

A. Rotator Cuff Repair in the U. S. Adult Population Rationale and Supporting Evidence

Between 1998 and 2004, over 5 million physician visits were attributed to rotator cuff problems¹, an increase of nearly forty percent in the given time period. Research has indicated that the incidence of rotator cuff damage increases with age due to degeneration of the tendon^{5,6} suggesting that as the current population ages, rotator cuff repair will also increase. The overall complication rate of rotator cuff surgery is about ten percent³ and the costs per patient for rotator cuff repair in the United States averaged \$17,427 in 2004; an increase of over 50% since 1998.² The number of hospitalizations for rotator cuff repair procedures however, has decreased by almost 27% to 32,066 as less invasive outpatient surgical techniques have evolved.^{2,4}

The true incidence and prevalence of rotator cuff tears are difficult to determine in the general population because a tear can cause significant disability or little or no pain in afflicted persons. Per the American Academy of Orthopaedic Surgeons, 5-40 percent of people without shoulder pain may have a torn rotator cuff.³ These tears will progress in 40% of these patients, and there will be an enlargement of the tear within a five-year period.⁵ Twenty-percent of these patients will experience no pain, while 80% percent will.⁵

Treatment of symptomatic rotator cuff tears varies from non-operative to operative. Ruotolo and Nottage (2002) reported that operative repair has consistently shown a higher rate of pain relief in patients and better return of strength than non-operative treatment at long-term follow-up. In order to improve the quality of rotator cuff repair outcomes surgeons must be able to assess whether there is a correlation between operative outcome and intactness of the repair.

Treatment could be greatly improved and costs could be significantly reduced if physicians could tailor treatment techniques to the patient characteristics and severity of the rotator cuff tear identified. Treatment could also be improved if the factors that convert an asymptomatic rotator cuff tear into a symptomatic tear that requires surgery were identified. In those who are symptomatic, a rotator cuff tear can be disabling, but prompt accurate diagnoses coupled with effective treatment can profoundly improve outcomes.

B. Rotator Cuff Repair in U. S. Adults Questions to be Addressed

1. Is there a relationship between operative surgical approach (Open, Mini-open and all arthroscopic) and the patient's rate of healing (or intactness of the repair) for small, medium, large and massive tears (repairs)?

2. Is there a difference between non-operative and surgical options and the patients' rate of healing (or intactness of the repair) for partial and full-thickness rotator cuff tears (repairs)?
3. What is the relationship between patient surgical outcomes and the patient's rate of tissue healing (intactness of the repair)? i.e. is there a clinically important improvement in patients' symptoms with complete healing of the repair?
4. Is there a correlation between surgical option (surgical repair or surgical debridement) and patients' outcomes when repairing massive rotator cuff tears with muscle atrophy?
5. Is there a correlation between rotator cuff muscle belly changes (both pre-operative and post-operative) of atrophy and fatty infiltration and patient rate of healing (or intactness of the repair)? Functional status?

C. Plans for rapid translation of the evidence reports and technology assessments into clinical guidelines, performance measures, educational programs or other strategies for strengthening the quality of health care services, or plans to inform development of reimbursement or coverage policies.

To improve the quality of care and reduce disparities, many organizations, including the AAOS, have turned to the development of evidence-based clinical practice guidelines. Indeed, AAOS has been actively involved in the development of clinical practice guidelines since the mid-1990s, and that commitment to quality, evidence-based guideline development continues to this day.

In October 2004, the AAOS formally adopted the position that evidence-based practice guidelines should be developed and used in the care of orthopaedic patients. In 2006, AAOS embarked upon a comprehensive multiyear plan to develop evidence-based clinical practice guidelines according to a rigorous, transparent evidence-based methodology. *AAOS greatly appreciates the fact that AHRQ has already recognized our ongoing work in evidence-based clinical practice guidelines by providing us with a systematic evidence review on Knee Osteoarthritis in 2006-07.*

Thus far, AAOS has already completed two new guidelines according to our new rigorous development methodology. These two guidelines cover the topics of **Carpal Tunnel Syndrome Diagnosis** and **Pulmonary Embolism Prophylaxis in Orthopaedic Surgery**. These two guidelines will be released to the public in Summer 2007. The AAOS is continuing its aggressive plan to develop and publish evidence-based clinical practice guidelines based on rigorous systematic evidence

reviews, with the goal of completing additional guidelines in 2007 on **Knee Osteoarthritis** (based upon the systematic evidence review conducted by AHRQ in 2006-2007), **Acute Low Back Pain**, and **Carpal Tunnel Syndrome Treatment**. *Should AHRQ elect to select one or more of our proposed topics for systematic review, the resulting evidence would serve as a basis for a portion of the AAOS guidelines to be completed in 2008.*

AAOS plans to continue its aggressive initiative to develop and publish evidence-based clinical practice guidelines on an ongoing basis over the next several years. The core reasons behind this initiative are threefold:

- 1) Current disparities in the quality of medical care in the United States, as documented by the Institute of Medicine's book *Crossing the Quality Chasm* and other reports;
- 2) The current shift towards a pay-for-performance model for medical reimbursement; and
- 3) The demands and expectations of the AAOS member physicians who recognize the importance of this initiative.

Impact of Evidence-Based Guidelines on Orthopaedic Practice

The foundation for the best practice of medicine evolves from the published, peer-reviewed evidence. Yet the sheer volume of this information presents a significant barrier to the practicing surgeon. A recently published article indicated that 26,945 research papers were published between 1991 and 2000 in the top 7 peer-reviewed medical journals alone. Obviously, no one individual can keep pace with all that is being published. Evidence-based practice guidelines serve to assist the practicing orthopaedic surgeon in their quest to improve patient care by consolidating the relevant evidence, and indicating the strength of the recommendations for treatment options. AAOS would use any systematic evidence review conducted by the AHRQ's Evidence-Based Practice Centers to support and augment our ongoing efforts to develop useful evidence-based guidelines and performance measures for orthopaedics. Because AAOS' capacity for conducting systematic evidence reviews of its own is limited, AHRQ's provision of systematic reviews beyond our own capabilities will allow us to develop more evidence-based guidelines and performance measures (and on a more rapid timeline) than we could do alone.

Following is a brief summary of the AAOS' current work plan for developing and supporting evidence-based practice guidelines and performance measures, in which AHRQ's services could serve as a means for program expansion and increased efficiency.

Guideline and Performance Measure Development via the AAOS Evidence Analysis Workgroups

Guideline and performance measure development at the AAOS is conducted via subspecialty-focused evidence analysis workgroups of 5-8 volunteer physicians each (supported by relevant AAOS staff), who provide a balanced combination of knowledge of systematic evidence-based analysis and (where needed) expert clinical opinion. All guideline workgroup members are required to complete a minimum of 8 hours of CME training programs in evidence-based medicine and evidence-based analysis, courses which AAOS provides to its members free of charge.

Guideline Development Process

The volunteer physician workgroup works with AAOS staff and/or contracted vendors to form a list of Key Questions from which to frame literature searches on the chosen guideline topic. AAOS staff and/or contracted vendors then conduct systematic evidence reviews (or in lieu of AAOS staff/contractors, AHRQ will conduct systematic evidence reviews for the above-proposed topics.) Once the systematic review is complete, the volunteer workgroup and appropriate staff review the literature/evidence tables and make clinical recommendations based on the literature's findings. The recommendations are then compiled and formatted into the AAOS' standardized, evidence-based, and transparent Guideline Template. The draft guideline is then circulated to the AAOS Guidelines Oversight Committee and AAOS Evidence-Based Practice Committee for review and comment from a methodological perspective. Once the final draft is complete, it is sent for review/endorsement by the AAOS Board of Directors, then released to the public.

The AAOS Guidelines Oversight Committee (a committee of 15 volunteer orthopaedists with expertise in policymaking, evidence-based practice, and physician reimbursement), in partnership with the AAOS Evidence-Based Practice Committee (a committee of 10 volunteer orthopaedists with expertise in evidence-based medicine and analysis) provides direct oversight to the various anatomical evidence analysis workgroups and the overall guideline development process. AAOS plans to support evidence analysis workgroups on 12-18 topics over the next 3-5 years. Currently, AAOS guideline workgroups are working on the following topics according to the above-described process:

- Knee Osteoarthritis (using AHRQ's 2006-07 systematic review)
- Acute Low Back Pain
- Carpal Tunnel Syndrome Diagnosis

How AHRQ Can Help

AHRQ's provision of additional systematic evidence reviews on the topics of rotator cuff repair and hip fracture treatment will allow the AAOS to develop evidence-based guideline/performance measure sets far more rapidly (i.e., in 3-6 months) and at a much-reduced cost than via our regular internal process. Due to the high burdens of disease and cost for these conditions, the AHRQ's assistance is necessary to assist the AAOS in serving the needs of orthopaedists and their patients. The exigency for

rapid turnarounds in guideline development is an issue AAOS and other medical specialty societies must address, as efforts by industry, insurance companies and the Centers for Medicare and Medicaid Services (CMS) to develop performance measures continues to grow. Patients, practitioners, and healthcare in general will benefit from a cooperative approach to the development of measures, yielding meaningful outcomes. In order for physicians and their professional organizations to participate, programs that assist with the production of evidence reviews are imperative.

D. Plans for use and/or dissemination of these derivative products, e.g., to organization memberships, if appropriate.

The AAOS has been heavily involved in guidelines production in the past through the efforts of its physician committees, as well as a cadre of physicians who have been trained by the AAOS in evidence analysis. Previously, these groups have developed treatment guidelines that were later published on the AAOS web site and in the National Guidelines Clearinghouse (NGC) for use by our members, insurance companies, government entities, and the public. The AAOS will continue to maximize these and other emerging outlets for dissemination of guidelines and performance measure products, including the National Quality Forum's endorsement and dissemination process for evidence-based performance measures. AAOS also occupies a seat on the Executive Committee for the American Medical Association's Physician Consortium for Performance Improvement, a multi-specialty organization dedicated to developing physician-focused performance measures; the AAOS has been active in bringing its completed guidelines to the Consortium for use in performance-measure development.

The AAOS is also developing plans to use its evidence-based guideline/performance measure products to create utilization review guidelines for sale to private health insurers, which will facilitate the wider dissemination of evidence-based orthopaedic practice while providing a means for the AAOS to defray some of the costs of developing guidelines.

E. Process by which the nominating organization will measure the use of these products and impact of such use.

The AAOS will monitor and measure the use and impact of its evidence-based analysis guidelines and performance measures as follows:

- 1) The **National Guidelines Clearinghouse** and the **National Quality Measures Clearinghouse** provide annual viewing and download statistics to the publishers of all the guidelines/performance measures registered with their sites. The AAOS monitors these statistics closely as one means of measuring the usage impact of its guidelines products.
- 2) The **National Quality Forum (NQF)**'s performance measure endorsement

process provides a means for vetting evidence-based performance measures by a large, national group of healthcare providers, payers, researchers, and consumers. NQF's endorsement of a performance measure usually results in its widespread adoption and implementation by both public and private payers, and subsequently, healthcare providers.

- 3) In addition to the above national programs in which the AAOS participates, the AAOS conducts regular surveys of its members on various aspects of their orthopaedic practice. The AAOS therefore has the capacity to survey its members on the usage impact the AAOS' published guidelines and performance measures have on our members' orthopaedic practices.

References

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