Much health services research and project development is focused on defining appropriate, high quality care, and on developing instruments to monitor quality of care and facilitate health care decisions. Research is directed toward developing indicators of care and appropriateness criteria, and studying outcomes of care and practitioners' patterns of care. Additionally, projects are underway to develop clinical guidelines and practice parameters, as well as clinical algorithms. Along with guidelines and indicators, there are also longstanding standards of care, treatment protocols and policies, and medical criteria. Such an armamentarium can be confusing. How do these instruments differ from one another? How are they the same? The purpose of this article is to describe parameters, guidelines, and indicators, and to provide an update on who is developing them. Quality assurance instruments are beginning to play an important role in the provision of health care and to raise many important policy issues. It is prudent for occupational therapists and other health care professionals to develop a familiarity with them.

Most of these guides and monitoring instruments are not really new. Occupational therapists and other health care professionals have sought to define standard and accepted practices of care and have developed various treatment protocols and criteria as their professions evolved. In occupational therapy, treatment protocols and criteria were often used to guide student fieldwork, to convey to other health professionals what occupational therapists do, and to provide a general standard or guide by which occupational therapists could provide treatment. They were usually developed voluntarily, on an ad hoc basis, and the methodology used to develop them was informal. Most often, these documents were developed locally within a department in a facility.

However, the demands placed on health care professionals for quality assurance (QA) or, more recently, quality improvement (QI) have intensified. Clinical indicators are required documents to meet accreditation standards of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) and other accrediting bodies. Criteria and clinical algorithms are used by insurers and the professional review organizations (PROs) to justify reimbursement for services. Additionally, several states have enacted health care legislation with clauses that call for quality assurance instruments be developed with a higher accountability for the quality of care, it is also expected that quality assurance instruments be developed with a higher degree of validity and reliability than in the past. Guidelines and other protocols no longer simply describe accepted practice, but describe efficient and effective care with the expectation that health professionals will change those aspects of their practice that are inefficient or ineffective. It is expected that QA monitoring instruments be based on scientific data and expert consensus.

Along with the higher level of accountability for the quality of care, it is also expected that quality assurance instruments be developed with a higher degree of validity and reliability than in the past. Guidelines and other protocols no longer simply describe accepted practice, but describe efficient and effective care with the expectation that health professionals will change those aspects of their practice that are inefficient or ineffective. It is expected that QA monitoring instruments be based on scientific data and expert consensus.

The intense interest in determining appropriate care and monitoring the quality of care stems, in part, from the nationwide effort to control the escalating costs of care and use of services. However, there is also genuine concern about the quality of care. Over the last 10 years, health services research has documented that the treatment provided and the outcomes of care vary greatly from one area of the country to another, and from one hospital to another, even when clinical circumstances and diagnoses are adjusted to be comparable (Ellwood, 1988; Reiman, 1988). Such unexplainable variations in care appear to represent, in some cases, poor quality of care (Eddy, 1990).

A major contributor to this work is John Wennberg, MD, who since the early 1970s has been studying variations in the use of medical services. He found differences in utilization rates of common surgical procedures and other medical services around the country (Wennberg & Gittelsohn, 1982). He attributed these differences to variations in physicians' practice styles, which he introduced as a variable that contributes to rising health care costs. The problem of unexplained variations in treatment has also been documented by other researchers (Chassin, Brook, & Park, 1986; Hannan et al., 1990; O'Connor et al., 1991; Williams, Nash, & Goldfarb, 1991).

As questions about the quality of care arise and as quality assurance has come to be viewed as a potential mediator between cost and access problems, research on quality has intensified. However, until recently, the research seemed to lack a focus. Different organizations and agencies were developing guidelines and indicators and coming to different conclusions without giving attention to how their work would be useful in the field at large, or how their terminology overlapped with that of others or expressed idiosyncratic concerns. Within the last 5 years, organizations such as the JCAHO, the American Medical Association (AMA), and the Agency for Health Care Policy and Research (AHCPR) have begun to collaboratively address the relationship between guide-
lines and indicators and there is greater consensus regarding the methodology for developing guidelines and other quality assurance instruments. These developments are discussed below.

Definitions of QA Instruments

QA instruments can be separated into two broad categories: (a) guidelines, parameters, standards, and treatment protocols, and (b) indicators and criteria. Within each broad category, similarities and distinctions will be addressed.

Guidelines, parameters, standards, and treatment protocols are documents used to define and describe appropriate care for a given diagnosis or condition or to describe the appropriate use of a treatment procedure. In this general sense, these terms are often used interchangeably. Distinctions become important when considering how such documents might be used. For example, distinctions arise when such documents are brought before a court as evidence in malpractice cases. Distinctions are also important if a payer will be using such documents to make decisions on reimbursement. Professional groups, such as physicians, have become concerned about these distinctions because of the reasons mentioned above and because they want to preserve their clinical autonomy in diagnosing and treating patients. For these reasons, most organizations have begun to pay attention to defining their purpose and methodology when developing guidelines, parameters, and so forth. In 1992 the Institute of Medicine (IOM) published a report on clinical guidelines that appears to be the most thorough study on the subject to date. In the report, guidelines are defined as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” (IOM, 1992, p. 27).

The IOM definition makes the point that guidelines for a given diagnosis or condition should cover the full range of appropriate treatments that can be documented from the literature and from expert consensus. The full range of appropriate care refers to the fact that in many cases, if not most, there are several different kinds of treatment that a patient can be given for a specific illness or problem, depending on the details of the clinical and social circumstances as well as the patient’s preferences. Thus guidelines would discuss the entire range of treatments that could be administered for a particular diagnosis or condition, rather than discussing only the most usual or only the most effective.

Appropriate care is another concept that is important to understand but difficult to define. It refers to care that is proper, but not necessarily essential or required. The IOM defined it as care in which “the expected health benefit exceeds the expected negative consequences by a sufficient margin that the care is worth providing” (1992, p. 28). Thus guidelines would discuss the full range of care that is considered appropriate.

In 1988, the AMA undertook a project to coordinate the development of practice parameters by the medical specialty organizations. The AMA coined the term practice parameters to emphasize the idea that there is often a range of appropriate treatment, rather than only one way of treating an illness. The AMA defines parameters as “strategies for patient management, designed to assist physicians in clinical decision-making” (AMA, 1990, p. 2).

At the time the AMA was planning to develop practice parameters, some thought that the term guidelines might connote a more narrow view of treatment; for example, that a guideline might address only the most commonly used appropriate treatment. However, as the idea of describing a range of treatment gained attention, the term guidelines, as later defined by the IOM, has taken on the broader meaning. According to the IOM report, guidelines sometimes serve as an umbrella label for practice standards, protocols, parameters, algorithms, and various statements about appropriate clinical care (IOM, 1992). According to the AMA, however, parameters is the umbrella term that includes “standards, guidelines, practice options, practice advisories, and other patient management strategies” (AMA, 1990, p. 2).

A key point in the IOM definition of guidelines is that they “assist” in medical decision making. This point is also made by the AMA, regarding parameters. The word assist is specifically intended to convey that guidelines should not dictate treatment or be in any way prescriptive to the practitioner. The guidelines are intended to enhance clinical judgment, not supersede it. Thus clinicians might deviate from the guidelines when, in their clinical judgment, it is in the patient’s best interest to do so.

Another key point of the definition is that statements are “systematically developed.” This means that guidelines are expected to be developed from a comprehensive search of the scientific and clinical literature and a consensus of expert opinion. Such methodology is intended to increase the validity of the guidelines and their relevance to clinical practice. The major difficulty in using a systematic approach lies in resolving differences in expert opinion regarding the strength of literature and the degree of priority or importance a specific article should be given in writing guidelines, relative to other articles or studies in the literature.

To more fully describe parameters, the AMA developed the following list of attributes that parameters should have (AMA, 1990):

1. Parameters should be developed by experts in the field, such as the professionals who treat patients.
2. Reliable methodologies that integrate relevant research findings and appropriate clinical expertise should be used to develop parameters.
3. Parameters should be comprehensive and specific as possible. This means that parameters should discuss alternative patient care strategies when they exist and specify the indications and contraindications for each strategy.
4. Parameters should be based on current information. This means that parameters should be updated periodically as science, technology and clinical judgment advance.
5. Parameters should be widely disseminated. This means that parameters should be easily available. Plans for distributing them might include notifying members of the profession and others, through the scientific journals and newsletters, where the parameters can be obtained.

The Institute of Medicine also de-
veloped a list of desirable attributes of clinical practice guidelines as follows (IOM, 1992).

1. Validity, including the necessity to comment on the strength of the scientific evidence that supports the guidelines, and a comment on estimated outcomes when they are known.
2. Reliability or reproducibility.
3. Clinical applicability, referring to the relevance of the guidelines to specific population groups or their demographics.
4. Clinical flexibility, discussing where exceptions might occur and how patient preferences should affect the application of the guidelines.
5. Clarity, meaning that the guidelines should use specific terms and define terms that might not be clear.
6. Multidisciplinary process, which means that key affected groups should be involved in guidelines development.
7. Scheduled review, meaning that guidelines should be updated as scientific and technological advances require.
8. Documentation, which means that the methods, people, scientific evidence and assumptions used should be published in the guideline document, as an appendix or supplementary document.

As can be seen from the AMA and IOM lists of characteristics, parameters and guidelines have similar characteristics.

Although guidelines or parameters are currently the focus of attention, standards still bear mentioning because in some cases they apply and are used. The AMA stated that standards are generally accepted principles for patient management, whereas guidelines are recommendations for patient management which might identify a range of strategies (AMA, 1990). The AMA pointed out that there are times when only generally accepted principles are appropriate; parameters would encompass such a circumstance.

The IOM, in its 1992 report, defined standards as "authoritative statements of (1) minimum levels of acceptable performance or results, (2) excellent levels of performance or results, or (3) the range of acceptable performance or results" (IOM, 1992, p. 26). However, the various parties define standards, the general idea is that standards are more authoritative and set narrower limits on appropriate care; they are applied more rigidly.

Indicators are distinct from guidelines and parameters in that they provide measures or benchmarks of the quality or appropriateness of care, rather than explaining, describing, or prescribing appropriate care. Thus an indicator states an essential element or elements of the structure, process, or outcome of care. Indicators are conceptually similar to examination questions, which capture the important elements of a larger body of knowledge and can be used to assess understanding or performance relative to that body of knowledge. As with examination questions, the worthiness of an indicator is dependent on its reliability and validity in capturing the essential elements of care.

Although indicators are means of measuring quality, they are not absolute measures. Instead, they serve as flags for potential quality of care problems or for areas that require further improvement (JCAHO, 1990). As potential problems are uncovered, they must be analyzed to determine whether they actually are problems, to understand the underlying factors contributing to the problem, and to determine a plan for intervention. Because indicators are not absolute measures of care, it is more accurate to say that indicators monitor the quality of care rather than actually measuring it.

The JCAHO has done considerable work on indicator development and their definition of indicators is, perhaps, authoritative. The JCAHO defined indicators as "assessment tools used to monitor and evaluate the quality of important governance, management, clinical and support functions that affect patient outcomes" (JCAHO, 1990, p. 3).

The JCAHO also suggested that indicators be developed, through a combination of literature and expert opinion, to be valid and reliable measures.

Indicators are very similar to medical criteria and the terms are often used interchangeably. Typically, the term criteria is used by private insurers and the PRCs to justify reimbursement for services. The following definition of medical criteria, which was put forth by the IOM, can be compared to the JCAHO definition of indicators to highlight the similarity between the terms: medical criteria are "systematically developed statements that can be used to assess the appropriateness of specific health care decisions, services and outcomes" (IOM, 1992, p. 27).

The key feature of the definitions of both indicators and criteria is that indicators and criteria are for "assessing" care. Thus, the indicators and criteria must address an aspect of care in such a way that it can be monitored.

A set of indicators for a given medical condition or diagnosis would attempt to capture the essential elements of care. As an example, indicators for rehabilitation after a cerebrovascular accident might include improvement in activities of daily living (ADL) because ADL is an essential aspect of rehabilitation. The JCAHO also requires that the indicator be measurable and that a threshold of expected treatment be established, against which care provided can be compared. Thus, in the above example, the indicator might state that X percent of patients will increase their ADL skills. If possible to estimate, the indicator could be made more specific by specifying the length of time in which increases of skill would occur or specifying the degree to which ADL skills would increase. Additionally, because indicators are not absolute measures of quality, a violation of a threshold level would not necessarily mean that the quality of care is substandard but rather that care in that area, or in that specific case, bears further investigation. In the example, such investigation could entail a more focused review of ADL treatment in cerebrovascular accident cases, review of the patient record, or discussion with the therapist.

The JCAHO has described several types of indicators. Process indicators measure a specific activity that is carried out to care for the patient (JCAHO, 1990). Examples might be doing a range of motion test or engaging the patient in a therapeutic activity. Outcome indicators measure what happens as the result of a treatment process (JCAHO, 1990). An example of an outcome indicator is an increase in ADL skills because it is an outcome of the therapy.

Other types of indicators are rate-based and sentinel event. A rate-based indicator measures an even for which a certain proportion of the events that
occur are expected when state-of-the-art care is provided" (JCAHO, 1990, p. 11). Thus the example about ADL skills is not only an outcome indicator, it is also a rate-based indicator because it is expected that some patients will increase ADL skills and a certain percentage of patients (maybe because of the severity of the cerebrovascular accident or its location) will not increase ADL skills.

A sentinel event indicator "measures a serious event that requires individual review for each and every occurrence of the event" (JCAHO, 1990, p. 11). An example of an event that would be unexpected and serious would be breaking a patient's limb during treatment. Any time this occurred, the case, of course, would need to be investigated.

Indicators can also be classified as desirable and undesirable, in which cases the indicator measures an event that is desirable, such as increasing an ADL skill, or undesirable, such as a patient developing contractures (JCAHO, 1990).

Current Initiatives

Much of the work in guideline development has been initiated by professional associations and by the AHCPR. Many of the medical specialty associations, such as the American College of Obstetrics and Gynecology, had been developing and updating guidelines for years. However, in 1989 the AMA initiated the coordination of practice parameters development among the specialties. The AMA developed a list of attributes that parameters should have and established a committee of representatives from major medical specialty associations to evaluate parameter documents, submitted by specialties, for their compliance with the attributes. Although participation in this review process is voluntary, most medical specialties have cooperated with it and are using it as a source of feedback regarding their parameters.

The AHCPR is also developing guidelines; the first published, in March 1992, were the Guidelines on Acute Pain Management, which provide an excellent example. They can be obtained by telephoning the AHCPR. The AHCPR used a process that has come to be the standard for guideline development, combining a comprehensive literature search with expert opinion. In addition to the medical specialties and the AHCPR, guidelines are being developed by other professional associations, such as the American Nurses Association, and health care advocacy associations, such as the American Heart Association.

Although guideline development is being undertaken by many professional associations, it is highly controversial within the professions. The controversy is spurred by clinicians' fear that guidelines or parameters will be too prescriptive and will result in cookbook medicine. It is feared that such prescriptiveness will result in diminished clinical and professional autonomy and that it will too greatly limit the clinician's latitude in adjusting treatment to the patient's individual clinical and social circumstances, ultimately diminishing the quality of care.

Professionals also fear that guidelines will be misused by courts in determining malpractice cases and by payers in narrowing the criteria for reimbursement of services. Despite these reservations, many professional associations predict that guidelines will be required by groups external to the profession, such as payers, and that it is in the best interest of the profession to assume the responsibility for guideline development. By assuming responsibility, the profession will be able to maintain control of the content of guidelines and, hence, will maintain control of an important aspect of professional autonomy.

Hospitals and other health care facilities have been developing clinical indicators for more than 10 years to comply with the JCAHO's accreditation requirements. Often such facilities do not have the resources to develop indicators that have been tested for reliability and validity. Additionally, the practitioners who are expected to develop indicators are sometimes unsure about what indicators are and how to develop them. Nonetheless, they have had to confront the task and have reported varying degrees of success.

However, the interest in clinical indicators is increasing and indicator development is now proceeding on several national levels. As in hospitals and local health care facilities, the methods used to develop indicators vary, but the purpose is consistent, to find accurate and meaningful measures of quality. Implicit in all the indicator projects is the objective of developing databases that are more uniform and relevant to the quality of care. The quality measures currently being developed attempt to include all the dimensions of quality: effectiveness of care, appropriateness of care, safety, continuity, and access.

Some of the current indicator development projects seem to do a better job with particular dimensions than they do with others.

The JCAHO indicator development project has had the most widespread publicity and is the most rigorous in developing indicators that are specific and sensitive to what is being monitored. Over the last 4 years the JCAHO has convened panels of experts to develop indicators for diagnostic categories and procedures and is in the process of field testing the indicators to establish their specificity and sensitivity. However, the JCAHO is developing indicators to demonstrate methodology and formax, rather than to recommend particular elements of care to be monitored. The JCAHO indicators can be obtained from the JCAHO and provide an excellent example.

Indicators essentially outline what data are to be collected. As such, indicator development is related to many of the current health care data collection projects. The Maryland Hospital Association is a notable example. This association is conducting the Maryland Quality Indicators Project which, as of January 1992, consisted of 600 hospital participants in 46 states. The project has developed a list of data elements to be collected by participating inpatient hospitals and ambulatory and emergency departments. The data elements (indicators) were developed by consensus of medical staff and are different from those of the JCAHO in that they are not specific to diagnostic or procedural categories, but reflect more general patient care events that might illustrate the quality of care. A few examples of the indicators are hospital-acquired infections, inpatient mortality, unplanned readmissions, and patients who are in an emergency department more than 6 hours. The project is considered to be primarily a research project at this time to determine whether these data elements are useful in determining quality of care problems and in analyzing those problems.
Another project related to indicator development is the Health Care Quality Improvement Initiative, designed by the Health Care Financing Administration. The project's purpose is to facilitate the implementation of continuous quality improvement in the Medicare program. Basic to implementation is the development of a new data system, the Uniform Clinical Data Set, which collects information on a 10% sample of discharged patients who received services paid by Medicare. The information includes demographic characteristics, history, findings, and treatment. From this information, cases will be selected, via the use of algorithms, for physician review. It is expected that all PROs will be using algorithms by 1994. At the present time, only six PROs are using them (Jencks & Wilensky, 1992).

Most private payers, such as the insurance companies, health maintenance organizations (HMOs), and utilization review companies are also developing criteria and guidelines. Some examples that have used particularly careful methodology are the guidelines developed by the Blue Cross and Blue Shield Association and those of the Harvard Community Health Plan, an HMO.

Occupational therapists who are institutionally based will probably develop indicators as directed by their institution (or hospital) because the JCAHO will soon implement accreditation review based on hospital-wide indicators, rather than the department-focused accreditation reviews. However, if an occupational therapy department were interested in studying quality of care issues within the department, its staff members could develop indicators for that purpose.

Conclusion

Quality assurance is a mainstay in the provision of health care and it is likely that guidelines, indicators, criteria, and other aids to health care decision making and quality of care monitoring will continue to be developed. The methodology used to develop these instruments will continue to be a challenge and will have a great effect on how they can be used. A benefit of the collaboration that is now taking place between organizations is that methodology can be improved to increase the validity and reliability of QA instruments.

Many policy issues accompany the development of QA instruments, especially issues regarding their use and dissemination. The use of guidelines presents a difficult policy issue and is closely linked to the validity and reliability of guidelines. It is questionable whether guidelines can validate and reliably determine the effectiveness of care and whether they should weigh heavily in clinical decisions. Additionally, clinical guidelines and indicators can consider or address cost-benefit and cost-effectiveness of care. These considerations raise enormous ethical questions in clinical decision making. For instance, should a patient who has no private insurance be given, according to guidelines, the least costly treatment, or should cost not be a factor in determining treatment? Another example is to what extent patient preferences should guide treatment. In an ideal situation, guidelines would include patient preference factors, but guideline development might not, at this point, address every factor well.

Another policy challenge is whether clinicians' performance should be evaluated according to guidelines and indicators and, if so, to what extent and effect. If clinicians are to be so evaluated, in malpractice cases, for credentialing and privileges, or for reimbursement of services, dissemination of guidelines and indicators becomes crucial. Dissemination must be planned so that clinicians have fair access to those documents and have a fair opportunity to understand how to interpret them. If guidelines should be used by clinicians, another dissemination problem is how to effect behavioral and attitudinal changes so that clinicians will use guidelines.

Much of the immediate hope is that QA instruments will reduce unexplainable variations in care and unnecessary care, thereby ultimately reducing the costs of care. However, again, variations and unnecessary care can be reduced only if clinicians use the guidelines. Guidelines and indicators can also uncover underuse of necessary care and could in some areas increase use of services. It cannot be concluded, at this time, that guidelines will reduce the costs of care. It is more likely that they will provide important data by which to judge the value of services.

The foregoing is a summary of the most immediate policy issues that accompany the development of QA instruments. These issues are still unfolding and much of the debate toward their resolution is just beginning. However, it appears that quality assurance instruments will be used in the provision of health care and will play a major role in the work of health care professionals, including occupational therapists.

References