A. Treatment of Primary and Secondary Osteoarthritis of the Knee

Osteoarthritis (OA), also known as degenerative joint disease, is the most common form of arthritis, and a leading cause of disablilty worldwide. The incidence of OA increases with age, and disproportionately affects women. Osteoarthritis of the knee (OA Knee) is one of the five leading causes of physical disability in non-institutionalized elderly[1] men and women.[2] OA Knee, along with osteoarthritis of the hip, affects the ability to walk and climb stairs more than any other disease. The risk for disability attributable to OA Knee is as great as that attributable to cardiovascular disease, and greater than that due to any other medical condition in elderly persons.[3,4]

Osteoarthritis is a condition with a long history, and has been identified in both ancient and modern animals and humans.[5] Until the 1980s, OA was considered a primarily degenerative disorder and a natural occurrence of "wear-and-tear" on joints as a result of aging. Recent research evidence is changing this view, as knowledge increases regarding the pathogenesis and natural history of OA, particularly the metabolically active role of the disease and the process of remodeling and repair of damaged tissue. Current thinking is that it may be possible to arrest the progress of, and potentially even reverse, the disease.[5]

The primary effect of OA is pain that can lead to disability. The cause of the pain is generally due to an inflammation or joint incongruity, but the reasons for differing pain levels by individual patients with similar conditions is still unknown. Because some patients with radiographic OA exhibit few symptoms, the psychosocial impact of the disease, its associated pain, and disability may be underestimated in the general population.[6,7]

Numerous sources give estimates of the prevalence of arthritis, osteoarthritis and OA Knee. Within the United States, prevalence estimates are usually based on annual national healthcare databases. Prevalence estimates of arthritis range from as low as 6% of the adult[8] population in the US to as high as 90% of the population over age 40.[9] "Osteoarthritis of the Knee: Cost and Burden of the Condition," the American Academy of Orthopaedic Surgeons' (AAOS) companion piece to "Improving Musculoskeletal Care in America", highlights some of the national statistics for OA Knee. However, it is difficult to make actual estimates of the prevalence and incidence of the disease, as well as its impact on ability to function in daily life and psychosocial factors/considerations to the individual, because there is no definite and universally applicable criteria for the osteoarthritis. In addition, there is often no correlation between symptoms and clinical signs of OA Knee and the presence of radiographic signs of OA.[10]

Osteoarthritis of the knee usually occurs in knees, a weight-bearing joint, that have experienced trauma, infection or injury, and results from deterioration or loss of the articular cartilage, a smooth slippery fibrous connective tissue that acts as a protective cushion between bones. This loss of cartilage usually results in a narrowing of the joint space, an early detectable radiographic symptom of OA Knee. As the disease progresses, the cartilage thins, becomes fissured (grooved) and fragmented, while the surrounding bones react by becoming thicker, growing outward and forming spurs. Additionally, the synovium, a membrane that produces a thick fluid (synovial fluid) that helps nourish the cartilage and keep it slippery, becomes inflamed and thickens. The synovium may produce extra fluid, often known as "water on the knee," that causes additional swelling.

A joint affected with OA attempts to repair itself, and nonweightbearing joints, such as a finger, may slow down the process. However, in OA Knee, the repair process is usually unsuccessful, and over a period of years, the joint slowly changes. In severe cases, the cartilage may no longer cover the thickened bone ends, resulting in rubbing and wearing away of the bone. Deformity of the joint may occur, and normal activity becomes painful and difficult.

Although OA is often considered a disease associated with aging, the OA joint and the aging joint exhibit several notable and important differences.[5] Fibrillation (fine, rapid contractions or twisting of fibers or small groups of fibers) in chronologically aged cartilage occurs on nonweightbearing surfaces, while OA is primarily in weightbearing joints. The biological changes in the cell that occur with OA result in evident physical, chemical, synthetic, and degradative changes, while the aging joint does not reflect these changes. The water content in cartilage of the aging joint does not change signficantly, while the water content of cartilage in joints affected by OA increases early in the process. The subchondral (below the cartilage) bone changes associated with OA are not seen in the aging joint.

OA Knee can be diagnosed by either patient reported symptoms (pain, disability) or pathology (physical changes observed through radiographs). However, diagnosis of the disease is confounded because many subjects show radiographic OA Knee, but report few symptoms.[4,6,11] From a clinical perspective, the most compelling definition of OA Knee is one that combines the pathology of osteoarthritis (confirming radiographs) with the pain that occurs with joint use (patient reported symptom s).

Pain, instability, impairment, and disability are all problems associated with the OA Knee. Initial treatment is generally directed at pain management. It is generally accepted that pain in the OA Knee is likely to be heterogeneous, with different causes predominating in different individuals or at different phases of the disease.[7] Thus, treatment of OA pain is tailored to the individual and not consistent across the disease. To this end, the American Academy of Orthopaedic Surgeons would like to work with AHRQ to develop the evidence base for three treatments for OA Knee: intra-articular hyaluronic acid/hyaluron preparation injections, arthroscopy, and cartilage repair procedures.

B. Treatment of Primary and Secondary Osteoarthritis of the Knee

1. What is the effectiveness of intra-articular hyaluronic acid/hyaluron preparations injections, arthroscopy, and cartilage repair procedures in patients with primary OA of the knee?
2. What is the effectiveness of intra-articular hyaluronic acid/hyaluron preparations injections, arthroscopy, and cartilage repair procedures in patients with secondary OA of the knee?
3. How do the short-term and long-term outcomes of intra-articular hyaluronic acid/hyaluron preparations injections, arthroscopy, and cartilage repair procedures compare for the treatment of primary OA of the knee?
4. How do the short-term and long-term outcomes of intra-articular hyaluronic acid/hyaluron preparations injections, arthroscopy, and cartilage repair procedures compare for the treatment of secondary OA of the knee?

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.

Driven to improve the quality of care and reduce disparities, many organizations, including the AAOS, have turned to the development of clinical practice guidelines. 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. Accordingly, the AAOS has developed the following plan for aggressively developing and supporting evidence-based orthopaedic guidelines and performance measures over the next three to five 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 clinical 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 somewhat limited, the AHRQ's provision of systematic reviews beyond our own capabilities will allow AAOS to develop more evidence-based guidelines and performance measures on a more rapid timeline than the organization 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 staff), who provide a combination of expert opinion and knowledge of evidence-based analysis via the CME training programs AAOS provides for its members.

The AAOS Evidence-Based Practice Committee (a committee of 10 volunteer orthopaedists with expertise in evidence-based medicine) provides oversight to the various anatomical evidence analysis workgroups. AAOS plans to support evidence analysis workgroups on 12-18 topics over the next 3-5 years. These workgroups include:

- Shoulder and elbow pain
- Hand and wrist pain
- Low back pain

- Hip pain
- Knee pain
- Knee injury
- Ankle injury

Each workgroup will conduct evidence analyses to support the guidelines/performance measures that are produced.

How AHRQ Can Help AHRQ's provision of additional systematic evidence reviews on the topics of DVT prophylaxis in patients following total hip and knee arthroplasty and treatment options for osteoarthritis of the knee will allow the AAOS to develop evidence-based guideline/performance measure sets far more rapidly (i.e., in 6 months to 1 year). 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 Clearing House (NGHC) 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. The AAOS is 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, payors, researchers, and consumers. NQF's endorsement of a performance measure usually results in its widespread adoption and implementation by both public and private payors, 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.

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1 US Census of the Population: Non-institutionalized population excludes persons living in group quarters within correctional institutions, nursing homes, and other institutions. It includes persons living in college dormitories, military quarters, and other non-institutional group quarters.

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