the pilot program in June, 2011. A program evaluation workgroup was charged with evaluating the experience of each site with respect to privacy and legal issues and data submission methods. The workgroup also analyzed the integrity and content of data submitted and advanced recommendations for action to move to a full recruitment and production registry process.

In July, 2011 the AJRR Board of Directors received a report from the pilot program evaluation workgroup on the AJRR registry pilot program. Data on more than 6,000 primary and revision joint replacements were assembled from eight reporting sites [Appendix A]. The AJRR Board of Directors acknowledges and is grateful to our surgeon and staff champions at each site. The successful completion of the pilot program



represented a tremendous amount of work by the participants and the surgeon and staff champions were instrumental in ensuring a high degree of participation.

#### Key Lessons Learned:

- Elimination of manual data entry is essential for continued success of the registry
- The AJRR data system shall deploy standardized methods for data extraction and collection at the site, utilizing existing hospital electronic information such as administrative claims, electronic medical records, and orthopedic charting systems with subsequent electronic transfer.
- From the users' perspective, the creation of an AJRR website that includes answers to frequently asked questions, troubleshooting assistance, and user lists for information exchange will be essential.

Based on experiences with the pilot program, the AJRR Board formulated strategies for outreach recruitment, expansion of registry staff, and efficient data collection methods as the registry moves from the pilot program to full production. The AJRR staff is proceeding with new recruitment efforts which will target an additional 160 contributing sites in 2012 in keeping with the operational goals and timeline identified in our five-year business plan.

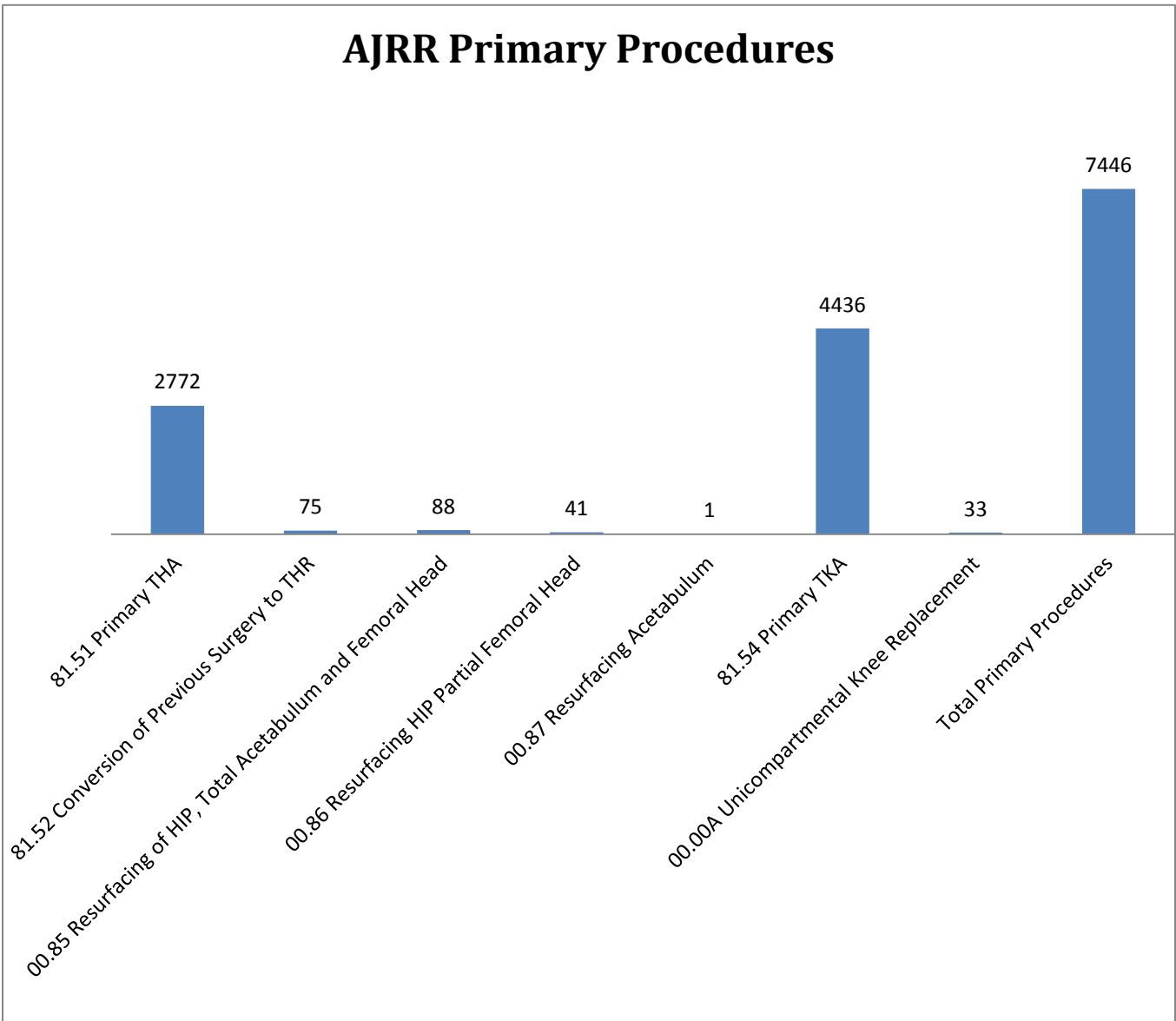
To enable efficient automated data acquisition, the AJRR began a search for a commercial registry product in June, 2011. A workgroup was formed to analyze the requirements for a production registry software package and evaluate both focused orthopedic charting systems and generic registry applications. After dissemination of a formal request for pricing to seven vendors, a total of five responded. Based on the proposal, a formal evaluation was conducted that included both qualitative and quantitative criteria. The vendor selection workgroup comprised of physicians and industry representation selected three vendors for the final step in the process and also participated in product demonstrations with each vendor. The process concluded in the selection of RemedyMD, a generic registry offering, based on features, performance and pricing. The AJRR is currently in the process of configuring the final registry application with a focus on reducing manual data entry, and expects the application to be ready in the first quarter of 2012. In the interim, the AJRR continues to acquire procedural information from the pilot program sites and is currently recruiting additional sites that have the capability to extract Level I information electronically and forward the information to the existing AJRR data system. [Appendix B]. All data acquired from the pilot program sites and during this interim phase will be migrated to the new software once available.

## AJRR Procedural Data Metrics

Table 1. AJRR collection statistics (N=8,308 total procedures)

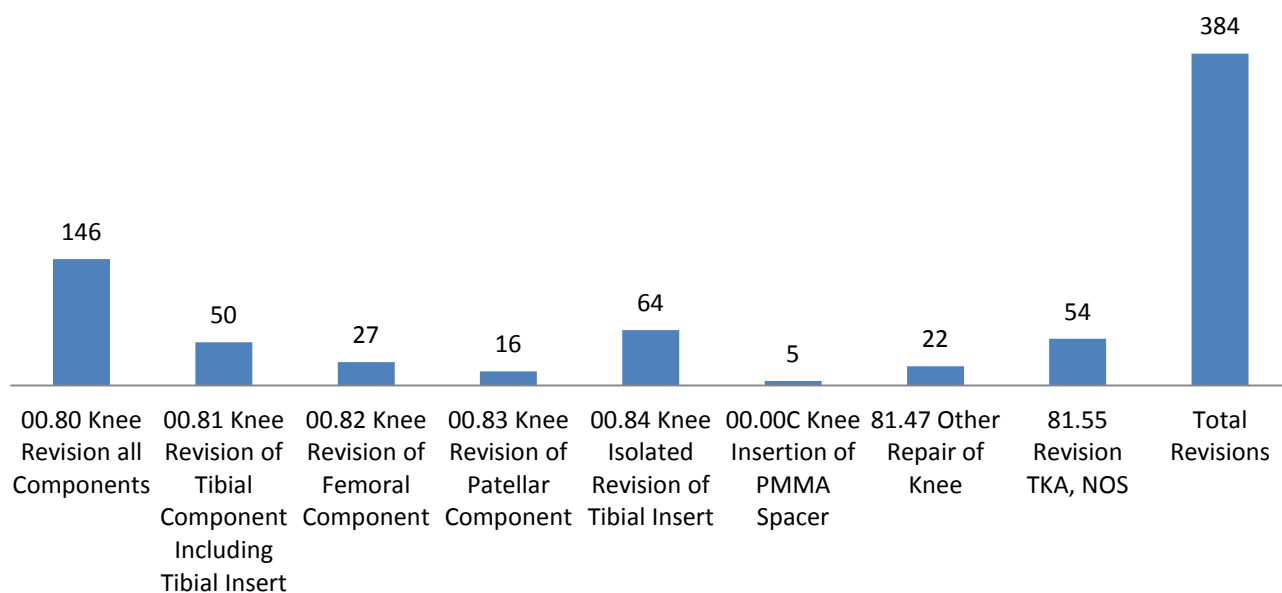
	N	
Total Procedures	8,308	
Contributing Institutions	8 (11 hospitals)	
Contributing Physicians	150	
	N	%
Patient age range (20 – 100 years) Mean age = 64.5		
Gender		
Males	3,381	40.7
Females	4,927	59.3
Primary Hip	2,977	40
Primary Knee	4,469	60
Revision Procedures (w/primary procedure in data set)	84 N=37 Knee N=47 Hip	1.011
Revision Procedures (w/o primary procedure in data set)	816 N=384 Knee N=432 Hip	9.8
** 0.5% data entry and analysis error rate		

## AJRR Primary Procedures

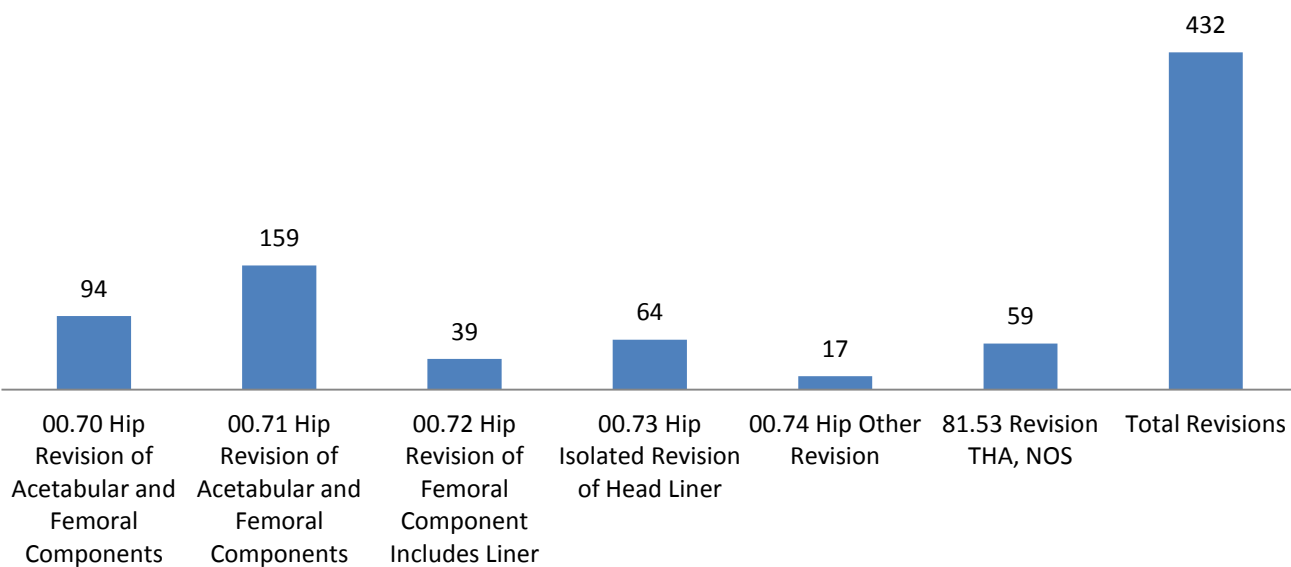




## Knee Revision Procedures



## Hip Revision procedures



## Business Planning and Funding

During 2010 the AJRR business plan workgroup developed a five-year operational plan for the AJRR. The plan was developed by various participants from the AJRR Board and staff, industry and payers. The five year plan included considerations for staffing, hospital enrollment forecasts, start up and long term revenue projections, and reporting. In December, 2010 the AJRR began presenting the business plan to the AJRR stakeholders including industry, payers, surgeons and orthopaedic professional societies to seek startup and longitudinal support for a national registry and commitments for startup funding.

The AJRR is committed to the major stakeholder governance and startup funding plan that emerged from those discussions. Following five years of full operation, this plan call for the AJRR to become self-sufficient by a combination of subscriber fees from hospitals and surgeons, and revenue from custom data reports provided to industry and payers.

## AJRR Committee Activities

### *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). Certain payers are now including questions pertaining to AJRR participation in materials provided to hospitals. 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 had two productive meetings with The Joint Commission in 2011 which focused on hospital recognition for participating and submitting data to the AJRR. During the first meeting, two possibilities were discussed related to The Joint Commission disease specific certification program in total hip and knee arthroplasty and the other in relation to general



accreditation. The AJRR Public Advisory Board membership includes a representative from The Joint Commission and we continue to have an active dialogue with The Joint Commission on these topics.

### *Influencers – American Medical Association (AMA)*

In 2011, the Physician Consortium for Performance Improvement (PCPI) convened by the AMA began the process of creating the National Quality Registry Network (NQRN). The NQRN will be a voluntary, coordinating network of individual patient registries designed to support performance improvement and innovation in health care. It will act as a coordinating mechanism among existing registries. The AJRR Director of Research and Board member Dr. Anthony Rankin attended the most recent NQRN meeting and has proposed becoming a member of the NQRN Council as a “developing national registry”. This creates an additional opportunity for AJRR to engage with multiple stakeholders in the registry community.

### *Government*

Representatives from the AJRR have been invited to several meetings with governmental agencies including the U.S. Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS). Recently the AJRR Board Chairman, Dr. Lewallen, was invited to speak on the subject of the Unique Device Identifier Rule (UDI) in relation to orthopedic implants:

<http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM272076.pdf> The AJRR continues its involvement in this area. Dr. Lewallen and members of the AJRR Board of Directors are also involved in planning discussions on the International Consortium of Orthopedic Registries (ICOR). Dr. Lewallen has been invited to become a member of the ICOR steering committee with a focus on ensuring that the AJRR is involved with this important initiative. The AJRR is examining strategies for receiving FDA funding through ICOR along with discussing how the registry may be able to contribute information to assist with product surveillance activities.

### *Governance*

The AJRR organization is currently beginning the effort to develop a full complement of policies and procedures that will govern data uses and reporting of AJRR information. The AJRR is currently communicating with other national registries to establish a starting point for AJRR workgroup activities. The AJRR expects to have these policies and procedures defined in the first quarter of 2012.

### *Data completeness and quality*

A primary focus and priority for the newly hired Director of Research, Dr. Caryn Etkin, will be to define the verification and validation processes staff will utilize to ensure that the



AJRR data set is complete and error free. Working with the AJRR physician workgroup the AJRR expects to have all policies and procedures defined in 2012 allowing the AJRR to publish a detailed annual report in 2012.

## AJRR Expansion

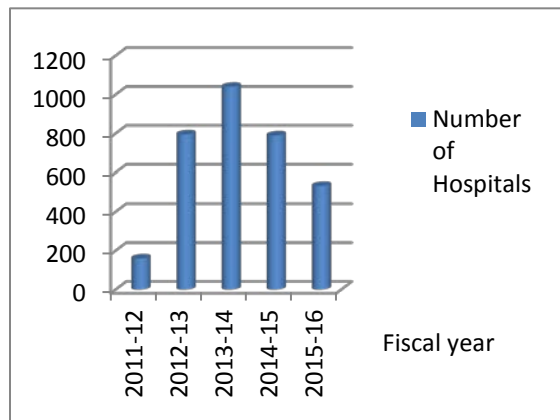


Figure 1. Enrollment of hospitals

According to our updated forecast, the AJRR is required to enroll N=160 more hospitals in 2012. As of January, 2012 the AJRR has received eight new Business Associate Agreements and is in discussions with 79 new sites [Appendix C]. It is our goal to have representation from all 50 states in 2012. We will also targeting large health systems and health networks in the coming months, to identify the possibility of network level business associate and participation

agreements. This may eliminate the need for individual agreements with each hospital which would accelerate recruitment efforts. The AJRR is also in the initial stages of collaboration with other state initiatives such as the California Joint Replacement Registry and The Virginia Joint Registry to identify strategies to leverage joint recruitment efforts and participation agreements. The AJRR staff recently developed a comprehensive recruitment plan to enable the AJRR to include over 3,000 sites by 2015-16. (See Figure 1 for the forecast of hospital enrollment by fiscal year).

## Existing Registry Collaborations

While AJRR is the first *national* joint replacement registry in the United States, several states have existing registries including the California Joint Replacement Registry, The Virginia Joint Registry, and Michigan Arthroplasty Registry a Collaborative for Quality Improvement (MARCQI). The Agency for Healthcare Research and Quality (AHRQ)-funded FORCE-TJR registry database also has 6 core clinical centers nationwide and numerous community partners. While these registries do not represent every hospital in their state, collaboration with such registries will enable rapid recruitment and resultant data acquisition. AJRR Board Chairman Dr. Lewallen has received commitments from the aforementioned registries that they would like to become designated affiliates of AJRR. The AJRR is currently in discussion with the California Joint Replacement Registry to identify synergies on recruitment and agreements and definition of a process to enable relationships with state registries.

## Affiliations

Several national and international initiatives relevant to AJRR have begun over the past few years. These include: International Society of Arthroplasty Registries (ISAR), International Consortium of Orthopaedic Registries (ICOR), U.S. Food and Drug Administration's (FDA) Unique Device Identifier Rule (UDI).

- International Society of Arthroplasty Registries (ISAR) is a global consortium of joint replacement registries. They facilitate the sharing of information to enhance the ability of participating countries to meet their own objectives. They assist in the development of collaborative activities and provide support to both established registries such as those in Sweden and the UK and developing registries such as AJRR. The AJRR is currently an affiliate member with intentions to become a full member.
- International Consortium of Orthopaedic Registries (ICOR) was established by the FDA as a workshop in May, 2011 to facilitate discussion among FDA and worldwide orthopedic registries that have orthopedic implant information and create a research network to advance the methodology of registries. Dr. Lewallen has recently accepted a position on the ICOR steering committee.
- 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. FDA will shortly begin developing draft regulations to implement these requirements. Dr. Lewallen presented "The Benefits of UDI to Medical Device Registries", which described the AJRR, at the UDI for Postmarket Surveillance and Compliance Public Workshop in Washington, DC in September.

## AJRR Level II and III data acquisition planning

The AJRR Board of Directors is currently examining the process to acquire Level II and Level III patient information [Appendix B]. In 2012, the AJRR staff will create a comprehensive plan to identify methods, tasks, resources and schedules to begin acquisition of this information. Primary consideration for Level II and III data acquisition include elimination of manual efforts at the site; mining of UB-04 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.



## 2011 Accomplishments

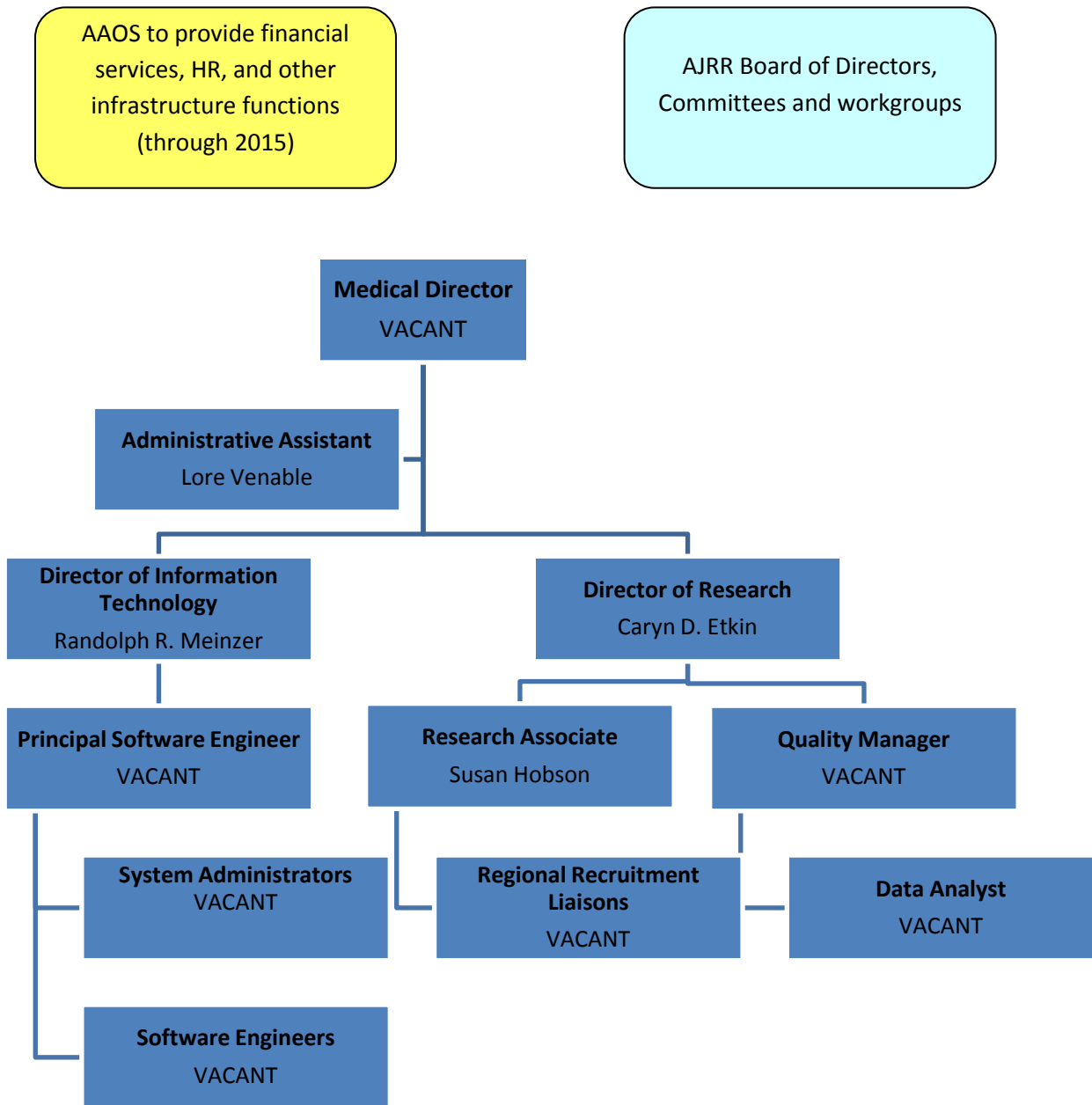
- Completed the AJRR registry pilot program in June, 2011 including a “Lessons Learned” activity with the AJRR Board in July, 2011. A total of eight out of fifteen sites participated with the remaining sites still in process to submit data to the AJRR once the AJRR production software is operational.
- Obtained data on over 8,000 hip and knee procedures proving the feasibility of a centralized national hip and knee registry for quality improvement purposes.
- Hired Caryn Etkin, PhD, MPH as Director of Research. Augmenting the AJRR staff is critical as the AJRR seeks to become a fully functional registry.
- Selected a final production software package, *RemedyMD*, enabling the AJRR to serve the data and reporting needs of the nation.
- Transitioned from the pilot study to full production registry activities and expanding hospital recruitment.

## 2012 Goals

- Launch final registry production software using lessons learned from the proof of concept pilot program.
- Eliminate need for manual data entry at hospitals through electronic interfaces.
- Expand the AJRR staff to accelerate 2011-12 hospital enrollment with the goal of over 160 institutions reporting data in 2012.
- Finalize and complete the AJRR policies and procedures for data reporting to leverage input from the multi-stakeholder AJRR community.
- Engage governmental agencies, medical societies, and the AJRR Public Advisory Board to ensure that the AJRR remains current in the requirements to and goals of improving patient outcomes.

## Existing and Planned AJRR Staff

The following represents the existing and planned AJRR Organizational Structure. As the AJRR expands in the coming years, we acknowledge that this structure will evolve to meet the needs of the registry.



## AJRR Employee profiles

### **Medical Director (recruitment underway, preferred target 1<sup>st</sup> quarter 2012 hire) –**

This individual will be responsible for medical aspects of the registry, staff prioritization and coordination efforts, and communication with AJRR stakeholders and medical societies. S/he will actively promote the AJRR to all constituents and potential customers.

**Administrative Assistant, Lore Venable** – Ms. Venable is responsible for maintaining relationships with all registry stakeholders, Board of Directors, committees and hospitals. She coordinates calls, meeting requests, manages and plans conferences, board meetings, and plans and executes projects. The administrative assistant currently supports the AJRR Directors and will ultimately support the Medical Director.

**IT Director, Randolph R. Meinzer** – Organizes, implements, and directs all technical operations of AJRR, including data input, storage, and retrieval, as well as supervision of technical staff and/or outside consultants. Evaluates and selects cost effective tools for the registry including hardware, software and services. Mr. Meinzer will recruit and manage IT staff and projects budgets and expenses. He also supports data contributors as required for manual data entry, automated data entry and other methods for collecting registry data. The following staff will report to Mr. Meinzer:

**Software Engineer(s) and System Administrator(s) (recruitment underway for a Principal Software Engineer, preferred target 1<sup>st</sup> quarter 2012 hire)—** The registry will need to employ software personnel to identify the requirements, architect interfaces or communicate and manage the development of vendor software efforts. Software will need to be maintained, formal procedures for software control; issue tracking and software development will need to be created.

**Director of Research, Caryn D. Etkin, PhD, MPH** – Dr. Etkin joined the AJRR in August, 2011. Her role serves two functions: recruitment and quality. Dr. Etkin oversees day to day operations of the training and recruitment of hospitals including prioritization of activities, development of processes and procedures, and direct the creation of hospital and employee training materials. Dr. Etkin will also be the primary supervisor for emerging hospital and physician requirements for the AJRR as they are developed. In regards to quality, Dr. Etkin is responsible for data analysis and validation, statistical services, reporting and development of policies and procedures for quality programs and activities. Additionally, she will serve as privacy officer for the registry and will oversee the creation and dissemination of all AJRR reports. The following staff will report to Dr. Etkin:



**Quality Manager** –The quality manager will collaborate with Dr. Etkin on data analysis and validation, statistical services, reporting and implementation of policies and procedures for quality programs and activities. Additionally the quality manager will be responsible for supervision of the data analyst, initiating quality assurance and quality control processes and procedures for the AJRR, serves on a privacy committee the registry and oversees the development and dissemination of all AJRR reports.

**Data Analyst** – Data analysts will be necessary to ensure that data is as error free as possible, to assist in generation of preliminary information requested by the research group and to generate and distribute the various period stakeholder reports. Even though the model only reflects error correction it is expected that software algorithms will be developed by the software group for years 2013-2015 reducing the amount of time spent on error correction allowing this team to transition to the other reporting tasks.

**Research Associate, Susan Hobson, MPH** – Ms. Hobson will join AJRR in February, 2012. To develop customer intimacy with the AJRR, a training and recruitment group will also be the main promotion arm of the AJRR bringing the voice of the stakeholders into the AJRR. Along with Dr. Etkin, Ms. Hobson will oversee day to day operations of the training and recruitment group including prioritization of activities, development of processes and procedures for the group, and oversee the creation of customer and employee training materials.

**Regional Recruitment Liaison**—The hospital liaison will be the main contact for hospitals and will be supervised by Dr. Etkin and Ms. Hobson. It is expected that in the coming years, we will adapt this position and add one liaison for each region of the U.S. to include 4 regional staff.

## Appendix A

### *Pilot program contributing hospitals*

HealthEast Care System (MN)—includes St. John’s Hospital, St. Joseph Hospital, and Woodwinds Health Campus

NYU Langone Medical Center (NY)

Rush University Medical Center (IL)

St. Francis Hospital (CT)

St. Francis Hospital (IN)

St. Mary’s Hospital/Western Slope Study Group (CO)

Thomas Jefferson University Hospitals (PA)

University of California, San Francisco

## Appendix B

### Core Data Elements

#### LEVEL ONE

- **Patient**
  - Name (Last, First)
  - Date of birth
  - SSN
  - Diagnosis (ICD-9 or ICD-10)
  - Gender
  
- **Hospital**
  - Name
  - Address
  
- **Patient**
  - Name (Last, First)
  - Date of birth
  - SSN
  - Diagnosis (ICD-9 or ICD-10)
  - Gender
  
- **Surgeon**
  - Name
  
- **Procedure**
  - Type (ICD-9)
  - Date of surgery
  - Laterality

#### LEVEL TWO

- Patient risk factors/co-morbidities (ICD-9), PQRI measures, surgical approaches, prophylaxis, ASA score

#### LEVEL THREE

- SF-12, SF-36, HOOS, KOOS, WOMAC, Oxford Hip and Knee Scores, Knee Society Knee Scoring System, Harris Hip Score, AAOS Hip and Knee Core Scale

#### LEVEL FOUR

- Radiographic Images

## Appendix C

### Hospitals in process of joining AJRR

#### Business Associate Agreement Received

Allegheny Singer Research Institute (PA)  
 Ball Memorial Hospital (IN)  
 Cleveland Clinic (OH)  
 Fletcher Allen Health Care (VT)  
 Indiana Orthopaedic Hospital (IN)  
 Lancaster General Hospital (PA)  
 Massachusetts General Hospital (MA)  
 Physician's Regional Medical Center (TN)

#### Conference call completed with hospital staff, waiting on BAA

Aurora Advanced Healthcare (WI)	Northwest Hospital (WA)
Cabell Huntington Hospital (WV)	Northwestern Memorial Hospital (IL)
Catholic Health Initiatives ( <i>preliminary</i> conversation)	Ochsner Health System (LA)
Duke University/Durham Regional (NC)	Palmetto Health Richland (SC)
FirstHealth Moore Regional Hospital (NC)	Siouxland Surgery Center (SD)
HCA ( <i>preliminary</i> conversation)	St. Luke's Health System (ID)
Houston Health Care (GA)	St. Luke's Hospital (St. Louis, MO)
Intermountain Healthcare (UT)	St. Vincent's HealthCare (FL)
Maine Medical Center (ME)	Stanford Hospitals (CA)
McLaren Health System (MI)	Texas Health Presbyterian Hospital (TX)
Memorial Hermann Surgery Center SW (TX)	The Hospital of Central Connecticut (CT)

#### AJRR Materials Sent

Advocate Lutheran General Hospital (IL)	Grant Medical Center (OH)
Anne Arundel Medical Center (MD)	Hackensack University Medical Center (NJ)
Appalachian Orthopedics (TN)	Hartford Hospital (CT)
Baptist St. Anthony (TX)	Heart of Florida Regional Medical Center
Barnes-Jewish Hospital (MO)	Jeanes Hospital (PA)
Bronson Orthopedics (MI)	Jewish Hospital & St. Mary's HealthCare (KY)
Center for Joint Surgery & Sports Medicine (MD)	Maine Medical Center
Central DuPage Hospital (IL)	Marquette General Hospital (MI)
Cheshire Medical Center (NH)	Memorial Medical Center (Ludington, MI)
Community Medical Center (MT)	Memorial Medical Center (Springfield, IL)
Community Medical Center (PA)	New York Methodist Hospital (NY)
Continuum Health Partners (NY)	NorthBay HealthCare (CA)
Deaconess Health Systems (IN)	Northern Berkshire Hospital (MA)
Denver Health (CO)	NorthShore University Health System (IL)
Flagler Hospital (FL)	OrthoCarolina (NC)
Gila Regional Medical Center (NM)	Orthopaedic Hospital of Wisconsin (WI)
Good Samaritan Hospital (OH)	Providence Hospital (OR)
	Queen's Medical Center (HI)

Renown Health (NV)  
Rochester General Hospital (NY)  
Sharp HealthCare (CA)  
Sinai Hospital (MD)  
Southwest General Health Center (OH)  
Sparrow Health System (MI)  
St. Elizabeth Medical Center (Utica, NY)  
St. Elizabeth Regional Medical Center (NE)  
St. Francis Hospital (NY)  
St. Helena Hospital (CA)  
St. Mary's Hospital (Duluth, MN)

The Miriam Hospital (RI)  
The Ohio State University Medical Center (OH)  
The Reading Hospital & Medical Center (PA)  
Towson Orthopedics (MD)  
UnityHealth (NY)  
University of Minnesota (MN)  
University of Wisconsin Hospitals (WI)  
Western Maryland Health System (MD)  
Winthrop Orthopaedic Associates (NY)  
Wooster Community Hospital (OH)







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