

Total Joint Registry Workshop

The Agency for Healthcare Research and Quality/
The American Academy of Orthopaedic Surgeons
Washington, DC
December 10-11, 2001

Final Report

Prepared by:
American Academy of Orthopaedic Surgeons
Department of Research and Scientific Affairs
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FINAL REPORT

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I. Total Joint Registry Workshop Summary

INTRODUCTION:

The American Academy of Orthopaedic Surgeons (AAOS), in cooperation with the Agency for Healthcare Research and Quality (AHRQ), implemented a two-day workshop in Washington, DC, December 10-11, 2001, to explore the feasibility of and clarify the level of interest in a national joint implant registry in the U.S. Practicing orthopaedic surgeons, leading researchers, government policy makers, executives of implant device companies, and representatives of domestic and foreign joint registries attended. This summary reflects the content of the 5 plenary sessions and panel discussions, the “next steps” section, and concluding remarks.

The goals of the workshop included 1) identifying and addressing issues concerning the planning, development, implementation, and management of a national registry; 2) identifying and addressing issues of liability, funding, and privacy; 3) examining existing registries for their applicability to a U.S. model; and 4) addressing questions concerning benefits to quality, safety, cost-effectiveness, research utility, and improved access to care.

Participants in the workshop came to explore the scientific utility of a national joint replacement registry, and a number of burning issues. These include the need to determine if newly released implants are equal or superior to current ones; the need to determine the true revision burden in the US; the need to determine if a reduction of the revision burden in the US is possible as has been demonstrated in other countries with registries; and the need to determine if premature failures are related to material defects or surgical factors.

Many believe that a national joint registry will improve patient safety. It may provide information that is helpful in detecting problems with joint replacement surgery, including the early detection of implant failure. The registry may generate information that is useful to researchers, physicians, surgeons, patients, and manufacturers that will help to improve the quality of patient care, medical decision-making, implant devices, and manufacturing processes.

SUMMARY OF PRESENTATIONS AND PANEL DISCUSSIONS

Session I: Clinical Economics of Total Joint Replacement and Cost Savings Associated with Decreasing Revision Burden

This section addressed the ways in which a joint registry may be beneficial in providing increased information about total joint replacement utilization rates, underutilization, and patient outcomes. The role of a registry in decreasing healthcare costs was also explored.

Benefits of a Joint Registry: Utilization Information

A national joint implant registry would increase understanding and accuracy of projections about arthroplasty rates. “The Dartmouth Atlas” has found variability in utilization rates in arthroplasty in terms of outcome and evidence of unmet need, especially by sex and racial groups. For example,

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females undergo revision more than males but are still underutilizing total joint replacement (TJR), and black males have the lowest TJR utilization rate of any group. Additional outcomes data is necessary to understand why underutilization occurs, how utilization by certain underserved populations can be increased, and how the public can make more informed choices.

Benefits of a Joint Registry: The Importance of Surgery Volume

A national joint registry could increase our understanding and the accuracy of projections about arthroplasty failures. For example, Medicare data from 1996 and 1997 describes hip revision rates at 18% and increasing. Poorer outcome has been found to be associated with certain surgical settings and practitioner characteristics. Most TJRs are done in private hospitals, which have low volumes of joint replacements, relative to teaching centers. Most surgeons in private hospitals do less than 10 joint replacement surgeries per year. Decreased volume is associated with increased mortality, complications, revision rates and decreased patient function. The elderly, poor, less educated, and rural patients tend to go to low volume centers and are most at risk of experiencing a poorer outcome.

Benefits of a Joint Registry: Issues in Revision Surgery

Revision surgery is more costly than primary joint replacement. It involves greater time, effort, risk, and overall resources. Revision surgeries have a marginal profit status, and the number of complex revisions, which may involve bone grafts, special components, impaction grafting, or massive lysis are increasing. Moreover, the percent of cases in which hospitals lose money (typically \$8-10,000 per case), is increasing. In keeping with the results of registries in other countries, establishment of a U.S. registry could lead to a decrease in the revision rate by 50% in Medicare patients alone. This would save Medicare \$100 million.

Benefits of a Joint Registry: Conclusions

- More information about arthroplasty rates would be beneficial to patients, clinicians, and scientists
- There is evidence that TJR is underutilized by certain minority groups
- Hospital and surgeon volume has an effect on patient outcome
- TJR revision rates are increasing, especially for complex revision cases
- Hospitals lose money on complex revision cases
- A registry could save substantial sums of money by reducing the revision rate

Session II: Opportunity for Improvement: Clinical and Scientific, Patient, Physician and Scientist Perspectives

This section addressed topics relevant to public safety and welfare. These included systematic monitoring of patient outcomes, medical errors, and quality of care; the effect of registry-guided outcomes information on clinical practice including the development of standardized guidelines and assessment tools; and the research advantages of a registry. Representatives of foreign and domestic registries shared their experiences.

Registry Concerns from Various Perspectives: Patients, Clinicians, and Scientists

The experiences of patients, clinicians, and scientists are key to the utility and success of a registry. Patients are concerned about the safety and the probability of success for a given surgery. Clinicians and hospitals want to make the most successful and cost-efficient use of their resources. Researchers want valid, reliable, and complete data. A registry must take into account the roles and needs of the

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parties involved, including the administrator, scientist, clinician, and patient, and how each will be affected by the structure of the registry. Defining the underlying goals of a registry is vital to its implementation and final form. Questions about the structure and mission determine what kind of data can be collected, how it can be collected, and how it can be disseminated. Registries from other countries, like Sweden and Ontario, Canada and private registries within the U.S., like the one run by the Mayo Clinic, may be able to provide a model.

Registry Concerns from Various Perspectives: The Mayo Clinic Registry

The Mayo Clinic joint registry is premised on the idea of improving care of patients. Their registry has been in place since 1969 and uses standardized variables for implant. The Mayo registry emphasizes its content, completeness, and the fact that it has been sustained over time. Follow-up is regular, systematic and complete. Mayo's concerns have related primarily to the administrative costs of its registry, estimated at \$400,000 per year, confidentiality issues, and legal costs.

Registry Concerns from Various Perspectives: Foreign Registries

Implant registries exist in other countries. In Ontario, Canada, the data is exclusively protected for the use of doctor and government, not the use of the public. It is not used to monitor physician performance but to increase quality, decrease revisions, and increase access. There is a strict procedure for determining who has access to data and who is responsible for the management of the registry. In Sweden, physician participation is voluntary and there is no compensation for participation. Much of the information is collected via the Internet and is entered by hospital administrative staff. The Swedish registry is a voluntary registry that has been in operation for twenty years. It is entirely owned and administered by the medical profession. Its goal is to improve the quality of surgery, not just implant design. The Swedish registry keeps data collection simple to enhance compliance and estimates the cost of each new patient entry at \$40. They try to improve patient outcomes through regular feedback and interpretation of outcomes to surgeons. Experts consider both countries' registries successful.

Registry Concerns from Various Perspectives: Conclusions

- Patients, clinicians, and scientists all have different uses and requirements for a registry
- Patients are interested in safety and successful outcome
- Clinicians are interested in quality of care and cost effectiveness
- Scientists want psychometrically sound data
- Foreign and small, private domestic registries have been successful at meeting multiple goals

Session III: Overview of Legal Issues

This section addressed the confidentiality and privacy concerns of patients, doctors and hospitals. Exploration of various options to protect privacy and the roles of government and AAOS in a registry were examined.

Goal of Registry: Improve Public Health

A legal analysis of issues surrounding the development of a nationwide implant registry and AAOS' potential role in a registry was commissioned by AAOS. The analysis was premised on the goal of improving public health.

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Legal Concerns: Privacy and Liability Issues are Major Issues

There are 2 major legal considerations in a registry: protection of information, also referred to as confidentiality, and liability associated with publication of outcomes data. According to the legal opinion presented, liability, especially anti-trust litigation and trade libel, are of little threat to the viability of a national joint registry in the U.S. Confidentiality is more difficult to ensure. HIPAA, the Health Insurance Portability and Accountability Act, regulations permit disclosure for discovery. Therefore, HIPAA will not protect the registry against litigation.

If the government is involved as a granting agency, a registry may receive specific Federal protections not otherwise available. For example, Certificates of Confidentiality are applicable to research that is sensitive, but are probably not applicable to physician information. Therefore, they would not be helpful in the legal protection of a registry. AHRQ involvement can help with the confidentiality protections, but it may make the data vulnerable to the Freedom of Information Act (FOIA). Therefore, there will be protections available to a registry with government involvement that are otherwise not available, but it is not clear if all information can be protected, especially the identity of the device.

Legal Concerns: Disadvantages of Governmental Control

Rigorous governmental control over the data also has consequences. For instance, there are disadvantages to strict protections of the data. The more protections on the data, the less utility it will have due to the difficulty of releasing information to researchers or others who may request it.

Legal Concerns: AAOS Relationship to Registry

The role of AAOS in the registry would need to be based on a balance between the need for control in contrast to protection against liability. Increased control of the registry by AAOS would mean increased liability for AAOS. It may be possible to set up an independent but related entity that would maintain strong involvement with AAOS. AAOS may further investigate this option.

Legal Concerns: Clinician and Researchers' Concerns

Clinicians' and researchers' concerns involve duty to warn, protection of patient confidentiality, and class action suits. According to legal opinion, duty to warn puts the onus on the operating clinician, not the registry, to warn patients of potential problems with their implant or surgery. Furthermore, even if some registry information becomes public, it would be unlikely that patient names would ever be released. However, once data leaves the registry, it is unprotected. Finally, there is potential for class action litigation. Regardless of the registry structure, legal challenges should be anticipated and sufficient funds will need to be allocated to withstand litigation while maintaining the registry.

Legal Concerns: Conclusions

- Liability should not be a concern in developing a registry
- Confidentiality will be difficult to ensure with a registry
- Governmental involvement may offer some protections to confidentiality but the protections are not complete
- The need to protect the data must be balanced with the limitations in utility that will come with more control
- The operating surgeon would be responsible for informing patients of any potential problems with their implant

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- Legal challenges should be anticipated and sufficient funds should be allocated to maintain the registry through all contingencies

Session IV: Operations and Governance of a National Registry, Data Management, Access and Governance

This section addressed data management issues including what data to collect, how to handle the data, who will have access to the data, and how the data and results will be disseminated. The performance metrics of available sources of data were debated.

Governance Issues: Mission and Goals Must Be Clearly Defined

Governance structure and registry purpose are closely related and need to be well defined. Governance issues include determining who owns, pays for, and has access to the data in a registry. The mission of the registry will guide the functional aspects such as implementation and what type of information is collected and disseminated. The mission will determine if a registry is to serve the purpose of surveillance or outcomes research, two very different goals.

Governance Issues: CMS, A Source of Data

The Centers for Medicare and Medicaid Services (CMS) database is a ready source of information about replacement surgeries and revisions. This data is currently used to supply much of the information available about primary and revision TJRs. However, the CMS database is missing some vital information, such as laterality and device information, and will need to be supplemented if it is to be used as the basis of a registry. According to CMS personnel, it is procedurally difficult to add fields to the Medicare form to collect additional information, but it is possible to develop and implement a separate data collection form for quality purposes. In addition, CMS reported that they have statutory authority over all payers; thus, data outside of Medicare may be available.

Governance Issues: Challenges of a CMS-based Data Source

Data on implant devices could be collected by the Medicare system. However, workshop participants cited a number of additional challenges associated with the Medicare database. These problems include unreliable coding, lack of clinical data, lack of information about patients under 65 years old, no incentives for HMOs to file claims with Medicare, data being restricted to events that result in a bill, and the evidence of both upcoding and downcoding. These problems would need to be resolved before Medicare data would be useful for a registry.

Governance Issues: A Registry is not a Complete or Short-term Data Source

Not all researchers agree with obtaining registry data through the CMS database. Some researchers expressed concern about the utility of the CMS data for several reasons: first, revision can be a late and insensitive measure of implant survival; second, a registry under CMS can have limited research potential. Any registry, whether under CMS or not, cannot replace research involving prospective, randomized clinical trials. Results of data collection through a national registry may involve years of data collection before analysis can proceed. In particular, surveillance of implant or surgical technique failures will take several years of data collection before problems become apparent. A registry should not be thought of as a short-term or complete information source.

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Governance Issues: Conclusions

- The mission of the registry should be defined before implementation as it will determine the type of data collected and the information disseminated
- The CMS Medicare database could serve as a source of data for the registry
- CMS data on TJR is not complete and would require, at minimum, inclusion of laterality and device information before useful registry results could be collected
- Several years of data collection are needed before meaningful results can be found

Session V: Next Steps

This section addressed the next steps after the workshop and closing recommendations.

Recommendations:

1) “Just get started and agree to keep it simple”

There were several recommendations on ways to involve workshop participants in future planning efforts and how to make data collection as easy as possible. There was consensus on “keeping it simple” and working with available or easily obtainable data, rather than building anew. Some suggested that orthopaedic surgeons should investigate to determine what data is already being collected through Medicare because this may be sufficient in many respects. CMS could do a coding change to reflect laterality and/or collect additional information necessary for the registry.

2) Define goals and parameters of the study

Defining the goals of the registry was seen as being very important, as this will determine what will be collected. Participants agreed that the registry should select a big enough issue to be important, but small enough to make the project feasible. Focusing on the short-term gains will keep people interested and excited. Foreign registry representatives believe that underlying causes for the revision rate will show up earlier than expected.

3) Look at domestic models, like Renal and Cardiac By-Pass

There are several good U.S. registry models with governmental involvement for development of an implant registry. The U.S. Renal Data System is a CMS-NIH collaboration. NIH and CMS share the burden of liability, there have been no lawsuits, and liability issues are not a big concern. The Cardiac Bypass Surgery Project, an all-payer registry in one state, is also a good model for a joint registry pilot project.

4) Link goals to interests of CMS, AHRQ, NIH

Representatives from several leading agencies expressed interest and support for a national joint registry. Addressing their strategic goals and missions will be a key to their continuing involvement. For example, generating research questions of interest to NIH and NIAMS may be important. CMS and AHRQ are interested in improving quality of healthcare, reducing medical errors, and reducing health care costs, all of which can be potential goals for the registry. Representatives from CMS and AHRQ had recommendations concerning their future roles. They expressed a willingness to assist in developing a registry structure and addressing legal issues for all parties. CMS might be open to serving on the registry’s Board of Directors in an ex-officio capacity. They would assist with the infrastructure, but want the “experts” to do the analysis and set the methodologies.

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5) Consider pilot study with Medicare data

CMS would consider cooperating in a pilot project using Medicare data in four possible scenarios:

- Use of existing Medicare Claims Data, nationwide
- Use of existing Medicare Claims Data, regionally or by state
- Additional data collection
- All payers registry in certain states

Most of the data needed is collected through Medicare records, which could provide the basic information desired. However, the Medicare data is missing the key elements of laterality and description of implant, but laterality could be addressed through a CPT code change. Description of the implant will be more difficult to capture.

6) Establish subsequent planning groups, involve interested parties

The AAOS leadership expressed their continued interest a national joint registry and suggested that the next steps would be to establish work groups to plan a pilot project and to explore the legal and governance issues in greater detail.

CMS indicated that they were supportive and willing to play active roles. NIAMS voiced interest in research aspects. The FDA stated that they were interested, but not necessarily ready for an active role. Industry representative voiced interest, but lack of support in the overall concept. They expressed the concern that industry cooperation would be difficult.

CLOSING REMARKS

The Workshop brought together stakeholders in government, industry, and orthopaedics for a positive dialogue regarding the development of a national joint registry. The ultimate feasibility of a national joint registry in the U.S., however, remains a subject for further exploration. The parties most likely to participate actively with AAOS in the future were identified, as well as some who would play a lesser role. Legal, liability and confidentiality issues were identified and addressed. Strategies were provided to reduce legal and regulatory risks. Existing domestic and foreign registries were examined. Models for effective medical specialty-government collaborations were presented. Sources of data for the registry were explored. The usefulness of existing Medicare data and forms were clarified. AAOS expressed its interest in moving forward with a pilot project and answering many of the remaining questions.

Remaining Questions

- What are the mission and goals of the registry?
- Who will have authority over the registry?
- How will it be structured, managed and staffed?
- How much will it cost?
- How will it be funded?
- Where will it be housed?
- How will the data be collected?
- Who will have access to the data?
- What is the incentive for joint surgeons and hospitals to participate?
- How will the implant be described in collection efforts?

II. Total Joint Registry Workshop Synopsis

Workshop Objectives

- Identify and address critical issues in the planning, development, implementation, and management of a national joint registry
- Identify and address important questions such as:
 - How will it improve patient outcomes?
 - How will it improve patient safety and reduce medical errors?
 - Will it be cost-effective?
 - Will it reduce Medicare costs?
 - How will it be financed?
 - Who will own and manage it?
 - How will it be used to further research?
 - How will it improve access to care for under-served populations?
- Identify and address challenges unique to the U.S., including legal issues, funding issues, and privacy issues
- Examine the purpose and achievements of domestic and foreign registries for their applicability to a U.S. model
- Identify and address key issues regarding contents of the database, data collection, data management, and access to data
- Clarify important perspectives on a national registry: Payer, Scientist, Physician, Manufacturer
- Identify ways in which interested parties can participate and become stakeholders

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What did the Workshop achieve?

A positive dialogue took place between government, industry and orthopaedics regarding the development of a national joint registry. The program moved this initiative to the next phase in planning and clarified which agencies are most likely to participate actively with AAOS. Levels of interest were identified as follows:

- CMS: Supportive, willing to play active role.
- AHRQ: Supportive, willing to play active role.
- NIAMS: Interested in the research questions; wants to take part.
- FDA: an “interested bystander”
- INDUSTRY: interested, but not supportive of the concept; “bruised and scared” by impact of recent implant recalls; believes cooperation will be difficult.

The liability and confidentiality issues were addressed and identified. Strategies were provided to reduce legal and regulatory risks.

Experiences with the Swedish and Ontario Registries were shared; their interest in assisting was made clear. Existing domestic models (renal dialysis, cardiac by-pass) were identified by CMS, reflecting effective medical specialty-government collaborations. It was learned that it might take years to establish a registry. There is extensive lag time between the proposal phase and implementation of a national registry. (Ontario, Renal required 6+ years).

Usefulness of existing Medicare data and forms were clarified. Most of the data needed is being collected through Medicare records and could provide the basic information desired. The key elements missing are laterality and description of implant. Laterality could be addressed through a CPT code change. Description of the implant may be more difficult to capture. The Medicare form is full; the collection system is antiquated, per CMS.

Overall, most participants agreed that a national total joint replacement registry was feasible. They endorsed getting started immediately taking a simple approach as the best way.

What specific questions remain?

- What are the mission and goals of the registry?
- Who will have authority over the registry?
- How it will be structured, managed, and staffed?
- How much it will cost?
- How it will be funded?
- Where it will be housed?
- How the data will be collected?
- Who will have access to the data?
- What the incentive will be for participation on the part of joint surgeons and hospitals?
- How the implant will be described in collection efforts (part, lot, family, company)?

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Where do we go from here?

AAOS will maintain dialogue with interested parties including AHRQ, CMS, NIH, FDA, and industry. AAOS will develop several task forces, which will include representatives from these agencies as well as foreign and domestic registries. One task force will further examine governance, legal, and policy issues. The second task force will develop a pilot registry project.

III. Total Joint Registry Workshop Agenda

Day 1: Monday, December 10, 2001	
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9:00 AM Registration

9:30 AM Breakfast Meeting

Welcoming Remarks

*John Eisenberg, MD, Director
Agency for Healthcare Research and Quality*

*William J. Maloney, MD, Chair
Osteoarthritis Registry Task Force
American Academy of Orthopaedic Surgeons*

I. Clinical Economics of Total Joint Replacement and Cost Savings Associated with Decreasing Revision Burden

Moderator: Daniel J. Berry, MD

9:45 AM Overview of Arthritis and Total Joint Replacement
*James Weinstein, DO, MS, Director
Surgical Outcomes Assessment Program at the
Center for the Evaluative Clinical Sciences
Dartmouth Medical School*

10:05 AM Volume Effect on Outcome in Total Hip Replacement
*Jeffrey N. Katz, MD, Director
Health Services Research
Robert Brigham Arthritis Research Center
Brigham and Women's Hospital*

10:25 AM CMS Perspective: Costs, Numbers, Types of Medicare Surgeries
*Steve H. Sheingold, PhD, Director
Div. of Operations and Committee Management
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services*

10:45 AM Hospital Perspective: Economics of Performing Revision Surgery
*Robert Barrack, MD, Director
Adult Reconstructive Surgery
Tulane University Medical School*

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11:00-11:20 AM Question and Answer Session

11:20 – 11:35 AM Break

II. Opportunity for Improvement: Clinical and Scientific

Moderator: Harry Rubash, MD

11:35 AM Overview of Domestic Registries: The Mayo Clinic Experience
Bernard F. Morrey, MD, Emeritus Chairman & Professor
Dept. of Orthopaedics
Mayo Clinic

11:55 AM Overview of International Registries: The Swedish Experience
Henrik Malchau, MD
Dept. of Orthopaedic Surgery
Sahlgrenska University Hospital

12:15 – 1:00 PM Lunch

A. Patient Perspective

Moderator: Harry Rubash, MD

1:00 PM How We Currently Monitor Safety and the MDR System
Susan N. Gardner, PhD, Acting Director
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
Food and Drug Administration

1:15 PM The Agencies' Roles in Promoting Patient Safety
Carolyn Clancy, MD, Director
Center for Outcomes and Effectiveness Research
Agency for Healthcare Research and Quality

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1:30 – 2:10 PM

Patient Perspective Panel

This panel discussion features experts in orthopaedics and policy makers from governmental agencies who will explore topics relevant to the public safety and welfare that may result from a national registry including systematic monitoring of patient outcomes, medical errors, quality of care, and the underutilization of total joint replacement by minority groups.

Robert Barrack, MD
Tulane University

Carolyn Clancy, MD
Agency for Healthcare Research and Quality

Richard Coutts, MD
University of California, San Diego

Roy Crowninshield, PhD
Zimmer, Inc.

Susan N. Gardner, PhD
Food and Drug Administration

A Seth Greenwald, DPhil (Oxon)
Lutheran Hospital

2:10 – 2:25 PM

Question and Answer Session

B. Physician Perspective

Moderator: John J. Callaghan, MD

2:25 PM

Dissemination of Information in Orthopaedic Surgery
Susan Adolph, Managing Director
Ontario Joint Replacement Registry

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2:40 – 3:25 PM

Physician Perspective Panel:

This panel will explore how a national registry may affect clinical practice including the development of standardized guidelines and assessment tools.

Daniel Berry, MD
Mayo Clinic

Miguel E. Cabanela, MD
Mayo Clinic

Charles A. Engh, MD
Anderson Orthopaedic Clinic

Bernard Stulberg, MD
Cleveland Orthopedic and Spine Hospital

Vernon Tolo, MD
Childrens Hospital Los Angeles

3:25 – 3:40 PM

Question and Answer Session

3:40 – 4:00 PM

Break

C. Scientist Perspective

Moderator: Charles A. Engh, MD

4:00 PM

The Registry as a Research Tool

Henrik Malchau, MD
Dept. Orthopaedic Surgery
Sahlgrenska University Hospital

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4:15 – 5:00 PM **Scientist Perspective Panel:**
This panel discussion will bring together researchers to discuss how a national registry could provide information that individual studies or smaller registries cannot provide (e.g., longitudinal studies, generalizability of results, and risk factors information).

John J. Callaghan, MD
University of Iowa

A. Seth Greenwald, DPhil (Oxon)
Lutheran Hospital

Jack Lemons, PhD
University of Alabama, Birmingham

Merrill Ritter, MD
Center for Hip and Knee Surgery

Timothy M. Wright, PhD
The Hospital for Special Surgery

5:00 – 5:15 PM Question and Answer Session

6:00 – 7:00 PM Reception

7:00 – 10:00 PM Dinner

Day 2: Tuesday, December 11, 2001	
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8:00 AM Registration

8:00 AM Breakfast

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Day 2: Tuesday, December 11, 2001(cont'd)	
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III. Overview of Legal Issues

Moderator: John J. Callaghan, MD

Legal Perspective

8:20 AM

Confidentiality and Liability Issues

Lynn Fleisher, PhD, JD
Sidley Austin Brown & Wood

9:00 – 9:40 AM

Legal Perspective Panel:

This panel will discuss a) the confidentiality and privacy concerns of patients, doctors, and hospitals as well as explore various options to protect privacy including Certificates of Confidentiality, PRO projects, and Demonstration projects; b) liability concerns associated with a national registry especially as they relate to device manufacturers. This will include an exploration of benefits (e.g., early alert for device failure, collaboration with hospitals, government and doctors) and challenges of possible litigation given the current legal system.

Miguel E. Cabanela, MD
Mayo Clinic

Carolyn Clancy, MD
Agency for Healthcare Research and Quality

Lynn Fleisher, PhD, JD
Sidley Austin Brown & Wood

James Herndon, MD
Partners Healthcare System

Jack Parr, PhD
Wright Medical Technology, Inc.

9:40 – 9:55 AM

Question and Answer Session

9:55 – 10:05 AM

Break

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IV. Operations and Governance of a National Registry

A. Data Management and Access

Moderator: Richard Coutts, MD

- 10:05 AM Data Currently Available in the Medicare Database
Nizar Mahomed, MD, Scientist
Div. of Outcomes & Population Health
Toronto Western Research Institute
- 10:20 AM What Data do We Need
John J. Callaghan, MD, Chair
Orthopaedic Surgery
University of Iowa
- 10:35 – 11:15 AM Data Management and Access Panel:
This panel will explore data management issues including what data to collect, how the data will be handled, who will have access to the data, and what are the rules for dissemination of data and results.
- Carolyn Clancy, MD*
Agency for Healthcare Research and Quality
- Lynn Fleisher, PhD, JD*
Sidley Austin Brown & Wood
- Jeffrey L. Kang, MD, MPH*
Centers for Medicare and Medicaid Services
- Dane Miller, PhD*
Biomet, Inc.
- Merrill A. Ritter, MD*
Center for Hip and Knee Surgery
- 11:15 – 11:30 AM Question and Answer Session
- 11:30 AM – 12:15 PM Lunch

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B. Governance

Moderator: William J. Maloney, MD

12:15 PM

Ontario Joint Replacement Registry
Susan Adolph, Managing Director
Ontario Joint Replacement Registry

12:30 PM

Swedish Joint Replacement Registry
Henrik Malchau, MD
Dept. Orthopaedic Surgery
Sahlgrenska University Hospital

12:45 PM

The Outcome of the Dialysis Registry
Josephine Briggs, MD, Division Director
Kidney, Urologic & Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases

1:00 – 1:45 PM

Governance Panel:
This panel will discuss the most effective way to oversee a nationwide registry.

Josephine Briggs, MD
National Institute of Diabetes and Digestive and Kidney Diseases

John J. Callaghan, MD
University of Iowa

Carolyn Clancy, MD
Agency for Healthcare Research and Quality

Tom Craig
Smith & Nephew, Inc.

Lynn Fleisher, PhD, JD
Sidley Austin Brown & Wood

Jeffrey L. Kang, MD, MPH
Centers for Medicare and Medicaid Services

Total Joint Registry Workshop
AHRQ/AAOS
December 10-11, 2001

Day 2: Tuesday, December 11, 2001	
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Anita M. Rayner, MPH
Food and Drug Administration

1:45 – 2:00 PM Question and Answer Session

V. Next Steps

Moderator: William J. Maloney, MD

Next Steps

2:00 – 2:45 PM Next Steps Panel:
This panel will discuss the implementation plan and timeline that would be necessary to develop a national registry.

John J. Callaghan, MD
University of Iowa

Carolyn Clancy, MD
Agency for Healthcare Research and Quality

Jeffrey L. Kang, MD, MPH
Centers for Medicare and Medicaid Services

2:45 – 3:00 PM Question and Answer Session

3:00 PM Meeting Adjourns

IV. Total Joint Registry Workshop Evaluation

Total Joint Registry Workshop Evaluation Results

AAOS Department of Research and Scientific Affairs obtained feedback on the success of the AHRQ/AAOS Total Joint Registry (TJR) Workshop in achieving its goals and objectives by developing a survey, which was distributed to all participants attending December 10-11, 2001. Thirteen of the 50 (non-staff) participants completed questionnaires, for a response rate of 26%.

Evaluation Method

The questionnaire asked participants to rate each of the eight panels on how satisfied he or she was in terms of quality, representativeness, and organization components of each panel; how much they agreed with the depth and breadth of each panel's discussion; and how well the workshop addressed the specific objectives that were planned for the workshop.

Evaluation Results

Participants rated all panels with a high level of satisfaction. Specifically, participant satisfaction with the panel on Data Management and Access was always ranked among the top two panels while the panel on Legal Issues was always ranked among the lowest two panels. Additionally, participants strongly agreed with statements that all panels addressed core issues, encompassed multiple viewpoints, and allowed the opportunity to voice concerns. Finally, participants reported the workshop best met the objective of identifying and addressing the critical issues regarding the planning and implementing of a national joint registry but least met the objective of answering questions about the cost effectiveness of a national joint registry.

Areas for Improvement

Participants comments included the request for more “actual patients” in the Patient Perspective Panel, the legal presentation was viewed as “too broad and should have focused on major issues”, and more industry participation would have been valuable.