## Methods to develop arthritis and osteoporosis measures: a view from the National Committee for Quality Assurance (NCQA)

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## ABSTRACT

**Objective**. Performance measurement at various levels of the health care system promotes improved processes that can result in the provision of more consistent and effective care. This chapter articulates the methodology and criteria utilized in measures development to ensure accountability and serve the information needs of physicians, health care systems, health plans and consumers, using arthritis and osteoporosis as example conditions.

Methods. Observational studies conducted to assess the validity and feasibility of performance measures focused on arthritis and osteoporosis. Clinical expert panels were convened to develop measure specifications based on guidelines and evidence supporting critical aspects of care. The aspects of care that were assessed included: DMARD utilization for patients with rheumatoid arthritis; appropriate gastrointestinal prophylaxis for patients utilizing NSAIDS; comprehensive osteoarthritis care; comprehensive symptom assessment and medical management of woman over 65 years who experienced a bone fracture.

**Results.** The implementation of performance measures for key aspects of arthritis and osteoporosis care is challenged by the availability of administrative data. However, potential for improvement is evident in each of the areas studied.

**Conclusions.** The key challenge to the feasibility of arthritis performance measures is the lack of administrative data to identify the eligible population. Administrative data capture suffers as a result of under-coding and under-recognition of arthritis. Consensus around a single set of measures creates a powerful tool for focusing on key components of care as a basis for quality improvement and allows for a valid comparison of care within and across health care settings.

## Introduction

Arthritis is one of the leading causes of disability in the United States, and effective interventions exist that can lead to improved quality of health care and potentially improve life for the millions of people with arthritis and osteoporosis. However, many patients continue to receive sub-optimal care. Performance measurement at various levels of the health care system promotes improved processes that may result in the provision of more consistent and effective care. However, no standard set of measures currently exists to assess the quality of arthritis care and bring effective care processes to the attention of health care providers, hospitals and health plans.

The quality of health care for millions of Americans has improved in most areas of care over the past seven years (1, 2)though somewhat disparately according to socioeconomic status, where gaps are widening. People enrolled in health plans that measure and publicly report performance data were more likely in recent years to receive preventive care and have their chronic conditions managed in accordance with clinical guidelines based upon medical evidence (4, 5). Due to the collective efforts of the health care system, a foundation for the systematic assessment of health care quality in this country now exists that was not present a decade ago. The rewards of this effort are substantial across the many dimensions of care being measured, as performance has trended steadily - and in some cases dramatically - upward.

Quality-assurance initiatives encourage adherence to evidence-based guidelines for the management of particular diseases and ensure that such adherence is monitored (3, 4). Defined, standardized performance measures are indicators that health care organizations can use to determine and demonstrate effectiveness at achieving results in virtually any aspect of health care delivery, from medical procedures and outcomes to administrative functions (6).

HEDIS®, previously the acronym for the "Healthplan Employer Data and Information Set" but more recently defined as the "Healthcare Effectiveness Data and Information Set", is a collection of standardized, reliable and valid performance measures designed to ensure that the public has the information it needs to accurately compare performance among health care plans and, more recently, at the physician practice level. HEDIS now includes more than 60 measures of clinical performance (such as screening for breast cancer) that address under-use, overuse and misuse. In the past year, the National Committee for Quality Assurance (NCQA) has also added six disease-specific measures of resource use which, when coupled with the related quality measures, can be used to examine efficiency.

Health care costs have continued to escalate rapidly over the past decade. Moreover, despite some improvement in quality as noted above, reports such as those from the Institute of Medicine (IOM) - e.g., "Crossing the Quality Chasm" - and research papers have documented that major gaps remain in quality (3-5). As costs have increased and concerns about quality have been raised, purchasers of health benefits, large corporations that purchase care on behalf of their employees, and the public and Medicare and Medicaid programs that purchase care on behalf of the senior and low-income populations, have become increasingly concerned that they are not receiving adequate value for the dollars spent on health care. As health benefits have consumed an ever-larger proportion of total expenses, purchasers have sought ways to assess the relative value of care offered by managed care health plans. HEDIS offers a means to make a valid and useful comparison of one health plan or physician practice against another.

Health care quality can be measured by assessing the intermediate or final outcomes of care provided to patients (*e.g.*, mortality, functional status, pain or blood pressure control) and/or by measuring the process or structures by which care is provided to patients (e.g., whether a practice has computerized order entry or if a patient with diabetes has received a yearly cholesterol measurement). For chronic diseases such as diabetes or arthritis, relevant health outcomes may take years to develop and waiting to assess outcomes may preclude timely interventions to improve quality and hence, outcomes. In contrast, processes of care can be measured continuously, allowing for the timely identification and correction of deficiencies (6). The defining question for all performance measurement - "Where can measurement make a difference?" - can be answered only after careful consideration of a number of factors. This chapter articulates the methodology and criteria utilized in measure development to ensure accountability and serve the information needs of physicians, health care systems, health plans and consumers. Arthritis and osteoporosis are used as example conditions.

## Measure development

The development of a performance measure for HEDIS involves multiple steps. A potential measure is refined and evaluated at several points in the process. NCQA's Committee on Performance Measurement (CPM), which includes representatives of purchasers, consumers, managed care organizations, providers and policy makers, assisted by NCQA staff, oversees the evolution of the measurement set. NCOA operates measurement advisory panels (MAPs) that provide the expert clinical and technical knowledge required to develop measures for particular clinical areas or specific populations. Additionally, NCQA has a Technical Advisory Group (TAG) and various other advisory panels such as pharmacy, coding and laboratory panels that provide invaluable assistance by providing input to and feedback on new measure specifications.

Three key steps in the development of new measures are: a) the creation of a Measurement Advisory Panel (MAP), b) the preparation of an initial measure work-up based on the existing literature and clinical guidelines, and c) field testing. Each step is described below. To support measure development activities, the staff conducts a thorough literature review. This process includes the review and synthesis of relevant clinical guidelines and peer-reviewed articles. This literature review fosters a greater understanding and allows the delineation of key criteria to evaluate performance measures. An essential feature of the measure development process is ensuring that prospective performance measures meet the desired criteria for evaluation.

NCQA has established criteria in three areas that must be met to ensure the success of a measure: relevance, scientific soundness, and feasibility.

The relevance criteria require that one or more audiences find the information produced from a measure useful for some purpose. This could be accomplished either through actions relating to selection and accountability or through changes in the delivery of care to improve performance. Measurement often focuses the providers' and the administrators' attention to the specific element of care or result being measured, so measures should be selected that are worthy of such focus. The degree of leverage is determined by the number of people who present or are at risk at each step in the care process, the demonstrated effectiveness of care or the expected results at that step in the process, and the current gap between actual and potential performance.

A measure is scientifically sound if it produces consistent and credible results when implemented. Much of the scientific acceptability of a measure can be determined through careful design and appropriate use. Considerable work is required to translate the conceptualization of a measure into an operational definition that can be implemented across a variety of settings. The elements of scientific soundness include: 1) precise specifications, 2) reliability, 3) validity, 4) adaptability, 5) adequacy of risk adjustment, and 6) inclusion of explicit conditions of use.

Measures must also be feasible to implement. An evaluation should take particular account of the way in which data can be obtained within the normal flow of clinical care (6).

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Field testing prospective measures provides valuable information on both scientific soundness and feasibility. The purpose of NCQA's field testing is to determine the feasibility of proposed measures for the HEDIS®. Prior to implementation, the specifications are tested in order to ensure the likelihood that the measures are valid and to identify any potential problems with their broad application. In addition, a field test offers the opportunity to gain perspective on the perceived importance and feasibility of the measure. The following components of field tests appear to be important: 1) the validity of the administrative algorithm in identifying a target population (denominator) based on the measurement period and continuous enrollment/exclusionary criteria; 2) the validity of administrative data in accurately capturing the diagnoses and the medical processes delivered (i.e., diagnostic tests, procedures, pharmacy) by comparing administrative results with data from a sample of medical records; 3) the feasibility of the measure specifications to identify the quality problem and to discriminate performance between health plans for public reporting; and 4) the reliability and feasibility of the measure specifications, so that all health plans or physicians can capture the required data elements and conduct programming.

# Developing measures for arthritis and osteoporosis

## Arthritis

From 2002 to 2004, NCQA worked on the development of measures relevant to patients with arthritis in two related collaborations and field test efforts. The first collaboration was with the Joint Commission on Accreditation of Healthcare Associations (JCAHO) and the American Medical Association (AMA) to develop nationally standardized performance measures relating to pain management that could be implemented across all levels of the health care delivery system (practitioners, provider organizations and health plans). The second collaboration was with the Arthritis Foundation on the development of clinical performance measures to assess care for important musculoskeletal conditions using arthritis indicators drawn from the Arthritis Foundation Quality Indicator Project (AFQuIP) indicator set (7).

Eleven measures were specified for field testing in provider offices, health plans and/or health care organizations. Out of the eleven measures identified by the Pain Management collaboration, only one was field tested at the health plan level – Comprehensive Arthritis Care: Symptom Assessment. The remainder were not tested because there was insufficient evidence to support implementation or because the burden of medical record review was not considered to be feasible in a health plan population.

The Arthritis Foundation collaboration identified four measures for testing from the AFQuIP set (7): 1) disease-modifying anti-rheumatic drug (DMARD) utilization for patients with rheumatoid arthritis (RA); 2) appropriate gastrointestinal prophylaxis for patients utilizing NSAIDS; 3) comprehensive arthritis care (*i.e.*, weight loss, physical activity and acetaminophen use); and 4) pain and functional assessment.

In an effort to minimize the field test site burden, while at the same time testing as many measures relating to pain management and arthritis as possible, NCQA ran two field test projects in parallel during the summer of 2003. The field test sites, described in Table I, were assigned to collect data under either the Pain Management or the Arthritis field test projects.

## Arthritis field test results

NCQA prepared a formal field test analysis report for each measure tested; an overview of the field test results can be found in Table II. Here we present high-level summaries for each of the measures, and recommendations regarding their potential deployment.

1. Comprehensive arthritis care: symptom assessment. The per-formance on this measure, which focused on whether patients with a diagnosis

Location	Approximate Number of Members	Products	Measures
West	> 2 million	Commercial, Medicare Advantage	• DMARD • Comprehensive Arthritis Care
Northeast	140,000	Commercial	• DMARD • Comprehensive Arthritis Care
Mid-Atlantic	200,000	Commercial, Medicaid	• DMARD
Mountainwest	500,000	Commercial	Arthritis Assessment
Northwest	420,000	Commercial, Medicare Advantage Choice, Medicaid	Arthritis Assessment
Midwest	200,000	Commercial, Medicare Advantage Medicaid	Arthritis Assessment

This table provides descriptive information (location, health plan size, products) and the measures that were tested by each plan. Commercial plans are those that privately insure members, typically employed adults, their spouses and other family dependents. Medicare Advantage and Medicaid plans are provided by government-sponsored organizations, typically Health Maintenance Organizations (HMOs). NCQA seeks plans of varying sizes and geographic distribution for the field tests.

### Table II.: Summary of arthritis field test results.

Measure Title	Plan Prevalence by Product / 1000 members			Performance MeasureRates (Total mean rates for all product lines combined)		
Comprehensive Arthritis Care: Symptom Assessment	Osteoarthritis	Commercial Medicare Advantage Medicaid	1.8 14.1 0.2			onal Assessment 56.1%
Medical record documentation of comprehensive pain assessment and assessment of function Health plan members, 18 years and	Rheumatoid Arthritis	Commercial Medicare Advantage Medicaid	1.4 7.3 0.2	77.0%	.0% 57.7%	
older with a diagnosis of arthritis (osteoarthritis OA, rheumatoid arthritis RA, inflammatory arthritis)	Other Inflammatory Arthritis	Commercial Medicare Advantage Medicaid	0.3 0.7 0.0	67.0% 55.39		55.3%
Comprehensive Osteoarthritis Care	Osteoarthritis of the Hip or Knee			Weight LossRecommended		48.4%
Documentation of: weight loss recommended, physical activity/ therapeutic exercise recommended, and acetaminophen recommended	Commercial		1.2	Physical Activity/Therapeutic Exercise Recommended		42.5%
Health plan members, 18 years and older with a diagnosis of osteoarthritis OA of the hip or knee	Medicare Advantage		16.5	Acetaminophen Recommended		15.1%
Disease Modifying Anti-Rheumatic Drug Therapy in Rheumatoid Arthritis		Rheu	thritis		1	
At least one ambulatory prescription dispensed for a DMARD	Commercial		1.0	66.7%		
Health plan members, 18 years and older with a diagnosis of rheumatoid	Medicare Advantage 5.4			76.5%		
arthritis	Medicaid 1.1		1.1	71.4%		
Appropriate Gastrointestinal Prophylaxis for Patients Utilizing NSAIDS	GI prophylaxis (eligible population criteria include: NSAID prescription, GI risk factor, age, continuous enrollment, and benefits)					
Documentation of assessments for the presence of GI complications, and if	Commercial		7.9	38.0%		
risk factors are present, medications prescribed to reduce the risk of serious GI complications	Medicare Advantage*		192.8		14.3%	
Health plan members, 18 years and older with a prescription for an NSAID	Medicaid			35.3%		

\*Note: Patients  $\geq$  65 years of age on NSAIDs were considered to be at high risk of GI complications. Because the majority of Medicare Advantage plan members were in this age group, they had a much higher population prevalence of GI prophylaxis.

of arthritis (osteoarthritis, rheumatoid arthritis, or other inflammatory arthritis) had documented pain and functional assessments, ranged from approximately 50-90% for the pain assessment to 50-60% for the functional assessment. There was variation in performance between the diagnoses included and the health plan product type (commercial, Medicaid, Medicare). The prevalence of osteoarthritis, as documented via outpatient claims, was extremely low and suggests both under-coding and under-recognition of the condition. Prevalence rates were approximately 0.18% consistently across plans, where the known prevalence is 15% and higher for adults (over 18 years).

The health plans participating in the field test indicated that they had some difficulty in determining whether the criteria for the components of the pain/functional assessment were met in the medical records. In addition, NCQA received feedback that it was difficult to determine what type of document would satisfy the standardized pain/functional assessment specification. Therefore, based on the field test results, feedback from the field test sites, and the significant burden of abstracting medical records, NCQA staff recommended that this measure not be included in HEDIS even though assessment of pain and functional status are key components of arthritis care,

2. Comprehensive osteoarthritis care. While the first measure focused on the broader arthritis population, this measure focused on osteoarthritis of the knee or hip, and assessed whether weight loss, exercise and acetaminophen were recommended as firstline therapies. Like the first measure, the prevalence of osteoarthritis of **Table III.** First year HEDIS results – 2006: disease-modifying anti-rheumatic drug therapy in rheumatoid arthritis.

Health plan type	Mean rate of RA patients receiving a DMARD	Nationwide variability*	Top state**
Commercial	80.9	19.6	New Hampshire (90.3)
Medicare Advantage	64.2	32.7	Missouri (71.8)
Medicaid	67.5	28.2	New York (72.4)

\*Undesirable variation in care is a critical area for improvement. Nationwide variability is the difference between the top percent and bottom percent of health plans for each measure.

\*\*The top-performing state on each measured aspect of care. This data provides insight into geographic variations in health care quality. Only states where five or more plans reported data were considered for inclusion.

the hip or knee captured by the field test sites was significantly lower than expected for the population, and the majority of those identified through administrative data were diagnosed with osteoarthritis of the knee. In addition, determining what recommendations had been made was far from simple as chart records were often incomplete or open to interpretation. This was a complicated measure that required calculation of the body mass index (BMI), as well as interpretation of the appropriate documentation regarding weight loss, exercise/physical activity, etc. Therefore, like the first measure, this one was not recommended for inclusion in HEDIS.

3. Disease-modifying anti-rheumatic drug (DMARD) therapy in rheumatoid arthritis. This measure assessed whether patients diagnosed with RA had had at least one ambulatory prescription dispensed for a DMARD. The NCQA advisory panel overseeing its development indicated that this reflected one of the essential components of RA management, and there was strong support for the implementation of this measure at the health plan level. Based on field test results, the potential for improvement seems to be low to moderate. The American College of Rheumatology Guidelines for Rheumatoid Arthritis Treatment recommend all that all patients diagnosed with RA be prescribed a DMARD (8); however, there are contraindications (e.g., pregnancy and immunosuppression) that may exclude a small number of patients.

The relatively low prevalence of RA

(approximately 1% in the general population, but increasing with age) challenges the meaningfulness and feasibility of this measure for smaller plans and for most smaller physician practices. The field test results indicated that the quality gap may not be as large as expected, and was significantly smaller than the gap detected by most first-time HEDIS measures. However, evidence from other studies suggests a substantial quality gap in prescribing DMARDs as an essential component of treatment for patients with RA. Therefore, this measure was approved for implementation in HEDIS 2006, and as such was published in July 2005. The first year of results was published in NCQA's State of Health Care Quality in September 2006 (2) (Table III). The results present the mean national aggregate rate by type of health plan (commercial, Medicare Advantage, Medicaid).

4. Appropriate gastrointestinal prophylaxis for patients utilizing NSAIDs. This measure recorded whether patients prescribed a non-steroidal anti-inflammatory drug (NSAID) were assessed for the presence of gastrointestinal complications and, if risk factors were present, whether medications to reduce the risk of serious gastrointestinal complications were prescribed. The pre-valence of NSAID prescriptions ranged from 12.1% in the commercial health plan population to 25.9% in the Medicare population. In the commercial health plan population, 65.5% of the NSAID prescriptions were for a nonselective NSAID (e.g., ibuprofen, naproxen), while in the Medicare population only 20.4% of the NSAID prescriptions were Cox-2-selective medications.

As specified, this measure relied on medical records to determine aspirin use, which decreases the GI protectiveness of Cox-2-selective NSAIDs. However, there was controversy about whether aspirin diminishes the effectiveness of Cox-2-selective NSAIDs. Prilosec (Omeprazole) was included in the measure specification as a GI prophylactic agent but is now available over the counter, which means that it would not be captured in the administrative data. In the field test, this medication comprised 18.9% of the total GI prophylaxis prescriptions. The measure looked for the first NSAID prescription, and then required plans to look for concurrent use of anticoagulants, a known risk factor for GI bleeding. The measure would not capture those members who start the use of anticoagulants after beginning NSAID therapy; thus, some of the atrisk population would be excluded. Based on the field test results and concerns raised about its ability to capture relevant data, this measure was not recommended for deployment. However, NCQA has since pursued measures focusing on drug safety in the Medicare Advantage population. In 2007, a measure entitled "Potentially Harmful Drug-Disease Interactions in the Elderly" was included in HEDIS as a firstyear measure, meaning that results will not be available until September 2007. One of the rates required for Medicare Advantage plans is the use of non-aspirin NSAIDS or Cox-2-selective NSAIDS in patients with chronic renal failure.

## Osteoporosis

NCQA began the development of a performance measure focusing on osteoporosis (OA) in 2001. Its development followed the methodology outlined above and the proposed measure was field tested in 2002. Following review by expert panels and the NCQA Committee on Performance Measurement,

"Osteoporosis Management in Women Who Had a Fracture" was approved for inclusion in HEDIS 2004 (published in July 2003). This measure estimates the percentage of women 67 years of age and older who suffered a fracture and who had either a bone mineral density test or prescription for a drug to treat or prevent osteoporosis in the 6 months after the date of the fracture. This is not a measure of fractures "caused" by osteoporosis, but rather uses the presence of any fracture as a "trigger" to look for underlying OA. The measure excludes women with fractures of the finger, toe, face or skull, and those who had prescriptions for preventive therapeutics in the 365 days prior to the fracture.

The measure is collected through pharmacy and claims data. 2004 was the first year of data collection and reporting based on treatment in 2003. In 2003, 114 Medicare Advantage health plans, with a mean Medicare enrollment of 32,113 members (18,628 females), submitted measure rates. Across the 114 Medicare Advantage plans, rates were uniformly low, although consistent with field test and other comparative published data. The mean measure rate was 18% ( $10^{th}$  percentile = 9.8%,  $90^{\text{th}}$  percentile = 26.4%). The eligible member population averaged over 800 women with fractures. However, on average more than 200 were excluded due to a recent history of osteoporosis treatment, leaving an average denominator of about 600. The denominator prevalence averaged 36 per 1000 enrolled women. In examining potential direct medical expense savings through the closure of quality gaps for the U.S. population, we estimate that sub-optimal osteoporosis care results in 2,100 subsequent fractures and \$7.2 million in avoidable costs for hospitalization and other related medical care. These costs and subsequent fractures could be avoided if all Americans received care through health plans performing at the 90th percentile for the measure - which still allows significant room for improvement. In subsequent years of reporting, the measure rates have improved slightly: for 2004 the mean was 19.0 and for 2005 the mean was 20.1.

## Conclusion

Using a well-developed and tested process, and the input of various multi-stakeholder panels, we have developed and tested a number of performance measures to advance improvement in arthritis and osteoporosis care. However, because of scientific soundness and feasibility issues with the measures, only two have been implemented at the national level. Arthritis is one of the leading causes of disability in the United States, yet no standard set of measures currently exists to weigh the quality of arthritis care and bring effective care processes to the attention of health care providers, hospitals and health plans. NCQA has embarked on projects to develop new clinical performance measures to assess the care of patients with arthritis. The key challenge to the feasibility of arthritis performance measures is the unreliability of most administrative data in identifying the eligible population and determining if the appropriate service was completed. Administrative data capture suffers from under-coding and under-recognition of arthritis. Developing measures that can be specified at the provider or provider group level could facilitate quality improvement in patient care; however, it is not known if such efforts would also improve diagnosis and coding to improve data capture. Even the use of chart review for areas such as counseling or recommending therapy poses substantial problems in our attempts to measure quality of care for persons with arthritis.

Morbidity and mortality related to osteoporotic fractures are a major health issue. In the US, 10 million people have osteoporosis and another 18 million are at risk for OA due to low bone mass (9). Of those with osteoporosis, 80% are women (10). Measure rates reported in HEDIS indicate that < 21% of female patients over 65 years of age who are not on treatment for osteoporosis and suffer a fracture receive follow-up care consistent with recommended guidelines. The majority of women with OA continue to receive less than optimal care, however, regardless of published clinical guidelines. The fact that women are not receiving appropriate osteoporosis care indicates there are thousands of preventable fractures in this population of women at risk.

Consensus around a single set of measures creates a powerful tool for focusing on key components of arthritis care as a basis for quality improvement, and allows for a valid comparison of care within and across health care settings. However, in the absence of reliable and available administrative data, quality improvement and performance measurement activities for arthritis might best be focused at the provider or provider group level. With the continued development of electronic data exchange, including laboratory and pharmacy data, as well as electronic medical records, there is hope that in the next ten years or so we will be able to develop and implement a much broader array of quality and resource use measures in the field of arthritis, which will allow us to fully characterize the value of care received.

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