Clinical practice guidelines may be defined as systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical conditions. The practice guideline is a management plan that enables healthcare providers to make sequential decisions about testing or therapy in a given clinical situation. Given the heterogeneity of disease presentations and the complexity of making therapeutic decisions, the development of guidelines in neurosurgery presents unique problems and challenges. Clinical practice guidelines were developed in part as a method for the assessment of quality of medical care processes. Practice guidelines serve as a tool for comparisons to be made within and between healthcare delivery systems. The implementation of guidelines also allows for the acquisition of clinical and financial data that provide for outcomes analysis and other types of information. The characterization of patterns of care in different institutions and the relationship between patterns of care and outcomes will in the future allow for quality improvement, enable physicians to offer predictability and accountability to third-party interests, and contribute to an understanding of how to offer the best care to neurosurgical patients.

The author provides an overview of clinical practice guidelines and illustrates their role in the assessment of quality of patient care, demonstrates how they fit into the methodology of quality assessments, and underscores the importances of practice guidelines for the development of disease management systems.

Key Words * clinical practice guidelines * disease management system * outcomes * quality of care assessment * socioeconomics

The fundamental goal of any healthcare delivery system is to provide a combination of health services to optimize the health of the patient. The key to achieving this goal is to ensure a continued commitment to improving the quality of health services provided to patients. Emphasis in recent years on socioeconomic issues in medicine has led to increasing interest in quality of healthcare assessments. Various methods to assess quality of care have been developed by which to examine and improve the delivery of care for specific disease processes. The use of clinical practice guidelines is one method that has been created to allow for the assessment of quality within a single institution and to compare patterns of care among several institutions.[8]
In recent years there has been growing interest among many surgical specialty societies in the development of practice guidelines. Clinical practice guidelines currently figure prominently in the planning of many healthcare delivery and managed care organizations.[2,13] Guidelines can be useful in managing care, because they often define the appropriate diagnostic and treatment interventions required to achieve particular outcomes while reducing variability in practice. This paper provides an overview of clinical practice guidelines and their role in quality of care assessments. It will demonstrate how practice guidelines fit into the methodology of such quality assessments, and additionally, it will illustrate the importance of practice guidelines for the development of a disease management system.

**CLINICAL PRACTICE GUIDELINES**

In the early 1990s, the Agency for Health Care Policy and Research (AHCPR) was legislatively charged with initiating programs and research to provide a more rational basis for decisions about which treatments to offer and which technologies to purchase.[2,7] Clinical practice guidelines developed by the AHCPR relevant to neurosurgery include those on acute pain management; depression detection, diagnosis, and treatment; and the management of cancer as well as low-back pain. The AHCPR has become increasingly interested in the development of practice guidelines in a variety of areas.[8]

The AHCPR defines clinical practice guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions."[13] Practice guidelines are often illustrated graphically as decision algorithms to reflect the complexity of clinical decision making. Given the heterogeneity of disease presentations and the complexity of therapeutic decisions, the development of guidelines in neurosurgery presents unique problems and challenges.

One reason for recent emphasis on developing guidelines is the belief that they will provide a vehicle for assuring conformity of practice. Although clinical guidelines are being promulgated as a means of assisting physicians in making therapeutic decisions, the implementation of these guidelines also reflects the goals of managed care health organizations to promote practice conformity and thus reduce the cost of care.[13] The reasons for adopting guidelines by managed care organizations include the following beliefs: 1) the use of guidelines will eliminate inappropriate interventions; 2) the cost of care can be more accurately gauged; 3) the cost of care may be decreased; and 4) quality of care can be defined in terms of adherence to guidelines.

Current approaches to the development of clinical practice guidelines have been outlined by Woolf[14] and include informal consensus methods, formal consensus methods, evidence-based guidelines, and the assessment of outcomes to choose between alternative practices (explicit method).[13] It should be noted that "clinical practice guidelines," which detail the appropriate tests and treatments, differ from "critical pathways," which lay out a plan of how to perform these tests and treatments.[13] Critical pathways are centered on the timing of medical procedures and are usually derived at the institutional level.

The type of guideline most frequently developed is the path guideline. Figure 1 outlines a typical clinical practice guideline for a neurosurgical disease process. The path guideline is a management plan that enables providers to make sequential decisions about testing and therapy for patients with a given type of tumor,[13] and such decisions are often presented in the form of a treatment algorithm or "decision tree" which spans the time from diagnosis to final treatment.[1] The treatment pathway is composed of various treatment "pathsteps" (or "boxes") that indicate the possible alternative treatments at each point in the decision tree.
It must be recognized that for many stages of a disease two different treatment options might be considered standard and that some options would encompass multiple modalities (for example, surgery followed by radiation therapy or chemotherapy followed by surgery). Pathways must also encompass the potential complications of therapy, be modifiable when the treatment paradigm changes, and include screening and prevention guidelines. For patients who become permanently disease free, "final" treatment might involve a return to community care. For terminally ill patients who are receiving palliative care, the pathway must account for all the appropriate treatment options.

A neurosurgical practice guideline should include information on the initial workup, initial therapy, alternative adjuvant therapy, surveillance, and management of recurrent disease and any complications. Practice guidelines must be comprehensive, including all ancillary tests, diagnostic procedures, various treatments, and healthcare provider encounters. Supportive care must also be taken into account. Economic analysis is increasingly being incorporated into guideline development to help shape the final treatment recommendations of guideline panels.

A practice guideline for a specific neurosurgical disease process would ideally identify critical management decisions, control technology use, and isolate high-risk and high-cost pathsteps. This information would allow for the determination of specific treatment-component costs, would provide a basis for comparative studies, and could be used to educate all healthcare professionals within the center or network.

For purposes of assessing quality of care, it is essential that developers of practice guidelines establish operational definitions of adherence and nonadherence to the guidelines and provide definitions for key clinical concepts in the guidelines. Clinical terms must be explicitly defined to evaluate whether a
particular patient is eligible for a portion of the guidelines and thus to assess adherence to the guideline. The most important consistent finding from studies on guideline adherence is that there is substantial variability in compliance among physicians. Furthermore, when guidelines are first implemented, adherence tends to be fairly low. In one study of the effect of several guidelines on medical practice it was shown that rates of adherence were frequently well below 50%. [5]

QUALITY OF CARE ASSESSMENTS

The Institute of Medicine has defined quality of medical care as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." [8] Quality of care assessments are conducted by selectively examining different dimensions of the health delivery system. There are two approaches to assessing performance quality: the first is to examine the health services delivery system itself without reference to specific clinical problems or treatments; the second is to examine quality of care from a clinical perspective, focusing on specific health conditions or services, and evaluating care delivery to the population of patients with those health problems or those who require particular services. [7] Both methods may be used to assess quality within a single institution ("internal assessment") or to compare quality among several institutions ("external assessment").

The HMO (Health Management Organization) Quality of Care Consortium has proposed criteria for selecting health conditions or problems that should undergo formal quality of care assessment based on the expected impact of improved quality of medical care. [8] These criteria are applicable when: 1) the condition is highly prevalent and/or has a significant effect on mortality and morbidity in the population; 2) there is reasonable scientific evidence that efficacious or effective interventions exist for primary, secondary, or tertiary prevention of the condition; 3) improving the quality of service delivery will enhance the health of the population; 4) recommended interventions are cost effective; and 5) recommended interventions are under the control of health plans or providers.

The most commonly used conceptual framework in quality of care assessment is the one proposed by Donabedian. [3] This framework identifies three dimensions of quality: structure, process, and outcomes (Fig. 2).
Structural Quality

Structural quality refers to those stable elements of the healthcare delivery system that facilitate access to and provision of services;[8] the elements include community characteristics (such as prevalence of disease), healthcare organization characteristics (such as number of hospital beds per capita), provider characteristics (such as specialty mix), and population characteristics (such as demographics and insurance coverage). Structural characteristics can be used to describe both the need for healthcare (prevalence or incidence of disease) and the capacity of the community or healthcare delivery system to meet those needs. Few structural factors have been found to be associated with significant variations in health outcomes, although they are frequently associated with differences in the delivery of care. One conclusion from several small-area variation studies is that substantial reductions in utilization (and thus cost) may be possible without negative effects on health.[8,12]

Process Quality

Process quality refers to the interaction between patient and provider, including technical and interpersonal excellence.[8] The term technical excellence is used when the intervention was appropriate and was provided skillfully, and the term interpersonal excellence applies to situations in which the intervention was humane and responsive to patient preferences. The best evidence of the relationship between processes and outcomes comes from randomized clinical trials because such trials can prove conclusively the efficacy of an intervention. The definition of quality of care emphasizes this relationship between the process of service delivery and outcomes.

Four methods have been used to evaluate the quality of care processes.[8]
Development and Adherence to Clinical Practice Guidelines. This refers to the evaluation of the extent to which care is consistent with professional knowledge and is accomplished by examining adherence to specific practice guidelines adopted by healthcare providers. Many specialty societies have established standards for when and how treatments should be delivered. Because of the relative ease of evaluating adherence to such guidelines, they represent a common basis for quality assessment.

Appropriateness of an Intervention. This method is applied to determine if the expected health benefit from performing an intervention exceeds the expected health risks by a sufficient margin in patients with particular characteristics.

Practice Profiling. This method is designed for comparing the patterns of cost, utilization, or quality of processes among providers. Profiles are generally constructed as an occurrence rate of some process over a specified time period for a defined population. Profiling is most often used to examine utilization of a variety of services such as hospital admissions, ambulatory visits, laboratory tests, or medication prescriptions.

Consumer Ratings. This method is most appropriate for evaluating the interpersonal quality of care, and surveys of health plan enrollees are the most common method for eliciting information from individuals about their healthcare.

Outcomes Assessment

As part of the framework in quality assessment proposed by Donabedian,[3] "outcomes" refers to the ultimate results of efforts to prevent, diagnose, and treat various health problems.[8] Many view outcomes as the most important measure of the effectiveness of the healthcare delivery system. Outcomes assessment may be defined as research on the management of patients that assesses what treatment is effective and for whom in more realistic settings than that conducted in randomized, controlled trials. The emphasis of this study technique is on an array of outcomes beyond simple restoration of normal anatomical relationships and particularly on endpoints emphasizing the patient's assessment of pain, function, quality of life, and satisfaction with the results of the intervention.[6]

Outcomes assessment methods to evaluate the quality of healthcare delivered include condition-specific, generic, and "sentinel events" or adverse outcomes. With regard to using outcomes assessments for evaluating the quality of care, there are two factors that must be considered. First, to use outcomes assessment to make externally valid comparisons among health plans or providers, adequate methods must be used to control for differences in the severity of illness or the health profile of the populations being compared. Second, the issue of "attribution," which entails determining the extent to which the health plan or physician is responsible for the observed outcomes, must be considered. Health outcomes are affected by a variety of factors and not all of them can be modified by the health delivery system. Because these factors may be distributed differently among populations seeking care, these external effects must be controlled for in statistical analyses to understand the extent to which variations in quality of care contribute to the observed variations in outcome.[8]

An increasingly important role for outcomes assessment is in the evaluation of quality of care provided by caregivers.[11] However, in most cases, there is too much heterogeneity in patient characteristics, diagnoses, and treatments for comparisons among individual physicians to be appropriate. Instead, patterns of care and outcomes data have been aggregated at the level of the institution or network of institutions.[11] These multiinstitutional efforts were developed with the goal of assessing outcomes by
evaluating both treatments and providers. Data on outcomes associated with specific interventions will be used to provide an empirical basis for clinical practice guidelines in areas for which no randomized trial data are available. In addition, the characterization of patterns of care by providers in different institutions, and the relationship between patterns of care and outcomes, will inform quality improvement efforts, enable physicians to offer predictability and accountability to insurers and employers, and contribute to an understanding of how to offer the best care to cancer patients.[11]

There are various uses of quality of care assessments. As previously stated, quality assessments can be used for both internal and external purposes. The purpose of an internal quality assessment is to identify factors in a single delivery system that might be contributing to substandard performance on quality measures.[8] A second purpose is to identify factors that are associated with good outcomes to use in other settings as models of quality improvement. Internal quality assessment efforts are currently an integral part of quality improvement activities such as "total quality management" or "continuous quality improvement." The focus is typically on the process and outcome methods. Generally, these activities involve multidisciplinary teams that start with a specific clinical problem and attempt to uncover what caused failure to achieve performance goals. One important factor limiting greater intensity of internal quality improvement activities is the availability of clinically valid data. The creation of clinical practice guidelines is one means of obtaining such information.

The purpose of external quality assessment is to make information about quality available to consumers and purchasers to inform their ability to choose among health plans, hospitals, and physicians.[8] In recent years increased attempts have been made to use quality assessments for making external comparisons among health plans and physicians. Quality assessment measures for external purposes is selected based on the principles that:[10] 1) the methods should be population based; 2) the methods should focus on all dimensions of the delivery system rather than a single setting; 3) potential quality problems arising from either overuse or underuse of services should be evaluated; and 4) the methods should control for differences in the populations enrolled and for factors extraneous to the health delivery system that influence the processes or outcomes.

Quality assessment measures for evaluating the treatment of neurosurgical disease processes should include these four criteria for external comparisons to be made. The future use of external assessments will be determined by availability of a common set of assessment tools that allows for valid comparisons to be made between healthcare delivery systems. Clinical practice guidelines may serve such a purpose.

DISEASE MANAGEMENT

The ultimate goal of developing these clinical practice guidelines is to allow for the development of a disease management system. Disease management refers to the comprehensive, systems-based approach to providing care for a defined disease process.

The system incorporates:

1) Clinical practice guidelines.
2) Behavior modification and education interventions for both patients and providers.
3) Outcomes research for ongoing measurement of the results of healthcare processes.
4) Financial management tools for medical cost management.

Disease management efforts include:[4]
1) Prospective identification of at-risk populations to increase efficiency of resource allocation for prevention and treatment.
2) Tracking the natural history of the disease to help identify and quantify variables that typically drive variations in cost and quality.
3) Driving clinical processes based on diagnosis and appropriate treatment rather than reimbursement.
4) Building continuity of care to integrate all components of the healthcare system.
5) Including ongoing measurement of clinical, economic, organizational, and behavioral outcomes as part of a continuous improvement process.
6) Providing feedback on outcomes to healthcare providers, payers, and patients as a means of reinforcing adherence to disease management guidelines and processes.
7) Functioning as integrated systems, not individual programs or component interventions.
8) Using patient-centered information systems to follow the patient through the continuum of care, track utilization of healthcare resources over time, and link outcomes with interventions.

In a neurosurgical setting a disease management system incorporating clinical practice guidelines should provide a variety of benefits.[1] Quality of care can be improved by increasing the predictability of care from patient to patient and by eliminating unnecessary ancillary tests, which should lead to a reduction in patient charges. In addition, multiple measures of outcomes will be prospectively acquired and can be analyzed for validity. Finally, such a disease management system will allow for better calculations of resource consumption, especially between "standard" and research care. The end goal of the implementation of clinical practice guidelines is to accelerate the rate of learning of neurosurgical care providers so that continuous care delivery improvements can be made quickly and effectively.[4]

**CONCLUSIONS**

Emphasis in recent years on socioeconomic issues in medicine has led to increased interest in quality of healthcare assessments as well as clinical practice guidelines. In the future, clinical practice guidelines will be used by a disease management team to obtain detailed information regarding the delivery process of neurosurgical treatment strategies. The system will allow for the acquisition of clinical and financial data in real time, which will provide for outcomes analysis and other types of information previously unavailable from retrospective analyses.[1] This effort will ultimately lead to a new practice environment in which complex treatment paradigms such as those used in neurosurgery can be constantly modified and upgraded for the benefit of patients.

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