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Setting Appropriateness Guidelines for Radiology[1]

In April 1993, the chairman of the American College of Radiology (ACR) Board of Chancellors, K. K. Wallace, Jr, MD, addressed members of the House Ways and Means Health Subcommittee concerning the Clinton administration's 1994 Medicare budget. Dr Wallace indicated that the ACR stood ready to define a system of patient care guidelines for radiology to eliminate inappropriate utilization of radiologic services. He stated that radiologists would take leadership roles in defining the most beneficial procedures for patients and those that are most cost-effective. He proposed that such guidelines would produce substantial savings for the health care system without a negative impact on the quality of care. Dr Wallace's comments summarize the rationale for the formation of the ACR Task Force for Development of Appropriateness Guidelines for Radiologic Procedures. It is my intention to describe the basic principles for setting credible guidelines, which, if followed, will lead to broad acceptance of the guidelines by the health care community at large.

BACKGROUND

There are many factors involved in the current evolution of health care system reform. The underlying theme, however, is economics. Barbara J. McNeil, MD, PhD, of the Department of Healthcare Policy of the Harvard Medical School, recently addressed the subject of imaging technology and reimbursement in the United States (1). She pointed out that health care expenditure for physician services is a substantial factor in the overall rise in health care costs. She also wrote that expenditures for radiology are increasing at a higher rate than expenditures for most other specialties. The practice of self-referral certainly contributes (2–4) to these increases. Self-referral, however, is not the only cause, as the number of hospital procedures (which are performed primarily by radiologists) increased approximately 30%–60% during the 1980s (5). This was corroborated by Sunshine et al (6), who studied Medicare Part B charges and estimated an approximate annual growth rate of 10% between 1980 and 1990.

The Clinton administration's managed competition plan is proposed as the cornerstone of health care system reform. This proposed competitive system is designed to reduce health care expenditures. The introduction of competition will have a marked impact on the practice of radiology. In a recent article, William H. Straub, MD, stated his belief that the fee-for-service reimbursement model will most likely disappear (7). In fact, the transition from the traditional reimbursement pattern to managed care and direct employer-provider contracting is already under way. A recent Health Policy Report published in the *New England Journal of Medicine* (8) includes a description of the "market evolution" that is taking place. In many regions of the country, health maintenance organizations have achieved 30%–50% penetration into the marketplace. In the Minneapolis–St Paul (Minn) marketplace, for example, the penetration has exceeded 50%.

In view of this national trend, Dr Straub's article provides an insightful overview of the implications for radiology. Whether radiologists will remain in a fee-for-service arrangement or will provide services under a managed care system, it is clear that a premium will be placed on the efficient and appropriate use of radiologic services. As economic pressures mount, introduction of unwise cost reduction measures could lead to a decrease in the quality of care. Thus, a logical, systematic approach to resource allocation is preferred.

The ACR has received inquiries from radiologists, hospitals, health care provider organizations, and payers concerning appropriateness guidelines. These inquires underscore a developing trend of recognition of the radiologist as a gatekeeper. In that role, radiologists would be-

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come the decision makers for hospitals and at-risk physician provider groups concerning the radiologic portion of health care.

Radiologists are concerned about accepting this role because of the potential for introducing conflict with referring physicians and because of medicolegal implications. Furthermore, without recognized guidelines for the use of radiologic procedures, there are instances in which market forces may lead to underutilization rather than overutilization of services (9). In the absence of guidelines, entrepreneurs and individuals under contract to insurance companies have begun to emerge as "radiology brokers." They are interceding for payers, promising to establish appropriateness guidelines, and proposing to reduce radiology costs by as much as 30%–50%. This underscores the immediate need to develop nationally accepted, scientifically developed guidelines to assist radiologists and referring physicians. With guidelines at hand, radiologists can perform utilization review tasks and prospective screening without the need for these intermediaries. In fact, the ACR is now beta testing a new software program specifically for purposes of utilization review. Unfortunately, current technology assessment and outcome studies are flawed or nonexistent. Funding is needed for studies pertaining to radiology and the cost-effective use of technology, and future studies will have to be performed with sound scientific technique (10–14).

Just what role should radiologists play in health system reform? Dr James Thrall recently wrote that "radiologists will be increasingly challenged to develop the most cost-effective strategies for the imaging portion of care under their supervision" (15). The leadership of the ACR has decided to meet this challenge by taking a proactive role in establishing appropriateness guidelines for radiology. The first step in the process was formation of the Task Force for Development of Appropriateness Guidelines for Radiologic Procedures.

THE MECHANICS OF SETTING GUIDELINES

The Agency for Health Care Policy and Research (AHCPR) published a Program Note in 1993 that contains a definition of a "practice guideline." A clinical practice guideline is defined as a "systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (16). This document also describes attributes and methods of practice guideline development as proposed by the Institute of Medicine (17,18), for new guidelines or for the review of those that already exist. The following are summaries of these attributes and methods of guideline development. Also included is commentary on the essentials of the guideline statement itself, the use of consensus techniques, the subject of conflict resolution, and the subject of guideline implementation.

GUIDELINE ATTRIBUTES

Clarity.—Guidelines must be unambiguous with clearly defined terms. They should be stated logically and should be easy to follow.

Documentation.—The procedures used in development, the participants, the evidence, and the methods of analysis must be documented.

Validity.—Guidelines are valid if they lead to better outcomes. Validity should be measured on the basis of the methods of evaluation and the quality of the scientific evidence.

Reliability/reproducibility.—Another set of experts should be able to produce similar guidelines when using the same scientific evidence and methods. Different practitioners in similar circumstances should be able to interpret and apply the guidelines consistently.

Multidisciplinary process.—Affected provider groups should have representation in the development process.

Clinical applicability.—Guidelines should include an explicit description of the applicable patient population.

Clinical flexibility.—Guidelines must specify known or expected exceptions.

Scheduled review.—All guidelines should undergo a scheduled review. Each review should determine whether revision is indicated based on current scientific evidence or by consensus of qualified expert panels.

STEPS IN GUIDELINE DEVELOPMENT

The AHCPR has specified mechanisms to be used in the development of guidelines. First, selection of the clinical condition to be addressed should be based on the degree of variabil-

ity of the practice, the relative cost, the potential for morbidity or mortality, the potential for improved care, and the prevalence of the condition. The feasibility of reaching a conclusion and adopting the guideline should be considered, as well. The question should be refined and clarified to be as specific as possible. Scientific evidence should then be accumulated and evaluated for an estimation of the potential of patient care improvement, the morbidity and mortality related to the estimated benefits, and any new costs associated with the change. The initial draft of the guidelines should then be formulated and distributed for external review by affected parties. The final step before dissemination would be to make revisions based on the results of the external review and the analysis of any pretesting that may have taken place. The AHCPR is explicit in its intent that scientific evidence be used as much as possible, but it is recognized that judgment and group consensus will be necessary for many of the development steps.

THE GUIDELINE STATEMENT

Dr David Eddy, one of the leaders in the discussion of health care policy, has provided what he considers an optimal design of a clinical guideline statement, which he refers to as a "practice policy" statement (19). He proposes that each clinical guideline statement include (*a*) a summary of the policy, (*b*) background information, (*c*) a description of the health problem, (*d*) a listing of the health outcome addressed and the economic considerations, (*e*) a description of the scientific evidence and supplemental consensus judgments, (*f*) a quantitative estimation of the impact of the policy on health and economic outcomes, (*g*) methods used in the derivation of outcome estimates, (*h*) a description of the spectrum of preference judgments including the degree of unanimity and the sources, (*i*) instructions for tailoring guidelines for different patients or settings, (*j*) an explanation of conflicts with policies of other organizations and, if possible, reconciliation, (*k*) a description of any other practice policies to which the new policy can be compared, (*l*) a description of factors that could modify the policy, (*m*) a suggested review date, and (*n*) a listing of the authors of the policy, along with their background and any potential conflicts of interest.

Dr Eddy points out that his requirements "might appear stiff" but are justified, as they will result in recommendations that will largely determine what happens to patients.

CONSENSUS TECHNIQUES

Data available from existing scientific studies are often insufficient, for purposes of metaanalysis, in formulating guidelines. Because of this, broad-based consensus techniques are the next best available means for reaching agreement. Fink et al (20) have described the advantages and disadvantages of the available consensus methods (ie, the Delphi and nominal group techniques, the National Institutes of Health [NIH] development model, and Glaser's state-of-the-art approach).

The Delphi technique strives to achieve agreement by consolidating expert opinions by means of serial surveys, which consist of individual anonymous questionnaires. The survey results are tabulated, collated, and distributed after each round. Eventually, opinions are unified to the highest degree possible and the process is considered complete. This technique enables individual, unbiased expression, and it is economical, easy to understand, and easy to conduct. The number of individuals involved is not particularly limited. The disadvantages of the Delphi technique are primarily the loss of stimulation and the lack of personal contact.

Another consensus technique, the nominal group method, brings together representatives of groups interested in the subject area for a highly structured meeting that follows a specific format. Initially, participants list their own ideas on the subject without discussion; then, in turn, they present their highest priority item, and the process is repeated until all ideas have been recorded. The composite list is then presented to the group. The strengths and weaknesses of each item are determined through group discussion. Finally, each attendee ranks the list in writing. The rankings are collated and assessed, and a final list is achieved. The nominal group process is highly dependent on the ability of the meeting leader and on the spirit of cooperation existing within the group. This process has been successful in quality management settings, but it is expensive and limits the numbers of individuals involved. There is disagreement about the validity of this

technique according to Fink et al (20) in that strong personalities have the potential to introduce bias into the conclusions.

The NIH consensus development effort and the Glaser state-of-the-art method (21) have focused on problems related to health care. The NIH uses consensus to reach agreement concerning the appropriate use of medical technology and procedures. Panels of practicing physicians, consumers, and research scientists are brought together under the auspices of the NIH to achieve this goal. The Glaser approach emphasizes techniques that garner broad-based support. Well-known experts and recognized organizations are invited to participate in the process, although the leader is intentionally not an expert on the subject to be addressed and in fact may not be a physician. The individual must have an outstanding reputation with great credibility.

Fink et al (20) delineate basic principles for reaching consensus that are independent of method.

1. Focus on clearly delineated, solvable problems that can be addressed with cost and time efficiency in mind.

2. Synthesize all existing appropriate information in a format that can be understood by the participants and include expert, nonbiased critiques.

3. Select panel participants for their expertise in order to enhance credibility of conclusions. Use consumers when appropriate.

4. Select leadership carefully, based on objectivity and interpersonal skills.

5. Define criteria for consensus in advance, such as a set percentage of the final vote, the consensus after a set number of rounds, a minimum numeric ranking (if such a mechanism is used), or if a conclusion is actively opposed by a threshold percentage of participants.

6. Cultivate broad-based support. Accomplish this by inviting accepted leaders and representatives of national institutions to review and comment on conclusions. Seek financial support from professional societies, private foundations, and government.

7. Effectively disseminate outcomes at national professional meetings, in scientific publications, at continuing educational programs, and through direct mailings. When appropriate, use the media to communicate with the public.

8. Monitor negative and positive outcomes of consensus results.

CONFLICT RESOLUTION

Conflict resolution requires special mention. In 1990, Dr David Eddy addressed a conference dealing with conflict resolution convened by the Council of Medical Specialty Societies (22). He delineated the advantages and disadvantages of bringing together two or more organizations with conflicting opinions on practice policies. On the downside, conflict resolution means more work, possible loss of control, and the "possibility of embarrassment" if guidelines are found to have been incorrectly developed. Advantages, however, include reduced confusion among physicians, patients, and others. Practitioners would not be subject to making judgments of different sets of standards. Arbitration may be necessary, and at times it will be necessary to disagree. The idea of arbitration is a new one and will receive considerable attention and discussion. Independent evaluation of conflicting policies by mutually agreed on sources is recommended.

IMPLEMENTING AND DISSEMINATING GUIDELINES

There is little information available on how to effectively introduce change in practice patterns. Implementation of appropriateness guidelines will not be an easy task. Whenever possible, empiric methods used to determine the practice of medicine in the past need to be replaced by scientifically based practice patterns. This paradigm shift to "evidence-based medicine" requires re-education of today's practicing physicians and a revised curriculum for future generations of medical students (23). Market forces under capitated systems will force physicians and provider organizations to seek ways to reduce costs. The guidelines are likely to become the basis for the development of utilization review criteria for purposes of assessing individual practitioner practice patterns (24). Physicians contracting with managed care plans may be asked to agree in writing to comply with established guidelines. In fact, Blue Cross and Blue Shield of Illinois recently announced they would make adherence to guidelines a requirement of participating physicians.

The ACR plans to distribute completed guidelines throughout the radiologic community by means of direct mailing and publication in bulle-

tins. It is possible that a software version will be developed that can be updated and changed as necessary. The guidelines will also be submitted to radiologic and nonradiologic journals for publication. It is hoped the guidelines will be addressed at professional meetings and continuing medical education seminars. Guidelines with supportive materials will also be distributed to appropriate government agencies, physician organizations, consumer groups, and others. The content will likely be tailored for specific audiences. For example, the completed guideline and all background material will be submitted to organizations such as the AHCPR, whereas consumer groups would receive a modified and simplified brochure.

In summary, the ACR has begun the process of developing appropriateness guidelines for radiologic procedures. By following basic principles of setting credible guidelines, based on the analysis of existing scientific data and broad-based consensus techniques, radiologists will be in a position to play a pivotal role in health care system reform by providing cost-effective radiology without a loss in quality of care.

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