

# Quality and Outcome Determination in Health Care and Orthopaedics: Evolution and Current Structure

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## Abstract

Quality health care has many definitions. Among those definitions is "care that consistently contributes to the improvement or maintenance of the quality and/or duration of life." The current evolution in health care has been fueled by three necessities frequently demanded by payers and employers: improvement in access, lowering of cost, and definition and quantification of the quality of care. This evolution has been facilitated by the so-called industrialization of medicine. This concept includes the adoption of industrial economic principles and techniques that facilitate the measurement of processes and outcomes. Quality health care is currently recognized as health care that is characterized by three elements: the use of practice guidelines or standards, the implementation of continuous quality improvement techniques, and the use of outcome determination and management. Practice guidelines demand the adoption of evidence-based principles in evaluation and care, as well as minimization of variations in evaluation and care. Continuous quality improvement seeks to determine why variations in processes of care occur and then to minimize those variations. Outcomes may be measured in terms of both very objective and very subjective variables and also on the basis of cost-efficiency. Most tools currently used to quantify outcomes, especially in orthopaedics, involve measurements of general health and of specific body part or organ system function. This evolution in health care is producing significant alterations in methods of traditional health-care delivery. The accumulating evidence indicates that these changes, although frequently unpopular, are improving the quality of health care.

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In orthopaedics, as in the rest of the health-care industry, there is currently a great deal of interest in, and activity related to, the definition and implementation of outcome measures. Many factors, including financial incentives instituted by payers, have led to this recent emphasis on outcomes. However, outcomes do not exist in a vacuum; they are only one aspect of the attribute of quality in health-care delivery. The need to measure outcomes is simply part

of an effort to quantify and then improve the quality of health care.<sup>1</sup>

The term "outcome" can have several meanings, depending on the setting in which it is used. This article describes the current status of the various determinants of quality and patient outcome in health care and orthopaedics by describing the evolution and relationship of its various components and considering implications for the future.

## Definitions

Quality determination in health care has many definitions. The American Medical Association defines quality care as "care which consistently contributes to the improvement or maintenance of the quality and/or the duration of life."<sup>2</sup> The operative word "consistently" suggests a process of care, which should be reproducible in every application and hints at the use of clinical guidelines.

Donabedian<sup>3</sup> defined quality health care as "that kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts." In that definition, the use of the term "measure

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of patient welfare” suggests the recent emphasis on subjective measures of outcome in addition to the traditional objective physician-determined outcome indicators.

Beyond definition, the determination of quality in health care has two aspects. The first is the technical aspect, which consists of applying the right method of care or the most appropriate surgical procedure to the patient’s condition in the most effective manner possible. This technical aspect is the object of clinical protocols and practice guidelines. The second aspect is the nature of the interaction between the patient and the provider, which consists of satisfying the patient’s expectations in regard to the problem for which he or she presented to the physician.<sup>1</sup> This subjective aspect of quality is the portion of the outcome measures that we are now attempting to quantify.

## **Recent Developments in the Evaluation of Quality Health Care**

Within the past two decades, many factors have caused health-care providers to focus on both quality determination and patient outcomes. With the recent evolution of managed care, three imperatives in health-care delivery have taken precedence: improved access,<sup>1</sup> lowered costs,<sup>4,5</sup> and improved quality.<sup>4</sup> As both patients and payers have perceived improvement in access and cost control, the focus has turned to quality. Its measurement in terms of quality and outcome determination is becoming an important factor used to differentiate among providers.<sup>6,7</sup> In addition, research in many medical specialties, including orthopaedics, has called into question some practices by our profession. It has influenced us to reevaluate what constitutes quality and how to most ef-

fectively measure the outcomes of our work.<sup>5,8-15</sup>

The rise of managed care organizations has demanded risk sharing by practitioners, which has necessitated a reevaluation of both the processes and the outcomes of health care. This economic mandate has forced us to consider both the efficacy and the efficiency of many treatment modalities. The demand for value necessitates measurement and, ultimately, accountability. Although these forces have had a less direct effect on orthopaedics as a surgical subspecialty, payers are beginning to demand that this accounting be done.

The “industrialization” of medicine has had a significant influence on the issue of health care in at least three ways. First, the impact of market forces has forced us to consider the service that we render to be a commodity subject to many of the same economic principles as the commodities produced by industry. Second, the metaphor of industrialization has allowed us to consider the service that we perform for patients to be the result of clinical processes and thus subject to the same forms of quality control as an industrial product.<sup>16</sup> The work of Deming and others in industry stressed the importance of elimination of variance in the process of generating a product. They focused on the process or system rather than the individual performer or physician.<sup>17</sup> Third, industrial applications have helped the health-care industry to adopt the hardware and statistical techniques used to maintain and analyze large databases, permitting us to more easily measure outcomes and process variance (clinical indicators).<sup>18</sup>

## **Current Elements of Quality Determination**

A prescribed consistent and efficient process of clinical evaluation and

treatment leading to an expected outcome is termed a “practice guideline.” The continuous evaluation, alteration, and improvement of these processes is termed “continuous quality improvement.” Continuous quality improvement is different from the traditional quality assurance activity, which seeks only to identify and stigmatize the practices of outliers on the low side of the quality curve. Continuous quality improvement seeks to improve the entire process of care for all subsequent patients and practitioners.<sup>16</sup> Outcomes are quantifiable results that we should expect to achieve after treatment of the patient has been completed. Thus, in summary, the current quality triad includes practice guidelines, continuous quality improvement, and outcome determination.

## **Practice Guidelines or Algorithms**

A practice guideline or algorithm is a defined method of dealing with a clinical problem that seeks to minimize or eliminate the wide variances that may be seen when different approaches are taken to the same problem. It is based on the presumption that there is a single best approach to the evaluation and treatment of an individual clinical situation.

Some confusion may arise relative to other terms that may be used to describe these guidelines or algorithms. Ranked from least to most authoritative, these algorithms may also be known as clinical policies, practice options, clinical protocols, clinical guidelines, or clinical or practice standards. Guidelines may be written for treatment of established diagnoses or for evaluation of presenting complaints. Guidelines are evidence-based, less authoritative, and generally represent the consensus of

a panel of acknowledged experts on the subject. The more authoritative clinical or practice standards take into account established evidence-based literature, and variation from these standards would be quite inappropriate. It is imperative that these standards be modified at regular intervals on the basis of new evidence.

The ideal outcome for a particular clinical situation should be the end result of all the steps involved in the guideline. Because a guideline generally represents, at a minimum, the consensus on the best practice available for dealing with a given problem, variations in implementation of the steps of that process may potentially lead to a less than optimal result. Thus, making certain that each step in the process is employed and that appropriate decision paths within the algorithm are followed is an important element in ensuring the best possible outcome.

Guidelines may be written by any group that can assemble an expert panel and publish the results. However, in practice, guidelines are frequently written by the specialty organization that most commonly deals with or should deal with that problem. In the past, the Department of Health and Human Services and its Agency for Health Care Policy and Research also published practice guidelines, most of which were related to primary-care situations. However, the Agency for Health Care Policy and Research has now officially withdrawn from writing guidelines.

By 1996, the American Academy of Orthopaedic Surgeons (AAOS) had published 15 clinical policies. The AAOS, in conjunction with other organizations, is also developing evidence-based clinical algorithms for dealing with common presenting musculoskeletal complaints. Virtually every spe-

cialty society has published guidelines for common clinical situations in its domain or in an attempt to establish the initial pathway in an area overseen by more than one specialty. The terms "critical pathway" and "care maps" are used for detailed descriptions of care plans that exist within the overall framework of the guidelines. Most frequently, these involve a course of care during hospitalization.

In theory, the use of practice guidelines should improve outcomes. Until recently there was not a large amount of documentation of improvement in quality based on the application of practice guidelines, nor were there appropriate measurements with which to judge the quality of the outcome. However, published evidence has begun to appear to document improvement after the use of practice guidelines.<sup>19-21</sup>

Most organizations that write practice guidelines, and some payers that utilize them, are facilitating patient access to those guidelines. By doing this, both payers and patients feel that they can ensure a specific level of care by determining that the guidelines are followed. In addition, the patient is made a partner in his or her own care.<sup>7</sup> Anecdotal evidence suggests that this facilitates the doctor-patient relationship and generally enhances patient compliance and participation in a treatment plan.

A frequent concern of practitioners is the possible legal implication when a poor outcome appears to be the consequence of following a guideline. However, in those instances in which a legal decision has been rendered, it seems clear that the use of an authoritative guideline, which had been frequently and appropriately reviewed and updated, served to assist the physician-defendant.<sup>22</sup>

## Continuous Quality Improvement and Process Measures

"Continuous quality improvement" is the act of revising and improving the processes of patient evaluation and treatment on the basis of data about the processes themselves. It may not even assess the actual end result by objective or subjective evidence, but simply the process. The clinical outcome achieved by the patient as a result of the evaluation and treatment process is viewed as the end product of the steps or processes defined in the practice guideline. Less than ideal outcomes may be viewed as variances in the application of all the steps in the process or as the result of inappropriate or ineffective steps in evaluation or treatment. In theory, the outcome may always be improved by either eliminating variances in the application of the steps of the process (that is, missed steps or steps carried out inappropriately) or improving steps that are found to be ineffective.

The continuous quality improvement process looks at the elements of the process to ensure that they were all carried out appropriately and that each step was determined to be effective in producing the desired result. If a problem is identified, a plan is developed to correct the variance in application of the steps or the effectiveness of the steps, by using techniques adopted from industry. The steps in a guideline, which are routinely reviewed in the process, are termed "clinical indicators" or "medical review criteria." The frequency with which the indicator or criterion was appropriately used in a series of cases is considered a process or performance measure. For example, in the context of total hip arthroplasty, the timely prescription of an effective anticoagulant may be used as one clinical indicator of appropriate care. In a series of arthroplasties,

the percentage of cases in which this was done in a timely and effective manner is the process or performance measure. That measure may be compared to some goal or benchmark. Continuous improvement in all performance measures is the goal.<sup>23</sup> However, improvement may not correlate with a treatment outcome, such as a decrease in the rate of deep venous thrombosis or pulmonary embolism.

Particularly in retrospective reviews, process or performance measures may become surrogates for true outcomes. The rationale is that virtually all undesirable outcomes are related to a variance in process. Although not as accurate as a true outcome measure, such information is far easier to obtain. For example, the critical pathway for total hip arthroplasty calls for use of prophylactic antibiotics, postoperative anticoagulation, and physical therapy for gait training. The determination that these process steps were observed is easier to confirm in a retrospective review than the obtaining of detailed outcome data on patients. Therefore, some agencies, particularly payers, are currently looking to such data as a surrogate for true outcome indicators.<sup>6</sup> Other groups, such as the Foundation for Accountability, are delving deeper into the needs and desires of individual patients.

## **Outcome Measures**

Determination of outcome may be different from determination of quality. Outcomes are now more than the simple accounting of objective measures, such as morbidity, mortality, and infection. An outcome is the patient's health status subsequent to the application of a clinical process.<sup>24</sup> It includes changes in physiology, symptoms, function, and perception. Clinical experience has taught us that pa-

tients with excellent radiographs or good range of motion are not always satisfied with their outcome. Because impaired physical, social, and emotional function may be the end result of many conditions, our evaluation of the outcome of treatment must take into account the patient's overall health status, work ability, satisfaction, expectations, and perception of pain.<sup>5</sup> In addition, the cost-effectiveness or value of the treatment must be determined.<sup>5,25</sup>

Today, in all of medicine, outcomes may include any or all of three basic types of information: (1) the traditional, very objective factors, such as mortality, complications, and strength or range of motion; (2) less objective determinations, such as function, health status, pain, and satisfaction; and (3) an assessment of the value of the intervention. Value is most easily defined as the product of the outcome of the intervention divided by the costs incurred. Emerging evidence suggests that more cost-efficient care may be higher-quality care.<sup>26</sup>

## **Specific Orthopaedic Outcome Tools**

The recent changes in health care have influenced not only the practice of orthopaedics but also the clinical research being performed. There is currently an emphasis on studies assessing treatment effectiveness from the patient's perspective. This trend has highlighted its omission in older clinical research studies and has perhaps led to improvements in our understanding of the effectiveness of treatment modalities and changed the way clinical research has been done.

Recently, emphasis has been placed on the systematic design of tools (instruments) that are both consistent (reliable) and valid (mea-

sure what they are intended to measure). The process of designing and testing an instrument is complex and beyond the scope of this article; however, a brief discussion of validity follows.

"Content validity" refers to how adequately the sample questions represent the entire pool of possible questions that could be asked (i.e., the comprehensiveness of the sample questions and the extent to which they meet the aims of the instrument being designed). Content validity is most commonly established by asking patients and physician-experts to review the content of the instrument to establish clinical credibility.

"Criterion validity" refers to whether the instrument correlates well with the "gold standard" measure. Statistical analysis is used to test the criterion validity of each question ("item analysis") and of the entire instrument.

"Construct validity" is used in instances in which there is no "gold standard" measure that can be compared to the instrument being designed. Construct validity is a complex process that requires assembly of evidence (such as correlational evidence) to prove the validity of the instrument. A vast array of validated outcome instruments are now available for the assessment of patients with musculoskeletal conditions. Some instruments measure a patient's general health status; others measure outcomes related to a specific anatomic region, body part, or condition.

Validated measures of general health status, such as the SF-36 Health Survey<sup>27</sup> and the Sickness Impact Profile,<sup>28</sup> take into account various qualitative and quantitative facets of a person's life; they do not refer to the specific disease or problem that is causing compromised health. One method by which general-health-status measures may be used in orthopaedics

is to study the effect of a particular musculoskeletal condition on general health. For example, Gartsman et al<sup>29</sup> showed a statistically significant decrease in general health (as measured by the SF-36 Health Survey) in patients with five common shoulder conditions. Furthermore, the authors showed that these shoulder conditions had an impact on the patient's perception of his or her general health on the same order of magnitude as several major medical conditions. General-health measurement tools can also be used in orthopaedics to assess the effect of a treatment intervention on general health status. A number of authors have shown statistically significant improvements in general health status after operative intervention for an orthopaedic condition.<sup>30,31</sup>

Other types of instruments currently being used in musculoskeletal outcome research are those that evaluate a specific organ system, body part, or condition. The Musculoskeletal Function Assessment is an example of a validated instrument designed to measure outcome in regard to a specific organ system.<sup>32,33</sup> This instrument facilitates the evaluation of a wide range of musculoskeletal disorders and contains ten categories (self-care, sleep/rest, hand/fine motor, mobility, housework, employment/work, leisure/recreation, family relationships, cognition/thinking, and emotional adjustment/coping/adaptation). This instrument has been shown to have good construct validity, content validity, and reliability.<sup>32,33</sup>

An example of a validated instrument that measures the outcome of treatment of a specific body part is the Constant Shoulder Function Scoring System.<sup>34</sup> Examples of validated instruments that measure outcomes of specific conditions include the Western Ontario and McMaster Universities

Osteoarthritis Index (WOMAC)<sup>35</sup> and the Carpal Tunnel Syndrome Evaluation Instrument of Levine et al.<sup>36</sup> A number of other instruments and research techniques have been used for musculoskeletal outcome studies.<sup>37-39</sup> Examples include the Brief Pain Inventory<sup>40</sup> and the Time Trade-off Technique.<sup>41,42</sup>

The AAOS has taken a leadership role in coordinating outcome studies for orthopaedic surgeons throughout the United States. The AAOS has collaborated on a joint project with the individual specialty societies to produce the Musculoskeletal Outcomes Data Evaluation and Management System (MODEMS). The MODEMS contains a number of questionnaires and modules: the Lower Limb Questionnaires (which include the Lower Limb Questionnaire, the Foot and Ankle Questionnaire, the Sports Knee Questionnaire, and the Hip/Knee Questionnaire), the Pediatric Questionnaires (which include the Pediatric Parent [child] Questionnaire, the Pediatric Parent [adolescent] Questionnaire, and the Pediatric Adolescent Questionnaire), the Spine Questionnaires (which include the Cervical Spine Questionnaire, the Scoliosis Questionnaire, and the Lumbar Spine Questionnaire), and the Upper Limb-DASH (Disabilities of the Arm, Shoulder, and Head) Questionnaire. A Hip and Knee Module, a Patient Satisfaction Module, a Physician Assessment Module, and an Employment Module are also available. The intent behind the development of the MODEMS was to build a national database for the purpose of establishing normative standards for musculoskeletal conditions and treatments.

Region-specific outcome instruments accrue data regarding the functional abilities of the region or body part and the perceived degree of pain therein. In general, these instruments do not measure traditional

orthopaedic research variables, such as radiographic phenomena and joint range of motion. Patients are primarily concerned with body-part function and pain. Radiographic phenomena (such as osteolysis and evidence of implant loosening) may be important in predicting long-term outcomes, but they are rarely the focus of outcome from the patient's perspective. For example, the Upper Limb-DASH Questionnaire of MODEMS includes questions regarding general health problems and questions from the SF-36 Health Survey. The DASH portion of the questionnaire consists of a number of items regarding upper-extremity functional abilities and pain.

## The Future of Quality and Outcomes in Health Care

Quality determination and outcome evaluation in health care are a work in progress. The reliability, validity, and accuracy of both processes, as well as outcome measures themselves, are constantly being reevaluated and improved. In fact, a practice guideline or outcome tool is in all likelihood not accomplishing its goal unless it is constantly being improved on the basis of the data it has previously produced.

The demand for continued development of practice guidelines and outcomes management on the basis of statistically validated studies of large populations will be emphasized both by individual specialty societies and by larger health-care organizations. This population-based emphasis is different from the traditional subjective approach to individual patients.<sup>6</sup> In orthopaedics, it may signal an emphasis on the prevention of musculoskeletal disease and injury.

There is now a mandate to deal with individuals and populations across the entire continuum of care,

from prevention through the traditional acute care and into rehabilitation and chronic care. This emphasis on whole populations and the continuum of care has already created a demand for a more accurate, more accessible, easily transferable medical record. Developments in information systems will continue to accelerate to meet that demand. The electronic medical record or computerized patient record may, in addition, become the resource to access and implement practice guidelines. As the clinical indicators and outcome measures become part of that record, the record itself may also become a means for evaluating the quality of care.<sup>4</sup>

Outcomes of technical procedures will be examined to determine the relationship between the volume of procedures performed by an institution or individual and the outcome. What this might mean for the general orthopaedist who performs a wide array of surgical procedures, each in moderate numbers, as opposed to the specialized orthopaedist who performs a large volume of one or two procedures, remains to be determined.<sup>43</sup>

It is clear that the emphasis on determination of a patient's satisfaction with the health-care process

will continue to an even greater extent than is currently being seen. In addition, health-care institutions—particularly payers—might link credentialing and the granting of privileges in their networks to the use of approved practice guidelines and the continuous quality improvement process.<sup>7,44</sup> However, that approach is controversial, especially when an approach other than an approved guideline is more appropriate to a specific patient.<sup>44</sup>

The transition signaled by these developments may be difficult for some physicians, who see these changes solely as a threat to their autonomy. However, other physicians will see these changes as an opportunity to develop a more focused approach to health care and as a means to document quality.<sup>45</sup>

## Summary

Outcome determination, which has gained so much attention in health care recently, is not an entity unto itself. It must be remembered that it is the end result, or product, as well as the measure of the entire process of health care. Perhaps it is best viewed as a tool to improve our practices.

In the new paradigm, quality health care is the outcome of a series of defined processes of evaluation and treatment, termed practice guidelines. Practice guidelines are generally the evidence-based consensus of experts in a given field as to how a particular clinical situation ought to proceed from presentation to outcome. The steps in this process are continually being refined to further improve the outcome.

Because of the persistent changes in health care today, practitioners may feel burdened by outside agencies attempting to assess their performance. However, the current mandate for quality, necessitating the measurement of results, may be an opportunity to reclaim the initiative in the ongoing evolution of health care, as we continue to improve what we do as a profession.

Current evidence demonstrates that the entire quality improvement process may produce improvement in outcomes as well. There is obviously much that remains to be done in this field. It is important that we, as practitioners, become involved in these new protocols, rather than having them mandated by outside agencies.

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