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## **28th BETHESDA CONFERENCE**

### **Practice Guidelines and the Quality of Care October 21-22, 1996**

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***BETHESDA CONFERENCE REPORT*****28th Bethesda Conference: Practice Guidelines and the Quality of Care\***

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## 28th BETHESDA CONFERENCE

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### Introduction

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Until recently, the primary distinguishing characteristic of health care in the post-World War II era has been the explosive introduction of new medical therapies. Today that characteristic is giving way to a marked emphasis on refining medical care to optimize its value for individual patients. This newly prominent task is one that demands processing of large amounts of diverse information—all of which is aimed at considering clinical characteristics of an individual patient, appropriately sequencing decisions and providing services that yield the greatest value (1). Practitioners can accomplish this only if they continually update their own medical knowledge and consistently place newly acquired knowledge in context with existing information to produce a beneficial impact on clinical practice.

Knowledge of basic principles of disease processes and their clinical management—largely provided in medical textbooks and review articles—is essential, but not by itself sufficient, to optimize individual care of patients. Another element, increasingly recognized as also essential for optimizing individual care, is the medical guideline. Guidelines are gaining such recognition because they uniquely provide a coherently sequenced set of recommendations that tightly links specific information sources with specific information uses (2).

The growing interest in medical guidelines has outpaced the standardization of terminology used to characterize their diversity. The words “guide” and “line” were first joined to refer to a physical object, such as a rope that marked the optimal course along a treacherous path. They can be viewed as maps of common paths taken, derived from synthesis of past experience, with annotations that list advantages and disadvantages of reasonable alternatives. Guidelines will of course vary widely from one to another in their characteristics, just as characteristics of maps needed by a long-distance trucking company will differ markedly from those needed by hikers on mountain trails. In other words, the formatting of both maps and guidelines must respond to intended use. Terminology used in this document to refer to some of the most common guideline formats related to cardiovascular care is presented in Table 1.

Medical guidelines typically address either of two primary concerns: 1) *the structure of health care*—emphasizing appropriate facilities, equipment and personnel for delivery of care for specific disorders; and 2) *specific clinical circumstances*—

emphasizing the process of making appropriate decisions and properly rendering needed services.

The 28th Bethesda Conference explored the unifying principles of both of these broad concerns—principles that can aid generalization of medical information into a guideline structure that is most likely to add quality to health care delivery.

A medical guideline is constructed by completing a task that may at first seem simple, but is in fact deceptively difficult. That task, in essence, is to formulate coherent statements of acceptable responses to common clinical situations. But those responses in most cases have been internalized by experienced providers to such an extent that they have become intuitive. These providers, when confronted with a familiar clinical scenario, have little difficulty pursuing a reasonable care plan that is derived from a professional lifetime of internalizing and structuring a large amount of diverse information. Such plans, often referred to as paradigms or common practices, have formed naturally as accumulating experience combines with logic. That means even highly articulate practitioners can articulate these intuitively understood structures only with a reorientation and refocusing of thought.

The largely intuitive application of information in providing clinical care is analogous to the way information is used to drive a car. Both tasks require continuous processing to separate a large amount of irrelevant information (that which describes the general environment and decision alternatives) from the relatively small amount of immediately relevant information (those core elements that are perceived as having an immediate impact on benefit and risk). Information in the domain considered most urgent drives the cognition that directs response to the current specific situation. When behind the wheel, for example, a speeding driver who has been paying attention to road signs in order to identify an urgently needed rest stop will involuntarily and instantaneously cease this activity and slow his vehicle on spotting a police patrol car. A similar process, demonstrating a similarly tight linkage between information need and information source, forms the core content of a guideline recommendation—and is similarly easy to visualize but difficult to express.

The core task of the guideline development process is to use knowledge derived from specific information sources to construct a coherent set of generalizations that serve information needs in specific health care delivery situations (Fig. 1).

**Table 1.** Definition of Guidelines

Term	Definition	Example
Guideline	A related set of generalizations derived from past experience arranged in a coherent structure to facilitate appropriate responses to specific situations	Trail map
Health care guideline	A guideline related to any aspect of medicine, including healthcare process, policy, regulation, financing, administration, education and clinical practice	Guideline for technology assessment
Clinical practice guideline	A guideline developed to aid practitioner and patient pursuit of the most appropriate healthcare responses to specific clinical circumstances	AHCPR guideline for diagnosis and management of unstable angina; ACC/AHA guideline for management of the patient with acute myocardial infarction
Care plan	A clinical practice guideline detailing the usual sequence of decisions and nature and duration of services for a defined episode of care	Care plan for coronary artery bypass graft surgery
Care module	Focused descriptions of care delivery for conditions that often occur as a component need of many care plans for different primary illnesses and for which specific recommendations are influenced little by the character of the primary illness	Care module for management of acute atrial fibrillation in patients admitted to the hospital
Critical pathway	The core set of decisions and services described in an appropriate sequence and schedule most likely to effect an efficient, coordinated program of treatment	Description of the critical features of the care experience essential to most efficiently manage the usual patient undergoing coronary artery bypass graft surgery

ACC = American College of Cardiology; AHA = American Heart Association; AHCPR = Agency for Health Care Policy and Research.

Common sources of specific information useful in formulating guidelines include clinical studies, patient care experiences, general medical knowledge, clinical databases and results of using previously adopted related guidelines (Fig. 1).

Guideline development and use require precise characterization of information under three interrelated descriptors of content: care process, disease severity and time. The last two of these domains are familiar to the clinician: The *time relationship* of medical information may be described in real time or by event occurrence, such as defining a sequence of care before or after cardiac catheterization. *Disease severity*, on the other hand, is usually described by prognostic markers, for both the primary and comorbid disease.

Medical guidelines that address care delivery introduce an additional domain of information that relates to structure and/or process in health care delivery:

1. *Structure* is defined to include the qualification of personnel and types of facilities needed to support care delivery for specific disorders. Examples of guidelines that are primarily concerned with descriptions of the structure of care delivery include those that address credentialing of providers, the need for referral to a more comprehensive care environment and

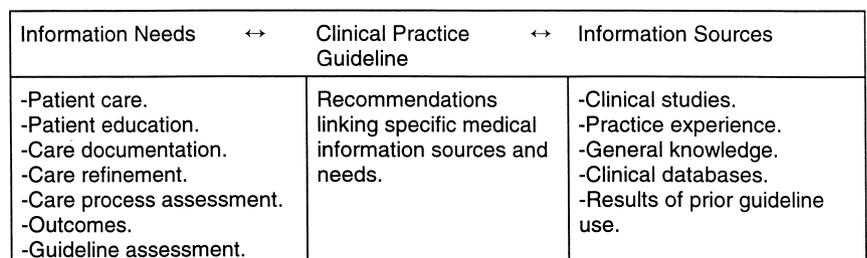
the assessment and application of medical technology. Typically, such guidelines implicitly assume the process of care delivery to be optimal.

2. Guidelines directed primarily to the process of health care delivery commonly address care decisions (doing the right thing) and optimal delivery of those services (doing the thing right), while implicitly assuming the proper structure to be in place.

Three of the five task force reports presented at the 28th Bethesda Conference address structure; two relate directly to process. The reports address issues that apply directly to the development and implementation of clinical practice guidelines, as well as guidelines for credentialing practitioners, specialty referral and regulation of medical technology.

This Bethesda Conference explored and defined contemporary principles for formulating and using medical guidelines that share the common objective of enhancing the quality of cardiovascular care. To achieve this aim, broad input from diverse interested parties was sought. Among these were organizations representing managed-care plans; private groups, such as the Institute of Medicine; professional societies representing both generalists and specialists; coalitions of

**Figure 1.** Clinical practice guidelines as unifying generalizations of information.



patients; and many government organizations, including the Agency for Health Care Policy and Research; the National Heart, Lung and Blood Institute; the Department of Veterans Affairs; the Library of Medicine; the Health Care Financing Administration; and the Food and Drug Administration.

The task force reports that follow, therefore, reflect not only the initial efforts of appointed writing groups, but also the broader input gained from the entire conference. We hope that these discussions and recommendations, as guided by the American College of Cardiology and the American Heart

Association, will provide a broad framework for the ongoing development and use of guidelines by the cardiovascular community.

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### Character and Uses of Clinical Practice Guidelines

Clinical practice guidelines are developed primarily to serve patient care needs. Other uses are secondary in importance (1). Guideline recommendations focus on the usual management of the average patient with a specific disorder and are not expected to be applicable to every patient because of the complexity of human biology and the fragmented nature of medical knowledge. Guidelines are used most effectively when the linkage to the underlying evidence is described, so that any necessary deviations from usual practice can be placed in proper context. Guidelines may serve to reduce practice variation, enhance care continuity, and improve interprovider communication during the care process, especially when decisions are made and services rendered by multiple providers and in different care settings (2,3). Guideline statements of common medical practice also provide starting points for patients and providers to discuss care options most consistent with individual patient needs and preferences (4,5).

Medical guidelines highlight critical clinical information needed at the major decision points in disease management and therefore define the core content of the medical record (6). Explicit, standardized definitions characteristic of good guidelines, encourage consistent entry of this information into the medical record and thereby facilitate meaningful comparison of quality and costs of care among institutions and practitioners. The burden of care documentation can also be diminished by incorporating templates of commonly used order sets or notes in a form that can be easily individualized for each patient.

The quality of a guideline is measured in terms of clarity, clinical applicability, and flexibility both for the individual guideline recommendations and for their coherent integration into a functional form (7). These attributes and the reliability and reproducibility of a guideline are assessed objectively by quantitating their impact on measured outcomes of care. Results of guideline assessment provide useful information to aid revision and continuous improvement of the instrument (8).

Clinical practice guidelines may be created for a variety of cardiovascular conditions and procedures. The final form of a specific guideline will be determined by the projected scope of

the topic and its intended audience and uses. General principles basic to the guideline development process can be defined that are readily adaptable to the needs of different guideline development situations. This document offers such a guideline for the development of clinical practice guidelines that appears well suited to the needs of the American College of Cardiology (ACC) and the American Heart Association (AHA). The principles described can readily be adapted by other groups for other specific uses.

A comprehensive process beginning with consideration of development of new clinical practice guidelines for common cardiac conditions and ending with a process for continuously improving these guidelines based upon results of their implementation can be divided into eight discrete phases defined by the general sequence of work objectives. These phases are described separately to facilitate communication of specific recommendations most appropriate to the principal work objective of each phase, with the realization that the actual process will represent a continuity of phases that overlap in time and contribution by different individuals.

### Guideline for Development of Clinical Practice Guidelines

#### *Phase 1. Administrative Oversight*

**Task 1.** Responsible individuals from organizations contemplating guideline development identify the specific goals of the guideline to assure that expectations are consistent with the basic mission and resources of the organization.

**Task 2.** Knowledgeable experts prioritize possible guideline topics based upon the number of patients affected, the seriousness of the condition, and the magnitude of change in health outcomes likely to result from adherence to the proposed practice guideline.

**Task 3.** A literature review is conducted to better define the scope of the topic, anticipated development costs, and timeline for completion of each phase of work.

**Comment on phase 1 work.** Underestimating the scope of the task is a common problem in guideline development. The production costs should be matched with the long-term benefit

expected by the developing organization. Topics should be selected to fit needs, and redundant guideline development efforts must be avoided. To avoid duplication, the ACC and AHA should provide all interested parties with a list of planned and ongoing cardiovascular guidelines.

The cost of development of a clinical guideline is determined primarily by the extensiveness of literature review, the quality of evidence synthesis, travel, and publication costs. Existing guidelines differ greatly in the number of citations supporting the recommendations and on the processes used for retrieval, review, and evaluation of those citations. Although extensive literature review and distillation should yield the best guideline, the most cost-effective methods for doing so have not been determined. Guidelines developed by the Agency for Health Care Policy and Research (AHCPR) have usually cost about \$1,000,000, and much of this cost was incurred by the extensive literature review conducted. Analysis of literature review for three early guidelines developed by this group suggest that only 1%–5% of the 6,000 to 18,000 references reviewed were ultimately cited in the final document, suggesting that this approach could be shortened (Cahn M, Jones RH. Personal communication, 1996). Many professional societies have developed guidelines using member volunteers supported by a small professional staff at a cost ranging from \$10,000 to \$200,000. These less expensive approaches streamline the literature review by combining references cited by recent high quality review articles on the clinical topic, to which more recent articles are added by focused literature reviews and expert panel knowledge of the literature.

### *Phase 2. Select Expert Panel*

**Task 1.** An expert panel balanced for diversity of experience and expertise, must be motivated and possess group interaction skills. They must also commit to the timeline for work completion.

**Task 2.** The expert panel should be convened by e-mail, teleconferencing, or videoconferencing to discuss the initial guideline development plan and suggest further work to be completed before the first face to face meeting.

**Task 3.** The expert panel should revise or accept the topical outline and begin the design of a patient flow algorithm and consider the step-by-step guideline recommendation linkages to identify areas of controversy as a basis for focused literature review.

**Comment on phase 2 work.** An ideal clinical practice guideline development process joins information distilled from the scientific literature with knowledge of expert practitioners to form the set of recommendations that are specific, precise, coherent, and comprehensive. The paucity of hard data evaluating efficacy of treatments for most conditions and the complexity of placing the evidence that does exist in proper clinical context, argues for evidence to be evaluated by experts who know both the strengths and the weaknesses of clinical study methodology. Conditions or procedures for which little scientific evidence of efficacy exists are often also those in

greatest need of practice guidelines, which must be derived primarily from expert opinion.

An expert panel should include practitioners with intimate familiarity with the clinical realities of patient care and expertise in evaluating the quality of the scientific evidence. Cardiovascular specialists bring knowledge essential to contextualizing information about cardiac conditions. Members of other related specialties who care for cardiac patients bring a broad clinical perspective. Primary care physicians, such as internists, pediatricians, and family practitioners, contribute unique insights.

### *Phase 3. Literature Search and Evidence Gathering Review*

**Task 1.** A computerized literature search constrained by publication time and language should focus on key words most likely to yield articles related to guideline topics of greatest controversy.

**Task 2.** All relevant abstracts related to each topic should be matched to the guideline outline and coded by an index of study design (A = randomized trial or meta-analysis; B = well controlled clinical study; C = other clinical study).

**Task 3.** Results from relevant articles should be compiled into evidence tables that include the best evidence available for each topic. Class C evidence should be reviewed for those topics without class A or B evidence.

**Task 4.** Evidence should be reflected by precise wording of each recommendation to emphasize the importance of each recommended action, and an associated strength of evidence code should correspond to the highest level of evidence available.

**Comment on phase 3 work.** The completeness of the search is determined primarily by the number of key words used, the publication date, and publication language. The cost-effectiveness of the search product will be enhanced by a detailed outline of the full guideline to organize key words and to use general knowledge of the literature to identify times and languages most likely to yield major scientific contributions. For example, a literature search on a procedure might focus on only that time when the procedure became clinically mature. Conversely, some of the most important natural history key words might also be searched during an early time period before newer treatment modalities altered the natural history of a disease. Commercial software programs facilitate abstract review and organization.

The full scientific studies must be reviewed by one or more individuals to evaluate the strength of study methodology and clinical relevance. Published meta-analysis of good quality can be used as published or updated by more recent trials. Randomized trials not suitable for meta-analysis and good clinical studies are often best synthesized using an evidence table. These tables are designed to compare study results by properly weighing differences in study methodology and the manner of reporting results. The major difficulty in using nonrandomized data is that physician bias in selecting alternative treatments

may be difficult to separate from intrinsic therapeutic efficacy. The major concern about the use of conclusions from randomized trials relates to the generalizability of results to a broader population than that included in the trial. A number of quantitative schemes have been advocated to grade "evidence" in the scientific literature, but none has evolved as standard. However, all evidence based guidelines should explicitly describe the methodology used.

All schemes used to relate evidence to individual guideline recommendations should convey the magnitude of difference of the alternate care strategy recommended and the certainty of this difference. The strength of a recommendation therefore relates most to the benefit or harm expected if a recommendation is followed or ignored. The strength of a recommendation can be conveyed by precise and consistent use of language, especially verbs such as "must," "should," or "may be considered." Alternatively, a predefined numeric code, such as that used by ACC/AHA (Class I, II, III\*) may rank the strength of each recommendation. The certainty of a recommendation relates to the strength of the scientific literature or expert opinion or both.

It seems intuitive that strong recommendations would be those with a large amount of evidence. However, some of the most obvious components of care delivery that are uniformly considered necessary, such as putting pressure on a bleeding site or performing a history and physical examination, have not been and are unlikely to be subjected to rigorous scientific testing. Therefore, a strategy that separates these two components of recommendation validity may appear contradictory on the surface, with recommendations using the words "should always" also having weak strength of evidence. Conversely, some recommendations may clearly state there is no difference between two therapeutic alternatives, with a strong strength of evidence grade, if a number of randomized trials support this conclusion.

#### *Phase 4. Consensus Process*

**Task 1.** Guideline authors must converge upon specific positive or negative recommendations by consensus or by a confidential vote using an explicit process that ensures an equal voice for each participant when controversy exists.

**Comment on phase 4 work.** Many recommendations can be made with little discussion and unanimous consent. However, panel consensus on controversial recommendations should be addressed by a structured process using confidential voting to eliminate pressure to conform and to reduce the dominance of forceful personalities or authority figures. This process also serves to document the extent to which consensus existed after

the issues were discussed. Users of guidelines often benefit as much from knowing when experts disagree as knowing when they agree.

The most objective approach to quantifying expert opinion has been the RAND appropriateness scale (9, 10). This score has been used primarily to quantitate expert opinion about appropriateness and necessity of alternative treatment strategies (where a 9 indicates a clear positive action, 1 indicates a clear negative action, and 5 indicates an equivocal situation). This scoring system provides an approach to separate magnitude of benefit from certainty. If every panel member grades a decision as 5 making a mean of 5, the group seems certain that there is no difference between two therapies. However, a mean of 5 could also result from half the panel assigning a 9 score and the other half a 1 score where the statement of no clear benefit would be made with much less certainty.

"Negative" recommendations—a judgment that a service is not indicated—are as valuable as positive recommendations. When it is possible to make unambiguous statements, they have great value. When it is not, then the lack of consensus or agreement that "we don't know" is important information for practitioners.

The process for developing guidelines, including the methods for analyzing the evidence, selecting panel members, and distilling group judgments into specific recommendations, should be monitored and approved by the appropriate authorities of the convening body. The credibility of professional society guidelines is enhanced by the objectivity of a thorough outside review. The process of incorporating results of this review into final approval by the panel should be described.

#### *Phase 5. Computerize Guideline Documents in Format for Clinical Use*

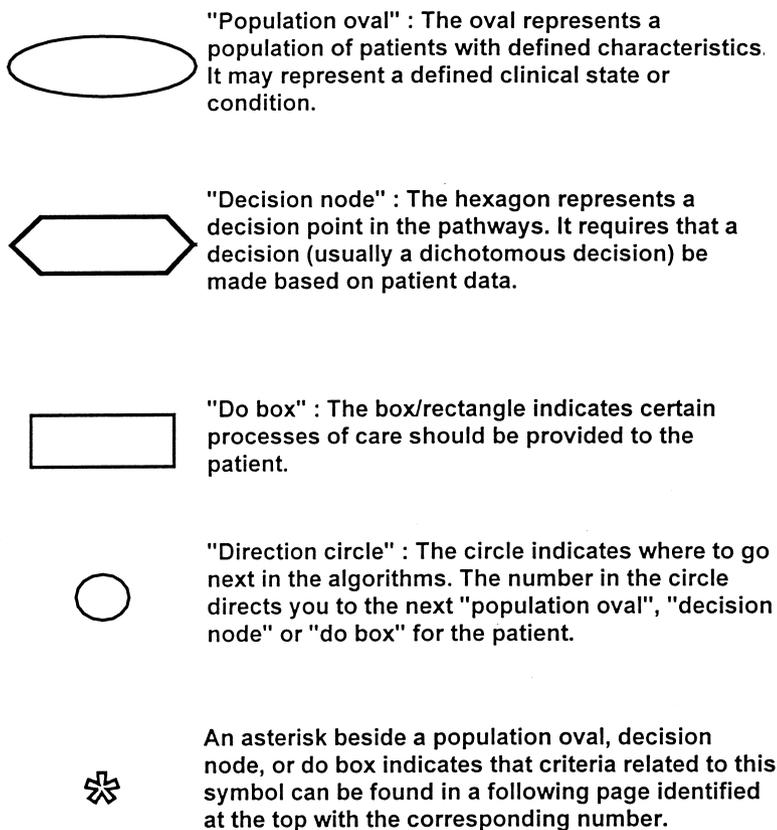
**Task 1.** Authors should construct a computerized form of the core guideline that links sequenced recommendations with related branching information trees constructed in hierarchical levels.

**Task 2.** A computer program organized by the core guideline algorithm should be prepared to capture information needed to create clinical notes, orders, and care records for common phases in the care delivery process that use preformatted information templates to simplify data entry.

**Task 3.** A computer program should be developed to link information from important variable fields in clinical notes into a structured database suitable for assessing adherence to guideline recommendations and monitoring performance measurements.

**Comment on phase 5 work.** Computerization promises to enhance the usefulness of clinical practice by facilitating three aspects of use. The most basic reason to convert text into electronic form is the ease of storage and transmission from physical compression of the document. However, a more meaningful organization of guideline documents results when information is arranged in hierarchically related information trees. This form of information storage permits users to search

\*Class I = conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective. Class II = conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. Class III = conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective, and in some cases may be harmful.



**Figure 1.** Standardized symbols for displaying guidelines in graphic algorithmic format. The **oval**, which appears at the beginning of each flow diagram, defines the population of patients under consideration. The **hexagons** are dichotomous decision nodes, which have one arrow (group of patients) entering and two leaving. An arrow going to the right from the decision node indicates the group of patients defined by a yes or positive response to the question posed, whereas an arrow going down indicates patients defined by a no or negative response. The **rectangle** summarizes a recommended process or set of diagnostic and/or therapeutic processes of care for the designated group of patients. Each oval, hexagon, and rectangle is numbered sequentially from top down and left to right. The **small circle**, which always contains a number, indicates that the sequence of care skips to the next hexagon or rectangle with that number. The **asterisk** indicates that a set of detailed criteria (for decision nodes) or processes of care are contained in an appended table numbered the same as the hexagon or rectangle. Reprinted, with permission, from Society for Medical Decision Making Committee on Standardization of Clinical Algorithms. *Med Decis Making* 1992;12:149-54.

on items of interest and retrieve topically oriented information at any level of detail appropriate to immediate needs. For example, information on aspirin use in patients with acute ischemic heart disease syndromes might be organized around specific recommendations so that users might branch into specific details of evidence cited related to dosage or route of administration. Moreover, detailed expert opinion about the relative risk and benefits of aspirin in patients who also have a comorbid disorder such as peptic ulcer disease might be explored in a level of detail that would not be reasonable in printed documents. However, the most compelling reason to computerize guidelines is to fully integrate guideline recommendations with the care process in real time by prompting entry of information on well defined clinical variables at the point of care. This structure will simultaneously generate notes and orders while prospectively recording information for later analysis by quality of care instruments. The current state of development of computerization of guidelines demonstrates that all of these potential uses are feasible.

Guideline computerization requires delineation of a core algorithm describing the usual order of patient management. Constructing this algorithm during the guideline development process is facilitated by identification of a coherent linkage of guideline recommendations. Clinical algorithms are guides to the stepwise evaluation and management strategies that include 1) ordered sequences of steps of care, 2) required observations to be made, 3) decisions to be considered, and 4)

actions to be taken. Clinical practice guidelines in an algorithmic format have been shown to be more effective in achieving guideline compliance than those in the usual narrative format (11-16). Multiple interlocking algorithms related to discrete phases of care are often more useful than a single extensive algorithm. Figure 1 illustrates a standard set of symbols for graphically displaying the ordered sequence of care adopted by the Society for Medical Clinical Decision Making (17). An algorithm requiring discrete yes/no decisions for specific patient circumstance may be difficult to develop but is basic for successful linkage of the clinical practice guideline to a medical information database (18).

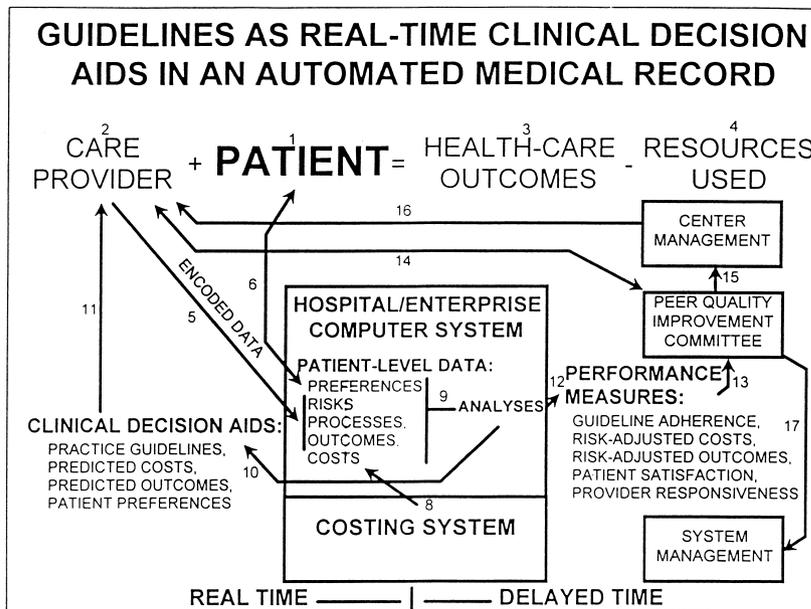
### *Phase 6. Test and Revise Guideline*

**Task 1.** The expert panel or their representatives should evaluate the computerized form of the guideline during actual patient care to assess the clarity and reasonableness of each recommendation applied during actual clinical care.

**Task 2.** Deficiencies of the guideline identified by initial limited use should serve as the basis of final revision of the guideline in a final printed and computerized version.

**Comment on phase 6 work.** Although the graphical, algorithmic format simplifies content and aids comprehension of guideline principles, many recommendations that appear reasonable when read prove unworkable in clinical practice. For guidelines to become a regular part of clinical decision making,

**Figure 2.** The Veterans Health Administration conceptual model for using a computerized guideline has as its center the patient (point 1) interacting with a care provider (point 2). This interaction results in measurable healthcare outcomes (point 3) minus healthcare resources used (point 4). Data representing the prespecified, minimum information content describing the patient-care provider interaction is input (arrow 5) in encoded format (continuous or discrete variables), as opposed to the commonly used free-form, narrative format. The patient may also enter encoded information describing his/her illness and preferences for care (arrow 6). The data input in encoded format are used in the logic required to retrieve patient specific practice guidelines and other clinical decision aids (arrows 9 and 10) for delivery in real-time to the point-of-care (arrow 11). A by-product of this approach to documentation of care is a clinically detailed database that can be used for quality assessment and improvement, health system management, and research. The right half of Figure 2 illustrates how this database might be used. The first step is aggregation across groups of patients (e.g., defined by medical center) and analysis to produce risk-adjustment of outcomes and costs (arrow 12). After review and interpretation by the peer quality improvement committee (arrow 13), the data should be sent to the care provider for comment. Data made available to medical center and system management (arrow 15) may prompt communication with care providers (arrow 16).



they should be incorporated smoothly into the usual activities of care delivery and recognize the need for variation of care for specific patients (19,20). Some of these variations in processes of care should be reflected in the guideline content to enhance clinical applicability. Incorporation of the guidelines into an electronic medical record offers the advantages of storage of individual patient data which can drive retrieval and display of a guideline based upon characteristics specific to the illness of that specific patient (Fig. 2) (21). Figure 2 illustrates the conceptual model of how an automated medical record might incorporate practice guidelines as a real-time, point-of-care clinical decision support tool. Integration of care documentation with care delivery facilitates extraction of performance measures.

### Phase 7. Disseminate Guideline

**Task 1.** Disseminate the guideline in full and summarized printed forms and in appropriate computerized forms.

**Task 2.** Encourage use of guideline content in a computerized version that facilitates customizing and revising by users while retaining functionality of databasing and assessment of frequency of adherence to major guideline recommendations.

**Comment on phase 7 work.** A printed or computerized version of a guideline with uniform content is useful in the role of a medical textbook, but the guideline is more likely to find direct clinical use if it can be adapted to local practice while

retaining core content (22). A program permitting practitioners to customize a guideline to their own use within an acceptable boundary of variation might be effective (23).

### Phase 8. Revise and Refine Guideline

**Task 1.** Maintain ongoing annual literature review by adding new evidence and revising the wording or strength of evidence grading of corresponding recommendations.

**Task 2.** Use data from guideline use to define management strategies based upon risk stratified outcome variables.

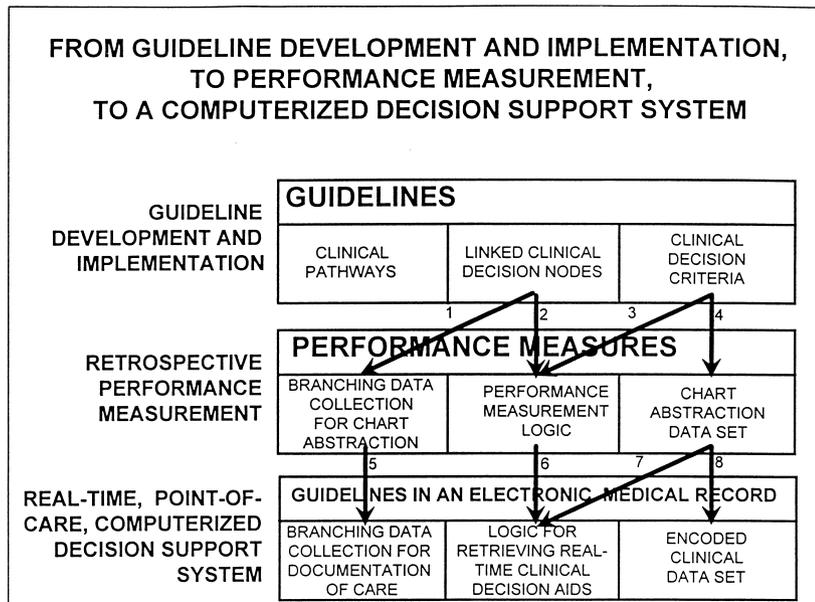
**Task 3.** Develop increasingly explicit guideline paths for management decisions that are supported with good outcomes.

**Comment on phase 8 work.** Improvement of the quality of care is the only justification for implementing clinical practice guidelines. Clinical data acquired during clinical care directed by a guideline can be used both to assess the quality of care delivered and the quality of the guideline used (24).

## Overview of General Principles of Assessment of Quality of Care

### Evolution of Quality of Care Assessment

Evaluation of quality has always been an integral part of good medical practice. Practitioners regularly assess the appropriateness of their decisions and monitor the outcomes of patients under their care. The thoughtful review of care by



**Figure 3.** A relationship exists between practice guidelines and performance measures. Performance measures consist of three parts: 1) a chart abstraction data set, 2) logic statements that use the chart abstraction data set to categorize the status of a performance measure in a given patient, and 3) branching data collection so that every data element does not have to be collected for every patient. The chart abstraction data set is derived directly from the clinical decision criteria (**arrow 4**). The performance measure logic is derived from clinical decision node criteria and the flow diagram showing the linked, dichotomous, clinical decision nodes (**arrows 2 and 3**). The structure for branching data collection is derived from the flow diagram (**arrow 1**). The automated medical record/computerized clinical decision support system may be derived from the practice guideline in an algorithmic format. The encoded data set (minimum information content) is derived from the clinical decision criteria of the guideline (**arrow 4**) and the chart abstraction data set of the performance measure (**arrow 8**). The logic required for retrieving the real-time clinical decision aids is derived from both the chart abstraction data set and logic of the performance measure (**arrows 6 and 7**), whereas the design of the branching data collection can be derived from the linked clinical decision nodes of the guideline (**arrow 1**) and the performance measure branching data collection (**arrow 5**).

individuals or small groups of healthcare providers remains the cornerstone of quality of care efforts. No integrated approach for consistent review of quality of care has been universally accepted. Early quality improvement efforts often used random screening of a fraction of medical records to identify noncompliance with specified targets. This emphasis on the identification and justification of occasional outliers from accepted principles of care delivery ignored information describing usual patterns of care which better reflect quality in most patient care settings. The opportunity to make good care even better was lost. Quality assessment programs designed to identify care deficiencies proved expensive, burdensome and effective only in identifying low quality care. The punitive aspect of this approach to quality assessment often prompted practitioners to concentrate excessively on the way information was entered into the medical record. Physicians were occasionally tempted to treat the patient's chart so as not to be judged as providing deficient quality of care.

Evaluation of quality of care has been redirected more recently toward the primary goal of providing healthcare practitioners with information that might be used to improve the overall quality of care, with a secondary goal of identifying deficient care. Methodology to accomplish these goals is still evolving, but initial work has identified a number of attributes of evaluation programs that enhance quality of care. The best programs are voluntary and not compulsory, and the incentive for implementation by practitioners is recognition that the resulting information is likely to make care more effective and less costly. Standardized definitions are essential to appropri-

ately characterize important clinical variables, especially those that relate to the severity of illness at the time of presentation. Evaluation programs must be applicable to an increasingly complex set of medical technologies and systems where patients may be transferred among different practitioners and different care environments to receive care for a single illness. The cost of evaluating the quality of healthcare has the potential to exceed the cost of care actually provided, and priority must be given to developing evaluation instruments that are inexpensive and largely invisible to good practitioners. This implies that, whenever possible, information used to evaluate quality should be that routinely obtained during patient care (Fig. 3).

#### *Relationship of Clinical Practice Guidelines to Quality of Care Assessment*

The purpose of both clinical practice guidelines and evaluation instruments is to increase the quality and value of healthcare (25). Clinical practice guidelines provide definitions of clinical conditions and outline commonly used care strategies. This organization of information facilitates the development of objective instruments to evaluate quality of care. While the guideline explores the rationale and evidence behind recommendations for care, the evaluation instruments turn the guideline recommendations into quantifiable measures of care actually provided. Evaluation instruments may be structured to assess compliance with all guideline recommendations under the assumption that the uniform application of these recom-

**Table 1.** Definition of Quality of Care Terms

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<b>Medical review criteria:</b> Statements of specific patient care processes or outcomes developed to monitor appropriateness of healthcare
<b>Outcome performance measures:</b> Statistical tools that appropriately adjust factors which influence observed outcomes but are outside the control of healthcare providers
<b>Outcome performance measurements:</b> Quantitative statements of outcomes of care given by individual healthcare providers, groups of healthcare providers, healthcare institutions, or healthcare systems adjusted by performance measures for comparison with specified standards of quality to indicate quality of patient care being evaluated
<b>Process performance rate:</b> The frequency with which a specified process of care is followed in actual practice
<b>Standards of quality:</b> Quantitative statements of the goal or range expected for outcome performance measurements or process performance rates calculated for a specific medical review criterion when applied to care received by a defined patient population

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recommendations will enhance quality of care. However, a more practical approach emphasizes the major recommendations of guidelines, especially those well supported by scientific evidence, to identify aspects of care most likely to relate to overall quality. The use of evaluation instruments provides data from actual clinical practice that can be used to validate or revise the guideline recommendations from which these instruments were devised, thereby providing a framework for continuous improvement in the organization of information used in patient care.

### *Structures, Processes, and Outcomes as Quality of Care Indicators*

Terminology related to instruments used to evaluate quality of health care is defined in Table 1. Appropriately structured support systems must be in place to permit delivery of high quality health care. Indicators of these structures of care describe the availability of appropriate personnel, resources, and care environments. The components essential to the structure of care are often explicitly specified in the clinical practice guideline. Therefore, the evaluation of process and outcome indicators of care delivered by the guideline is undertaken with the assumption that the structure of the care delivery system is appropriate.

Process indicators include decisions made or services used in the course of diagnosis and treatment of patients. Process indicators describe the clinical practice guidelines recommended response to a specific set of clinical circumstances. These indicators are most useful for evaluating quality when applied to well defined individual steps of care, but are less effective indicators of quality for evaluation of complex management decisions requiring subtle clinical judgment.

The degree of compliance with process indicators measured by these evaluation instruments is dependent upon the com-

pleteness of the list of exceptions to the indicator which account for variations in clinical circumstances among patients. The more extensive the list of exceptions to the indicator, the more likely that compliance with that indicator will approach 100 percent. However, exhaustive descriptions of possible exceptions to the process indicators increase the complexity and cost of evaluation efforts. Therefore, descriptions of process indicators that include most common clinical exceptions will produce a usable instrument. The one exception that applies to all indicators is patient refusal to consent to the recommended treatment.

Outcome indicators are measures of the clinical result of care that has been determined by the structure or process of healthcare delivery. Improved outcomes usually result from improved structures and processes of care. The outcomes of care valued by patients and practitioners include survival, freedom from disability, reasonableness of cost, and satisfaction with the processes of care.

Simple tabulations of observed outcomes may be used to compare changes over time in care environments with reasonably constant patient populations. However, the use of unadjusted outcomes to compare quality of care given by different providers or healthcare systems is usually not appropriate, since outcomes may also be influenced by patient characteristics unrelated to the quality of care rendered, such as severity of illness, comorbidity, and age. Therefore, raw outcomes data must usually be adjusted for patient-based factors which are beyond the control of the healthcare provider if they are to be used as comparative indicators of quality. Failure to make these adjustments may bias providers against involvement with high-risk patients, who are more likely to have negative outcomes. When appropriately adjusted, outcome measurements can be compared to standards of quality and become a valuable tool for quality of care assessment.

Adjustment of outcomes data to control for severity of illness requires that a consistent set of data be collected and that valid statistical methods be used to adjust observed outcomes for baseline differences in populations. Variables of importance in patients with cardiac disease often include those relating to general health status, such as age and comorbid disease, and those specifically related to the severity of the cardiac disorder, such as coronary anatomy and left ventricular ejection fraction.

Process and outcome indicators have intrinsic strengths and weaknesses which must be considered in designing an ideal system for evaluation of quality of care. Simultaneous attention to both outcome and process indicators avoids the risk that providers may emphasize the desired documentation of process descriptions in the medical chart and decrease the feeling of responsibility for the ultimate outcome of the patient. Quality improvement programs must never encourage providers to improve process indicators at the expense of care focused on the needs of the patient.

Those who develop clinical practice guidelines are urged to simultaneously suggest specific outcome and process measures that can be used to evaluate quality of care for the disorder

addressed by the guideline. These measures will usually derive from recommendations that may be made with the strongest evidence. Additionally, the practicality of acquiring valid data for these assessments must be considered. Outcome measures are most applicable to groups of providers who treat large populations of similar patients. Process performance rates reflecting individual provider compliance with a guideline recommendation provide an indicator of quality, even for those who manage only a few patients with a disorder.

### *Appropriate Uses of Quality Indicators*

Quality indicators should be designed to meet the needs of specific care environments. Resources available for quality improvement initiatives should be devoted first to those areas of care which have the greatest potential for improvement. However, the areas of patient care requiring attention will vary by the setting and the sophistication of the quality improvement program. For example, the focus of quality improvement may be specific and well-defined, such as the perception that aspirin is being underutilized in the care of patients with unstable angina. Regardless of the complexity or simplicity of the evaluation program, it is important to state the goals and purpose of the program at the outset so that appropriate indicators can be selected. Proper use of these indicators in continuous quality improvement efforts is likely to greatly improve the care of patients with cardiac disorders.

### *Possible Future Uses of Quality Indicators*

All medical decisions regarding alternate strategies for diagnosis and management of patients balance potential risks and benefits. Excessive attention to only one side of the risk and benefit equation necessary to optimize a single measurement of performance may detract from overall quality of care. Therefore, future approaches to assessing the quality of healthcare are likely to balance values derived from more than one individual quality indicator. For example, it would be inappropriate to monitor only the rate of untoward events in patients evaluated for unstable angina but not admitted to the hospital without also monitoring the number of patients with an admission diagnosis of unstable angina that proved incorrect. Even a simple, apparently obvious indicator of quality, such as a low in hospital mortality rate for unstable angina, cannot be used as an isolated measurement of performance. A low mortality rate might reflect high quality but also could be achieved by admitting a high proportion of patients without coronary disease or by transferring high-risk patients to other institutions. The use of appropriate combinations of several performance indicators will generally best grade the overall quality of care given to such patients.

## **Conclusions/Recommendations**

The processes for developing effective clinical practice guidelines have been refined in the last decade and reviewed.

It is recommended that ACC/AHA follow these general steps: 1) prioritization of topics; 2) expert panel selection—to include both content experts and more generalist practitioners; 3) focused literature review and compilation of meta-analyses and evidence tables; 4) ranking of evidence; 5) specifying group processes, including confidential voting; 6) developing algorithms and computer-based products; 7) pilot testing; 8) development of performance measures; and 9) dissemination and updating. Additionally, it was recommended that the ACC/AHA maintain an inventory of guidelines planned and underway and share this information with all other potentially interested parties, with the aim of promoting cooperation and limiting duplication.

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## Task Force 2: Guideline Implementation

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The ultimate goal of guideline development is to improve care as manifest either in better patient outcomes or increased efficiency. Accomplishing either of these goals requires changes in physician behavior—a challenge that has proven difficult for several reasons, including the intense demands on physician time and, in some settings, incentives that encourage increased resource use. Implementation of guidelines therefore requires consideration of issues including:

- How can information be disseminated most effectively?
- If education alone is not sufficient to achieve the goals of the guidelines, what other strategies can be used?
- What is the impact of practice profiling?
- Can “real-time” interventions such as critical pathways allow integration of guidelines into routine care with a minimum of disruption to the physician?
- What are the medicolegal implications of guidelines?

Although there are limited data available on several of these issues, it is clear that no single implementation strategy is appropriate or likely to be successful in all settings. One major reason is that there are a variety of types of guidelines. Some describe general principles of care, while others define in great detail an optimal management plan. Others still describe ambitious targets, such as ideal lengths of stay or the time within which thrombolytic therapy should be administered.

The implementation strategies for these guidelines is also likely to be influenced by who developed them and who will be using them. For example, guidelines for the appropriateness of procedures that have been developed by government-sponsored groups or professional societies are most useful for their definitions of *inappropriate* care. These guidelines tend to have a broad definition of the indications for a test that can be considered definitely or possibly appropriate. A similarly broad

definition of appropriateness also usually characterizes the protocols used by payers to “precertify” elective procedures, because the consequences of classifying a procedure as inappropriate is denial of payment, which is sure to generate tension between the payer and the physician or patient.

In contrast, guidelines used *within* provider organizations do not necessarily have such dire consequences if a case does not meet certain criteria. For example, if a patient does not meet appropriateness criteria for a cardiac procedure, the next step may be a conversation between the patient's physician and a local medical director. Or, if a patient does not meet the target length of stay of a critical pathway, the consequence is not denial of payment for the last few hospital days, but rather scrutiny of the patient's clinical and nonclinical issues by the provider team. In that setting, stricter appropriateness criteria and more ambitious length of stay targets can be applied.

Regardless of the purpose or source of a guideline, a constant challenge is how to disseminate its contents, gain the support of physicians, and provide incentives for physicians to follow the recommendations. These incentives may include direct financial rewards or the avoidance of certain negative consequences, such as citations from quality assurance committees or identification as a cost outlier by a medical director. Thus, the goal of the guideline and the incentives created to encourage adherence greatly influence the method of guideline implementation.

### Educational Strategies

Traditional efforts to disseminate practice guidelines have relied upon passive, impersonal methods, such as publication of the recommendations in medical journals, but the impact of purely educational strategies is limited at best. Published information in the medical literature on randomized trials has

been shown to lead to changes in practice patterns (1), but implementation has been far from comprehensive for cardiovascular interventions that have been clearly shown to be beneficial in these studies. Well-designed studies in both primary care and inpatient studies have also shown that simply exposing physicians to clinical information and recommendations can achieve only modest changes (2-4). Distribution of printed materials alone has been shown in several investigations to be ineffective in reducing use of contraindicated antibiotics and other inappropriate prescribing patterns (5,6).

More success has been achieved with strategies that bring educational messages more directly to the attention of practicing clinicians. One such strategy is face-to-face consultation on a specific topic, which is often called "academic counterdetailing." The main principles behind this approach are to

- Conduct surveys to determine baseline knowledge, motivation, and barriers to implementing the practice guideline.
- Focus efforts on categories of physicians with practice patterns most at variance with recommendations.
- Establish credibility through a respected organizational sponsor.
- Provide authoritative, unbiased information and present both sides of controversial issues.
- Stimulate two-way discussion.
- Use concise graphic educational material.
- Repeat and reinforce a small number of desired behaviors.

Several studies, including one large randomized controlled trial, have shown that this approach can reduce inappropriate prescribing patterns and blood transfusions (5-7).

Because academic counterdetailing is expensive and must be targeted narrowly on a few specific issues, an alternative strategy employed in some organizations is the identification of physician opinion leaders as change agents. Opinion leaders are those physicians whose practice patterns—such as the adoption of a new drug or test—tend to be quickly adopted by their peers. Methods have been developed to identify physician opinion leaders through survey tools (8). One large Canadian trial demonstrated that opinion leaders in community hospitals were able to increase rates of trials of labor by 46% (as opposed to routine cesarean section) without adversely affecting maternal or fetal outcomes (9).

### Directed Physician Interaction

Although education alone may not be "sufficient" to cause change in physician behavior, it may still be "necessary" to build a foundation for other strategies. These other strategies tend to confront physicians with information and recommendations that are more specific to individual patients and their own practice patterns. During the last two decades, several researchers have evaluated interventions, including retrospective provision of information, profiling of institutions and

individual physicians, and "real-time" measures in which physicians are provided with recommendations at the moment when decisions must be made. Available data indicate that the effectiveness of these interventions varies widely, and, in all probability, physicians in many health care organizations are likely to be exposed to combinations of these interventions in the future.

### Retrospective Feedback

Direct feedback of information to physicians can achieve further improvements, but the magnitude and durability of the effects of such feedback have been limited. This approach usually relies upon audits of medical records, and presentation to physicians of profiles of their past practice as well as those of peers compared with standards based upon guidelines. Prior evaluations of such feedback have yielded mixed results (2), and some data indicate that feedback is more effective for *increasing* use of a recommended service than *decreasing* use of inappropriate services (10).

In a study based at a teaching hospital, medical residents improved the efficiency of their test ordering strategy during an intervention based upon concurrent chart review and discussion, but the impact of this intervention "washed out" after the intervention was concluded (11). Furthermore, this intervention was not considered sufficiently practical to be implemented as part of routine care at that institution—at least in the fiscal environment of the late 1970s.

Other data have raised questions about the effectiveness of "utilization review" as a method of collecting and feeding back retrospective data. For example, one study examined the impact of a temporary substitution of "sham" review for half of the participants in New York City's fee-for-service health insurance plan, while the remainder of the enrollees received care including actual utilization review (11). During an eight month study period, there was little evidence that actual utilization review decreased resource use.

In summary, retrospective feedback is most likely to be successful

- if led by clinical leaders known to the physicians;
- physicians are able to act upon the information;
- physicians received repeated feedback; and
- feedback is coupled with small group discussion.

### Practice Profiling

Physician and institutional profiling of clinical outcomes and length of stay is becoming increasingly common in both the public and private sector. Perhaps the best known initiative is the program in New York State in which the Department of Health has been collecting and disseminating information on coronary artery bypass graft surgery (CABG) since 1989. After adjusting for severity of illness, there was a decrease in mortality from 4.17% in 1989 to 2.45% in 1992 (12). The causes for this change are controversial, and hypothesized causes include

- Increased coding of comorbid conditions so that the predicted risk of surgery for individual surgeons and medical centers has increased.
- “Out-migration” of sicker patients to other states because New York State surgeons were reluctant to perform surgery.
- Discouraging surgery for higher risk patients even if their outcomes were likely to be better with surgery than medicine.

However, at least some data suggest that patients may be seeking care from more experienced surgeons who have lower complication rates. During the 1989–1992 period, the percentage of patients in New York State undergoing CABG by “low volume” surgeons (50 or fewer operations per year) decreased by 25%, and the mortality rate for low-volume surgeons fell by 60% (13).

Public initiatives are not limited to data on clinical outcomes. Other variables that are being collected and disseminated include length of stay, overall satisfaction with care, and compliance with quality standards. These quality standards tend to emphasize “process” variables, such as performance of cholesterol assays and mammography according to established guidelines. In addition, provider organizations and payers collect and analyze even more detailed information on physician and hospital efficiency and quality.

The rapid increase in use of physician profiling has been accompanied by several examinations of the limitations of available methods (14,15), ethical issues (16), and legal issues (17). For example, many individual physicians do not have a sufficient volume of patients in any one diagnostic category to allow meaningful analysis of their outcomes or resource use. Therefore, these profiling tools are often considered more appropriate for evaluation of a system of care, rather than any single physician.

Although controlled data on this subject are sparse, some research indicates that physician profiling is effective in reducing resource use. For example, one study found that introduction of physician-specific length of stay data at one hospital was followed by increases in the percentage of physicians who met benchmark goals, and that changes in length of stay were most pronounced for physicians who initially had the longest lengths of stay. Furthermore, reductions in lengths of stay occurred predominantly in patients with an intermediate severity of illness, and in the diagnoses with the largest economic impact (18).

In summary, several studies have documented marked variation in practice patterns between regions of the country and among individual physicians (19). Despite concerns about methodological limitations and potential abuses (20), the use of practice profiling seems likely to grow in both the public and private sector. The response to these data may be influenced by the highly variable financial relationships between payers and physicians (21).

### *Real-Time Implementation*

To achieve greater impact from guidelines than has been accomplished through education and practice profiling, many organizations are seeking to integrate guidelines with routine care using strategies such as decision aids and *critical* or *clinical pathways* (22,23). These “real-time” strategies—which seek to intervene at the moment when the physician is making key decisions—recognize the transient impact on practice patterns of information or recommendations.

Some data indicate that just making physicians aware of costs can decrease resource use. In one study, physicians at an academic primary care medical practice were informed of the charges for outpatient diagnostic tests by computer as these tests were ordered. During the intervention period, charges for tests fell 13% compared to a control group of physicians without any evidence of an increase in adverse outcomes. However, the impact of this intervention diminished during a 19-week follow-up period after it was discontinued (23).

Adoption of guidelines by physicians may be influenced by the content of the guideline, the implementation strategy, and the incentive system. Unfortunately, most studies examining practice guideline implementation to date have been performed prior to the widespread proliferation of managed care and capitation as a form of reimbursement for services provided. In the past, there were no direct financial incentives for physicians to follow practice guidelines. Since the use of capitation and physician “report cards” is now becoming more widespread, it is possible that many previous research findings regarding the success and failure of practice guidelines may no longer be relevant.

Although there are few prospective trials of the impact of implementation of critical pathways or practice guidelines, available data indicate that these should be evaluated as is true of any medical intervention. For example, retrospective data at one institution suggested that a practice guideline would safely reduce the cost of caring for patients with pulmonary edema and congestive heart failure (24). However, when the guideline was implemented and studied prospectively (25), it was found to increase lengths of stay and probably costs (an effect that was opposite of what had been predicted based on the retrospective study). Other previously published decision aids may also have clinical effects that are contrary to what would have been predicted based upon observational studies and hypothetical experiments.

Low-intensity strategies (e.g., education, written feedback) are of great interest—but unproved effectiveness—as a method of real-time dissemination of practice guidelines and prediction rules. On the surface, these strategies are inherently attractive because they are less intrusive, less confrontational, more likely to be approved by physician committees, and less costly. In a study with a time-series design, written information was concurrently provided to physicians regarding appropriateness of hospital admission and level of care for patients with acute chest pain (26). The information was provided on stickers without direct person-to-person interaction. This

method of providing information was not associated with a statistically significant change in patient care. Although the decision aids used to provide the information appeared to be very promising in retrospective studies, when disseminated using a low-intensity strategy, there were no improvements in patient care.

Another study of patients with acute chest pain examined the use of a decision aid that had been previously found to result in significant improvements in patient care when the information was presented to physicians by a research assistant (27). In a prospective, controlled trial, this information was used by physicians for only 2.8% of eligible patients. In a follow-up survey of the six physicians participating in the study, all of them believed that the predictive instrument did not provide them with information they did not already have and all recommended that the predictive instrument no longer be used for patient care. Therefore, the scientifically validated decision aid probably resulted in no significant benefit when disseminated in this manner.

Higher intensity—and more intrusive—guideline dissemination strategies have proven to be more effective. In a study of patients hospitalized with chest pain in a health maintenance organization, education, endorsement of a guideline by opinion leaders, and concurrent feedback using cues by nurses was used as the implementation strategy (28). This feedback was delivered verbally via telephone or in person. This approach was associated with a reduction in total length of stay from  $2.51 \pm 2.1$  versus  $1.96 \pm 1.3$  days (22% reduction,  $p = 0.03$ ). The reduction in length of stay for this condition exceeded the reductions in length of stay for several other conditions during the study period. Moreover, no adverse effect on serious complications or the hospital readmission rate was detected.

Other studies examined concurrent feedback of information by a respected physician as a dissemination strategy (29,30). Implementation of a guideline in this manner led to a 0.91-day reduction in hospital length of stay ( $p = 0.02$ ) and a total cost savings of \$1,397 per patient (direct and indirect costs summed together) ( $p = 0.03$ ) (29). There was no significant difference in hospital complications, complications following discharge, readmission rate, and patient satisfaction when measured 1 month after hospital discharge. The estimated cost savings was almost 15 times the cost of the intervention. Importantly, when concurrent person-to-person feedback was withdrawn, practice reverted back to patterns that had been present prior to the intervention, demonstrating that person-to-person feedback rather than widespread dissemination of the guideline was responsible for the observed effects. A second study evaluating the timing of transfer of patients out of the coronary care unit yielded similar findings (30).

Similar findings on the potential benefit from such direct interventions were reported by Eagle et al. (31) in a teaching hospital setting, where guidelines were developed for the management of patients with chest pain, pulmonary edema, and syncope. Practice guidelines were disseminated by direct person-to-person feedback (cardiologist to house staff) and

weekly review of patients. The provision of guidelines by direct feedback resulted in length of stay reductions of 1.2 days and increased compliance with the guidelines. There was no difference in mortality or hospital readmission rates.

In another study involving person-to-person delivery of information, a research assistant provided physicians with the probability of acute ischemic heart disease for individual patients (32). This intervention was associated with a decrease in patients not having acute ischemia hospitalized in the coronary care unit of 30%. The percentage of coronary care unit admissions that were classified as patients without acute ischemia decreased from 44% to 33%. Therefore, provision of risk information in this manner was associated with a significant change in physician behavior.

### *Critical Pathways*

Critical pathways have been borrowed from industry where they have been used as management techniques, and recently emerged as strategies for improving the quality and cost-effectiveness of medical care (23). These pathways are distinct from the practice guidelines developed by organizations such as the Agency for Health Care Policy and Research (AHCPR) and the American College of Cardiology (ACC) and the American Heart Association (AHA) in that they tend to be aimed at the achievement of a few resource use and/or quality goals. They can potentially represent the translation of the recommendations from a practice guideline into actual clinical practice. Unfortunately, there are very few available data regarding the effect of clinical pathways on patient care. Furthermore, many of the available studies have serious methodological limitations (23), but “case studies” suggest that this strategy has such potential that pathways are being implemented at many if not most institutions.

In one study, a critical pathway was implemented through a multidisciplinary effort of cardiac surgeons, anesthesiologists, nurses, case managers, dieticians, and physical therapists (33). Introduction of the critical pathway was associated with a reduction in total length of stay ( $11.1 \pm 6$  days versus  $7.7 \pm 2.3$  days,  $p < 0.0001$ ). The mean hospital cost was reduced by \$1,181 after implementation of the critical pathway (14% reduction in direct costs per patient,  $p < 0.0001$ ). There was no statistically significant difference in postoperative mortality and hospital readmission rates.

Another critical pathway technique was used to address the postoperative care provided to children with congenital heart disease. Implementation of the pathway with attention to key decision points was associated with significant reductions in length of hospital stay (34,35). Reductions in lengths of stay were achieved without compromising mortality, morbidity, readmission, unscheduled emergency room visits, or a negative family assessment of care. The critical pathway was associated with a decrease in length of stay without evidence of compromised patient outcomes.

An important issue in the development of any program aimed at improving the efficiency and quality of care is whether

all protocols and pathways must be developed locally, or whether national groups might be able to supply such guidelines. The similarity of the pathways and protocols in place at many institutions suggests that a national body might be able to provide the basic structure of a pathway, but the need for local "buy-in" suggests that the users of these pathways should have the opportunity to revise and update them.

Another important issue for the implementation of pathways or protocols is the need for a readily available approach for instances in which the patient and/or his or her physician do not agree with the recommended strategy. An appeals mechanism that provides rapid and well-considered responses is critical for the acceptability of any such program. Ideally, the discussion in these cases should not focus on whether a proposed intervention should be "denied," but rather on which of the available alternatives would best serve the patient.

Although considerable energy and teamwork are required to develop and implement a critical pathway, the greatest gains can come from using these tools as "sensory organs" to describe variations in the care for patients with a specific syndrome. Collection of data on when "variances" from a pathway occur can be used to identify physicians who vary in practice patterns from their colleagues, or instances in which the lack of availability of systems resources (e.g., weekend exercise testing) limits the ability of physicians to apply the recommended strategy.

*In conclusion*, the provision of guideline and protocol information via a high intensity intervention (e.g., person-to-person feedback) has often been associated with significant changes in physician behavior for patients with cardiac conditions (28-32). In an environment without direct financial incentives, the provision of guidelines via written information and education alone often failed to produce sustained changes in clinical practice (26,27). These findings in cardiology are entirely consistent with observations regarding the implementation of guidelines for other conditions (2,36,37). In general, high intensity strategies are much more likely to be effective, while low intensity strategies may have very limited effectiveness.

Research on practice guideline implementation is extremely limited. First, many of the studies have focused on hospital admission rates and length of stay in the acute care hospital. There is even less information known about the effectiveness of cardiology guidelines to sustain changes in patient care unrelated to length of hospital stay. Second, much of the research has been performed in urban, academic teaching hospitals. Moreover, the targets of the feedback were often house staff, who may respond differently to feedback from an attending physician than a peer (intimidation may have been a factor). Third, in some studies it is difficult to disentangle the effects of the guideline from secular trends that were occurring independently of the guideline. Finally, more comprehensive studies of patient outcomes are essential. Although length of stay may be reduced, less is known about the effects of this apparent reduction in costs on other important patient outcomes, such as discharge location (are patients

discharged to a rehabilitation facility or a nursing home rather than their own home?), care following discharge from the hospital, functional status, and patient satisfaction.

## Medicolegal Considerations

Practice guidelines represent standards of care, and therefore are potentially highly relevant to medical malpractice litigation in which the issue is whether treatment rendered by the defendant fell within an appropriate standard of care. Some health care reform advocates support use of guidelines as a strategy for *decreasing* malpractice risk and lowering health care costs. Since guidelines allow standards of care to be more clearly articulated, uncertainty surrounding the appropriate standard of care can be reduced or even eliminated. This clarity might help physicians meet the standard of care if the guideline is implemented effectively, and reduce the need of physicians to practice "defensive medicine," whereby costly tests or procedures that are not medically necessary are ordered as a defensive posture to a potential medical malpractice suit.

Despite this optimistic assessment, the few data available suggest that the overall impact of practice guidelines on malpractice litigation is complex. Guidelines have been used by both plaintiffs and defendants in malpractice litigation for over a decade, but only a fraction of medical malpractice cases come to trial. A recent review of 259 litigation files found that 17 involved the use of practice guidelines, and these guidelines were twice as likely to be used against the defendant as for the defendant (38). However, information from guidelines might also persuade an attorney not to take a case; or lead a plaintiff to seek an early, lower settlement. Hence, case files provide a biased assessment of the impact of guidelines.

A more balanced assessment of the impact of guidelines was provided in the same study (38) through a survey of approximately 600 attorneys whose area of interest is medical malpractice. Over 25% of the plaintiffs attorneys claimed that a factor in their decision not to take a case was the existence of a guideline favorable to the defendant. A similar proportion (31%) claimed that guidelines unfavorable to the defendant influenced them to take a case. Over 25% of attorneys who responded to the question indicated that they had been involved in a case that had been settled because of a guideline. Thus, guidelines appear to be influencing malpractice litigation in ways both favorable and unfavorable to the defendant and health practitioner.

Additional data were recently provided by a computerized search of cases (39) published from 1980 to 1995 that mentioned any of the 57 professional societies, agencies, or other groups that were listed as guideline sources in the 1992 edition of the American Medical Association's *Directory of Practice Parameters*. This search yielded 52 cases. In 26 cases, guidelines were used successfully by the plaintiff, and in 8 cases guidelines were used successfully by the defendant. "Successfully" in this context does not refer to the ultimate outcome of the case, but to the fact that the particular issue before the court involving

standard of care was decided in favor of the party relying on the guideline as evidence. In the remaining 18 cases, guidelines were unsuccessfully cited by plaintiffs in 12 cases and defendants in 6 cases. Cardiology societies were not among the sources of guidelines cited in these cases.

### *Admissibility of Guidelines Into Evidence*

The survey of malpractice attorneys (38) indicated that guidelines are generally viewed as admissible evidence, but at least two jurisdictions have specifically disallowed guidelines on evidentiary bases. For example, in *Stang-Starr v. Byington* (248 Neb. 103, 532 N.W.2d 26,28 [Neb. 1995], the court held that the testimony of the plaintiff's expert on the contents of an American College of Obstetrics and Gynecologists technical bulletin was inadmissible as hearsay. In other words, the court did not consider the guidelines direct testimony from the expert panels that had developed the guidelines. However, at least one court has held, in affirming a directed verdict for the defendant, that standards admitted into evidence by themselves and not through an expert witness do not require that the standard of care be established by expert medical testimony (*McAnn v ABC Insurance Co*, No. 93-CA-1789 [La. App. 1994].

Even if a guideline is admitted as evidence and presented through an expert witness, a review of case law indicates that courts will exercise discretion in determining the weight to be given the guideline in question. For example, in *Washington v. Washington Hospital Center*, 579 A.2d 177,182 (D.C. 1990), the court held that the guidelines constituted the standard of care—despite arguments by the defendant that the guidelines of the American Society of Anesthesiologists relied upon by the plaintiffs were only “emerging,” and were not “mandatory,” but instead “encouraged.” In contrast, in *Shuford v. McIntosh*, 104 N.C. App. 201, 408 S.E.2d 747 (N.C. Ct. App. 1991), the court refused to admit a pamphlet entitled “Standards for Ambulatory Care” into evidence, stating that the pamphlet appeared to offer recommendations rather than standards of care.

To date, the absence of recommendations for the use of a test has not provided protection for defendants against suits claiming that the test should have been performed (*Short v. U.S.*, Civ. No. 1:93CV233 [Dis. Vt. 1995]), but the increasing number of guidelines addressing a wide range of topics may cause the absence of recommendations to carry greater weight in the future.

*In summary*, experience to date indicates that courts vary markedly in their interpretation and consideration of guidelines. Factors that appear to influence the courts' use of guidelines include the intent of the guideline and its drafters, the situation in which it is to be applied, the general acceptance within the medical community, the cost of compliance, and its consistency with the existing standard of care. Guidelines clearly represent a two-edged sword for defendants involved in malpractice litigation. Available data suggest the certainty of

greater reliance on such guidelines in medical and legal communities in the future.

## Conclusions

Although practice guidelines and critical pathways are sometimes perceived as a threat to autonomy and intellectual growth for physicians, they are potentially tools for improving quality of care. That potential remains incompletely realized, and can only be achieved through collaboration among specialty and primary care physicians and other parties in the health care system. Practice guidelines should never supercede physician judgment in the care of individual patients; they are tools that cannot be expected to be relevant to all patients because of the variability in patients' problems and preferences. However, practice guidelines can be useful in discussions between physicians and patients of alternative management strategies. Properly developed and applied, practice guidelines and critical pathways may help physicians enhance their influence over quality of care.

A variety of methods for guideline dissemination and implementation have been used. Unfortunately, there is relatively little research to guide us on the most effective methods by which the goals of guidelines should be achieved. Most of the evidence that is currently available is based on either an anecdote or at best systematic observational study. Nevertheless, the evidence that does exist provides several general principles regarding guideline implementation:

1. Physicians appear to prefer guidelines that are simple, including those which use clinical decision algorithms or graphs rather than extensive, full-text documents.
2. Guideline implementation strategies that lead to repetitive exposure and/or reinforcement are more effective in influencing outcomes than those that are simply disseminated passively without reinforcement.
3. Guidelines that are delivered through opinion leaders are more likely to be followed than those that do not include such authorities among their advocates.
4. Practice guidelines supported by evidence from clinical trials are more likely to be adopted by physicians.
5. The provision of feedback to clinicians on their performance is likely to enhance adherence to practice guidelines. There may be considerable costs involved in the collection of these data; hence, the variables measured should be carefully selected, and data collection should be incorporated into routine processes to the extent possible.
6. The incorporation of practice guidelines into tools involved in the delivery of routine care (e.g., order sets) will most likely facilitate their implementation.
7. The major cultural shift that must accompany optimal use of practice guidelines suggests that their content and theory should become a major focus of training for physicians and other health professionals.
8. Provision of information to patients on practice guidelines

and critical pathways is likely to improve compliance with pathways and patient satisfaction.

It is also likely that nonclinical factors, including changing financial incentives or fear of litigation, may play a major role in determining the impact of guidelines. Unfortunately, data measuring the impact of these types of incentives are lacking. These incentives should be addressed explicitly as part of efforts to implement guidelines in any setting.

### Recommendations

- The ACC/AHA should consider strategies, including possible development of an Implementation Committee, to support appropriate implementation of practice guidelines in cardiovascular medicine.
- The ACC/AHA should develop core data elements to measure compliance with practice guidelines related to quality of cardiovascular care, and define the methods for collection and analysis of these data.
- The ACC/AHA should promote and set standards for development and implementation of practice guidelines that
  - are available in multiple formats and in simplified versions to facilitate clinical care, research, and/or education in the broadest range of settings;
  - develop and implement methods for evaluation of practice guidelines and critical pathways;
  - are sufficiently flexible to allow for local modification; and
  - support collection of performance data and documentation.
- The ACC/AHA should take steps to support health care providers in the development of practice guidelines and critical pathways. These steps could potentially include coordination of sharing of pathways among institutions; critical review of pathways on a clinical topic; or synthesis of critical pathways on a clinical topic into a strategy endorsed by the ACC/AHA.
- The ACC/AHA should support the incorporation of information on and use of practice guidelines into the training of physicians and other health professionals.

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## Task Force 3: Guidelines for Credentialing Practicing Physicians

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Credentialing and recredentialing of practicing cardiovascular specialists are emerging as increasingly important activities of hospitals, health maintenance organizations (HMOs), physician provider organizations and other medical organizations. Many of these organizations, as well as insurance companies, have also developed guidelines for clinical competency, many of which contain minimal and optimal volume and outcomes standards recommended for securing clinical privileges to perform various procedures. Inherent in many of these guidelines for credentialing is documentation of specialty or subspecialty certification, granted by recognized national organizations such as the American Board of Internal Medicine (ABIM). Recertification has been undertaken by such organizations more recently to ensure ongoing acquisition of knowledge deemed necessary for providing excellent care. Procedural competency, however, is still predominantly in the domain of local credentialing and privileging bodies at hospitals, HMOs or other physician-hospital organizations.

In this review, the major issues pertaining to physician credentialing and privileging are discussed, and recommendations for possible future initiatives are provided.

There is no doubt that the American College of Cardiology (ACC), the American Heart Association (AHA) and the various cardiology and cardiovascular surgery subspecialty organizations will become more involved in developing guidelines for clinical and procedural competency. The national cardiovascular organizations will be asked to publish competency standards that are evidence-based and endorsed by

experts. The processes for guideline development in this area, particularly when new technology emerges, await clearer definition.

### Certification Processes

Many U.S. organizations provide certification of professional accomplishment. The most prominent among those dealing with physicians is the American Board of Medical Specialties (ABMS), an umbrella organization comprising 24 independent certifying boards, including the ABIM. The ABMS certification process is linked to the Accreditation Council for Graduate Medical Education (ACGME), which sets standards for residency and fellowship training in each specialty and subspecialty. Only physicians who finish their training in programs approved by the ACGME (or the Royal College of Physicians and Surgeons of Canada or the Professional Corporation of Physicians of Quebec) can apply for certification by ABMS boards. The ACC recognizes the ABMS Boards as the preferred organizations for certification of its members.

Certification by ABIM recognizes excellence in the discipline of internal medicine, its subspecialties and areas of added qualification. The ABIM certification process is voluntary; lack of an ABIM certificate does not prevent one from practicing. Approximately 86% of those finishing approved residency training programs are ABIM certified within six years of completing their training. Indeed, many noncertified physi-

cians have completed specialty or subspecialty training and are currently practicing.

The ABIM requires certification in internal medicine prior to certification in cardiology. Certification in an added qualification, such as clinical cardiac electrophysiology or interventional cardiology, requires a valid certificate in the underlying discipline of cardiology.

The ABIM works in partnership with the training program directors, who must verify the requisite training for each candidate before he or she is admitted to an ABIM certification examination. Candidates are rated annually by their program directors on component skills judged to be essential to providing excellent care. Candidates whose skills are rated unsatisfactory by the program director are not admitted to the ABIM examination (1).

ABIM examinations are valid and reliable and are constructed by expert physicians, medical editors and psychometricians. The relevance to practice of each question is rated by an outside group of practitioners in the discipline (2). The standard for passing is an absolute score. Examination scores are positively correlated with program director ratings, and the practices of certified internists receive higher ratings than do those of uncertified internists (3).

Whenever the ABIM develops a new certification process in a new area, there is a five-year period during which "grandfather" physicians—established experts with little or no formal training—may apply. After this period, formal training in an ACGME-approved program is required to sit for a certification examination.

Although the ABIM does not directly test technical competence in procedural skills, it has worked with program directors and subspecialty societies to develop a list of procedural skills to be mastered during training. Program directors must validate the mastery of those skills directly as a prerequisite for certification. For cardiovascular training, ABIM requires skill in advanced cardiac life support; electrocardiography; ambulatory monitoring and exercise testing; echocardiography; cardioversion; arterial catheter insertion; and right heart catheterization, including insertion and management of temporary pacemakers. The ABIM does not prescribe the number of times procedures must be performed to ensure competency, but "Documentation may be provided by a procedure card, computer record, or logbook . . ."

The ABIM offers a certificate of "Added Qualification in Clinical Cardiac Electrophysiology for Diplomates of the Cardiovascular Diseases Subspecialty Board," for those who have completed an additional year of approved electrophysiology training and who have successfully passed an examination. The technical skills needed in this field are validated by program directors who can directly attest to the candidates' competence. In the future, the Board will establish a specified minimum number of electrophysiology procedures for all candidates. For this purpose, the Board "prefers to use a uniform set of quantitative standards that is widely endorsed and accepted by the subspecialty community."

ABIM certification of the added qualification of interven-

tional cardiology was recently approved by the ABMS. A specified minimum number of procedures will be required to establish eligibility. The ABIM and others are investigating the promise of new techniques that might permit direct testing of procedural skills.

All ABIM certificates issued after 1990 are time-limited: The duration of certificates in internal medicine, cardiology, clinical cardiac electrophysiology and interventional cardiology is now 10 years. Recertification is required to revalidate certificates. It consists of three steps: a self-evaluation process, assessment of clinical competence and a written final examination (4).

The need for professional standards and the desire on the part of physicians with special expertise to be recognized has led to the development of a variety of certification-type programs outside the ABMS. Some of these programs are sound; others are flimsy at best. In cardiology, several non-ABMS groups offer challenging exams for the purpose of recognizing special expertise. The North American Society for Pacing and Electrophysiology (NASPE) has given their NASPEExam® for many years. It is a test of knowledge predominantly regarding cardiac pacing. It is not a certifying exam; a letter documenting the successful completion is sent to those who pass.

The American Society for Echocardiography (ASE) has developed ASEeXAM®, a test of interpretative skills and knowledge of echocardiography. This test is open to all physicians. Passing this test results in a certificate of "Special Competence in Echocardiography."

The Certification Council for Nuclear Cardiology, an entity separate from the Society for Nuclear Cardiology, plans to offer an examination to validate competency in nuclear cardiology techniques. This process will be open to all qualified physicians (5).

The ACC has responded to the need to improve skills for electrocardiography by developing an educational process (ECGSAP) and examination (ECGEXAM) for electrocardiographic (ECG) interpretation. It is available to all physicians. An individual's pass/fail status is determined by an absolute standard and is reported to the examinee. The ACC plans to reassess this new effort after further experience.

ECGSAP/ECGEXAM is a valuable experiment that is testing "new waters." It raises most of the issues central to this Bethesda Conference and deserves more exploration by the ACC and, perhaps, the ABIM. For example, traditional evaluation bodies such as ABIM are required by the ABMS to couple certification with at least one year of ACGME-approved training. This makes cross-specialty recognition of component technical skills difficult. Development within the ABMS of common evaluation programs for internists, surgeons, family practitioners and emergency physicians, to name a few with overlapping skills, is therefore problematic. On the other hand, the ACC traditionally has been an educational institution and has little experience in processes that could be considered "certification."

**Table 1.** Initial Credentialling Process

	Academic (n = 28)	Urban (n = 39)	VA (n = 2)	Rural (n = 6)
I. Initial General Cardiology Credentialling				
1. Hospital credentials committee	27	37	2	6
2. Autonomous: yes	15	27	1	6
3. General cardiology privileges require board eligibility/certification	23	32	1	1
4. Proof of training by				
Training director	26	36	2	4
Chief of service	26	36	2	5
5. Does hospital administration participate in documentation	20	34	2	5
6. Approval of hospital privileges by executive committee and/or board of directors	22	35	2	5
II. Initial Credentialling for Procedural Cardiologists				
7. Logs required for training	14	15	2	1
8. Use of national guidelines	16	27	0	5
9. Local modification of national guidelines	22	32	1	5
10. Proof of training	24	37	2	4
11. Adherence to national guidelines for				
Echocardiography	17	17	0	1
Echocardiography/Doppler	16	17	0	1
Nuclear cardiology	16	20	0	1

VA = Veterans Affairs.

## Local Hospital Credentialling of Physicians

### Overview of the Credentialling Process

The literature in cardiovascular medicine is replete with descriptions of training program requirements to prepare cardiovascular specialists for the practice of cardiology. Content and duration of training programs have long been established by the ABIM. Verification of training and skills to satisfy board-eligibility requirements is provided by training program directors as well as section and department chairs. Confirmation of board certification and, now, recertification—established by passing specialty board examinations—is provided by the ABIM on request. This information, available for every individual completing (or not completing) a cardiology training program, would provide a local hospital credentialling committee pertinent information to establish criteria to judge acceptability of applicants initially applying for hospital privileges.

How often is this information being used by hospitals in the credentialling process? One might assume it would be applied universally, to satisfy the credentialling process established by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for hospital medical staffs. This process reads as follows (6):

The medical staff is responsible for the credentialling process. This credentialling process includes a series of activities designed to collect relevant data that will serve as a basis for decisions regarding appointments and reappointments to the medical staff, as well as delineation of clinical privileges for individual members of the medical staff. Although the specific information used to make decisions regarding appointments

and reappointments is at the discretion of the individual organization, the range of information used should be explicit. In addition, within, and at the discretion of, an organization, the specific information required for appointment may differ from the information required for reappointment. The required information should include data on qualifications such as licensure and training or experience, and data on actual performance that is collected and assessed initially in an ongoing process.

This provides a format for the individual hospital credentialling committee to decide what information is used and the process through which it is passed.

There is very little documentation in the literature as to how often this process is followed at the local hospital level.

### Results of a Survey of Credentialling Processes

What are the practices that hospitals have established for credentialling and recredentialling in cardiology? Is this process data driven? Is it uniformly applied? What information is used? To answer these and related questions, a survey was sent to cardiologists at 102 hospitals, 50 of whom were governors or state chapter presidents of the College. The rest were actively practicing physicians in academic centers, urban areas (non-university hospitals), rural towns or cities and Veterans Affairs (VA) hospitals. Seventy-five responses were obtained: academic (28), urban (39), rural (6) and VA (2). Table 1 provides a summary of questions and responses.

Analysis of the information obtained from this survey provides some general conclusions:

1. Virtually every institution has a functioning credentials committee, which in most cases is immune to a department chair veto. The great majority require candidates to be board eligible or certified and to provide proof of training. The institution's administration almost always participates in the documentation and granting of privileges, by requiring executive committee and/or board of director approval.

2. For the procedural cardiologist, the credentialing process is similar, but, in about half of responding institutions, also requires log documentation. Somewhat more than half of hospitals accept national guideline requirements for procedural training, but a majority of those may modify credentialing requirements for their own reasons.

3. For recredentialing, adherence to some interventional volume requirements for coronary angiography is required in slightly more than half of institutions responding, with ranges of 12 to 300 annually (Table 2). The same pattern is true for percutaneous transluminal coronary angioplasty (PTCA) volume, except for urban hospitals, 75% of which had no requirement. Ranges of 10 to 150 procedures were reported for those with such a requirement. Some institutions reported volume requirements for other coronary interventions, including stents, but more are tied to PTCA privileges. Less than 25% of hospitals require specific numbers of pacemaker or implantable cardioverter-defibrillator (ICD) insertions, electrophysiologic (EP) studies, valvuloplasties, intravascular ultrasound or peripheral vascular intervention.

A large majority of hospitals require a credentialing process for new technology. This process most often consists of industry courses, in-house training, outcome assessment and training by peers. Specific outcome assessment was not addressed.

To maintain procedural credentialing, most hospitals pursue ongoing efforts that include review of number of procedures performed, complication rate, success rate, physician attitude and tardiness. Volume of procedures as recommended by national guidelines is loosely utilized, if at all—not surprising given the heated debate over the concept.

An appeal process for physicians who fail to meet volume requirements is in place in a majority of hospitals. An open review process for invasive interventional procedures is in place at well over half of hospitals, most often with a nurse/physician assistant (PA) participating. Nearly every institution has a process in place to deal with the problem physician, including the potential for dec credentialing. Adherence to medical staff-established clinical pathways for rec credentialing is required in about 20% of hospitals, with another 20% seriously considering that choice.

Somewhat surprising was that only two-thirds required continuing medical education (CME) credits to remain credentialed (although this is often state mandated). None of the responses reported economic credentialing, and some indicated ignorance of the term. This could be taken to reflect inexperience with some managed care concepts, but may be a matter of survey bias.

The survey clearly shows that standards for credentialing by hospitals vary considerably. For credentialing, attention is paid to some measure of competence, but the parameters used to measure competence were not assessed in sufficient detail to judge their impact on either the general cardiologist or the interventionalist.

It would be useful to know if current rec credentialing processes utilize outcome parameters that embrace freedom from adverse medical events, quality of life, patient satisfaction and cost. Would it be helpful to hospital medical staffs to have a better defined method for monitoring physician performance in the periodic rec credentialing process? Would they use a guideline specifically developed to improve the credentialing process? Should the JCAHO consider modifying its recommendations to medical staff bylaw committees to suggest credentialing and rec credentialing requirements adhere to published national guidelines? Is there a better way to monitor performance of cardiologists—general and procedural? (7).

Although this survey suffers from a number of shortcomings, the clear message is that, despite a credentialing process in nearly every hospital, the information that is required and the credentialing process itself vary widely—even among academic institutions.

It is incumbent on cardiovascular practitioners to gather data that can be used to improve patient care. In our new environment of accountability, assessment is focused on the quality of health care delivered. That assessment should start with the systematic review by each local hospital staff of the value provided by each individual practitioner, an ongoing process that embodies the spirit of credentialing and rec credentialing and provides the link between “doing the right things” and “doing things right” (7).

## Credentialing by HMOs

In the past, a physician needed only a degree and a valid license to practice medicine. All one needed to do was find an office and “set up shop.” Patient volume increased over time, with ensuing professional and financial success almost guaranteed. This typical career path has changed dramatically in the current era of managed care, which, by definition, alters the traditional relationship between doctors and patients. Patients may now be directed to specific primary care and specialty physicians. The control of patient flow shifts from the individual and the local physician community to a gatekeeper, who makes decisions and offers choices based on a list of “participating” physicians. One of the basic functions of an HMO is to offer patients a select group of providers. When any panel comprises “select” participants, it suggests an inherent notion of meeting certain criteria. What are the rules? Who are the rule makers? How does one get listed and stay listed? Are those excluded from listing also excluded from potential success?

**Table 2.** Recredentialing Process

	Academic (n = 28)	Urban (n = 39)	VA (n = 2)	Rural (n = 6)
1. Interventional procedures (no. of procedures required)				
Coronary angiography	17 (12-300)	19 (25-300)	0	1 (100)
PTCA	18 (10-75)	9 (10-150)	1 (100)	2 (30)
Other (atherectomy, etc.)	5	9 (10-75)	0	0
Stents	5 (10)	6 (10-25)	0	0
Biopsy	3	5	0	1
Pacemaker	9 (5-25)	9 (5-25)	0	1
ICD	6 (5-10)	2 (10-20)	0	0
EP	8 (30-50)	7 (10-75)	0	0
Peripheral vasc intervention	4 (5-25)	3 (10-50)	0	0
Intravasc US	3 (5-10)	0	0	0
Valvuloplasty	4 (10)	3 (5-10)	0	0
2. Credentialing process for new technology (i.e., stents)	25	29	1	6
3. Does this process include medical	23	32	2	5
Industry courses	23	31	2	5
Inhouse training	23	30	2	5
Outcome assessment	23	26	2	4
Assessment by peers	21	22	2	6
4. To maintain procedural credentialing, is there a review process? What is reviewed?	25	36	2	5
No. of procedures	25	28	2	3
Complications	26	29	2	4
Success	23	27	2	3
Tardiness	18	13	2	1
Attitudes	15	19	2	3
5. With volume requirements, an appeal process for M.D.?	16	19	1	2
6. Hospital quality assessment committee?	28	38	2	6
7. Peer review committee for cardiology?	17	33	0	4
8. Same committee	7	8	—	3
9. Open review process for invasive interventions	22	27	1	3
10. Role for nurse/PA colleagues	22	27	1	3
11. Institutional process for problem physicians	26	36	2	6
12. Decredentialing process?	25	32	2	4
M.D. grievance	23	29	2	3
Patient grievance	18	24	2	3
13. Economic credentialing for physicians	0	0	0	0
14. Local physicians clinical pathway	6	7	0	1
Adherence a requirement for recredentialing?	(7)—under study—(7)			
15. Are CME credits required?	18	25	1	3

CME = continuing medical education; EP = electrophysiology; ICD = implantable cardioverter-defibrillator; Intravasc US = intravascular ultrasound; PA = physician assistant; PTCA = percutaneous transluminal coronary angioplasty; vasc = vascular.

### Types of Managed Care Organizations

Managed care plans generally are classified under three models, each with different financial risks and incentives, participation criteria and access to patients:

1. In-staff or group practice HMOs, physicians are generally salaried employees, with a patient and total provider population defined within the walls of the HMO.

2. In independent practice association (IPA) HMOs, physicians practice with some fraction of their patient volume determined by the HMO. Physician income is a blend proportional to the practice's payer makeup. They incur some financial risk for their managed care population with well defined lines and rules for referral of care and participation.

3. In preferred provider organizations (PPO), a group of physicians agrees to provide services to a health plan's members according to mutually agreed upon discounted fees. Criteria to participate are defined loosely by the "mother" organization, which may be a group of physicians, a hospital, or a health plan.

Different credentialing criteria from one plan to another stem largely from the driving philosophy of the plan (economics vs. quality), plan objectives (restrictive criteria vs. all inclusive), the maturity of the plan (growing vs. well established and "tightening") and the economic payment model (fee for service vs. capitation). In general, quality, tightening and capitation tend to produce harsher credentialing requirements.

## *Credentiailling*

Physician credentialling is the process by which a health plan selects and authorizes physicians to provide services to its members. Competition forces health plans to distinguish themselves in cost and the quality of the network that represents them. The two are exquisitely linked: One of the best methods to control cost is to control the network of physicians providing services. This strategy is justified by the credentialling process, which can produce a double benefit to the health plan and its members: Choice is limited only by criteria that produce the largest number of high-quality physicians who can achieve the necessary cost efficiencies. It has been argued that credentialling favorably affects both utilization rates and quality of service (8).

## *Response of the Provider Community*

Credentialling that is perceived positively by HMOs is generally perceived negatively by the provider community: It threatens independence and autonomy, with adverse economic impacts. Legislative movement to block the ability of health plans to tailor their networks has led to individual state activity which attempts to enact "any willing provider" laws. To date, at least 10 states have approved some form of this legislation.

The American Medical Association (AMA) has recommended stringent conditions to offset provider concerns. These include removing threshold exclusions, identifying objective criteria based on professional competence and clinical performance and providing due-process procedures for excluded physicians (9).

At the individual physician level, the requirements of the credentialling process add a significant administrative burden and obstacle. Among insurers, credentialling criteria and the associated documentation and questionnaires are as varied as the number of health plans. This lack of uniformity must be addressed and rectified.

From a clinical standpoint, a major argument against network credentialling and restriction is continuity of care. Subscribers may join a health plan only to find out that their doctor does not participate. Even when the doctor wants to join and meets general criteria, he or she may be excluded because the "network is closed."

Other broad arguments against narrowed networks that result from the credentialling process are limited provider choice, limited access to the best provider for a particular clinical problem and an arbitrary limitation to patient volumes. A final concern is whether HMOs are making decisions based on incomplete or inaccurate information. For example, administrative data alone lack clinical markers that are needed for adjustment based on case mix and severity, as recently described by Kouchoucos (10). Also, there is no scientific evidence that restricting panel membership enhances quality (11).

## *Why Credential?*

Credentialling by health plans—aside from tailoring a network to meet care outcome and financial goals while meeting the criteria of oversight organizations—must also address the alarming frequency of dishonesty that has recently been documented (e.g., Sekas and Hutson [12]). Similar misrepresentation has been reported in the ACC fellowship process and by the *Washington Post* (13), which documented misrepresentation of physician's board certification status and other incorrect information.

A rigorous credentialling process can also identify problems revealed, for example, through the analysis of physician decision making. And an arguably good may result: Recently, a group of surgeons was identified as having an excessive number of malpractice actions against them—until it was learned that every such case was related to a single class action suit for breast implants. A superficial process may have excluded this group from participation.

## *Credentiailling Criteria*

Various guidelines exist for specialist physician credentialling among the HMO communities. This can produce a hierarchy of conditions and restrictions, ranging from generally free access of providers in an immature startup marketplace to extremely restricted access in a tightly controlled mature market that is fully capitulated with a restricted number of physicians. Here, criteria may extend to board certification, achieving certain outcomes, and gaining specified CME credits.

In general, there are three stages of network modeling that influence the credentialling process. Early in the establishment of managed care in a given market, access and size of the network are dominant forces. In the second stage, price and economics are predominant, while the final stage centers on quality (14). HMOs that stress quality in credentialling are more often using tools such as the Health Plan Employer Data and Information Set (HEDIS) criteria, developed and produced by the National Committee for Quality Assurance (NCQA). The Foundation for Accountability (FACCT) and the Agency for Health Care Policy and Research (AHCPR)/Harvard University's Computer Needs-Oriented Quality Measurement System (CONQUEST) are developing similar tools for measurement of physician performance.

For the most part, there are no legal implications and ramifications of health plan credentialling activities except that 1) HMOs have been immune from Federal antitrust laws; 2) HMOs have been protected against suit when malpractice claims involve a quality of care issue; and 3) challenges to adverse decisions for credentialling have been denied when criteria are uniformly applied and open to general and peer review.

## *Initial Credentialling*

The initial credentialling of specialist physicians begins with verification of training, license, hospital affiliation, Drug En-

forcement Administration (DEA) license, specialty board certification or eligibility, history of disciplinary actions, unfavorable action by other organizations, history of alcoholism or drug addiction, practice experience and CME achievements. Also universally included is a query to the National Practitioner Data Bank (NPDB) and the need to document professional liability insurance. For many HMOs, this minimal activity encompasses the entire process and satisfies state insurance commission requirements; for others, it is a minimal screening tool. The next level or "qualifying" focuses on more specific needs and requirements of the individual HMO. This may include communication skills, computer literacy and staff association at specific institutions.

The NCQA, in addition to issuing HEDIS, conducts accreditation of HMOs in a manner similar to that of the JCAHO for hospitals. The NCQA's accreditation guidelines suggest that health plans visit the offices of high-volume specialists to review the physical site, the medical record keeping practices and conformance with the HMO's standards. The NCQA requires written guidelines for record keeping and states appointment availability expectations. This process allows a certain flexibility, beyond bare document gathering, that can be used either for inclusion or exclusion of physicians to tailor a network based on objective measures of performance.

Board certification is not a requirement for NCQA accreditation and is not a requirement legislated by any legal body. However, because it is a mark of specialty accomplishment and because the purchasers of health insurance frequently ask about the percentage of a health plan's participating specialists who are board certified, certification has been used both as a marketing tool and a way for HMOs to distinguish themselves among the competition.

The issue of board certification is highly charged and controversial. There is clearly no unanimity regarding its worth. Opponents of required certification cite a recent government report stating that research has failed to show that board certification results in better care (15).

The ABIM states only that board certification is voluntary. The American Society of Internal Medicine (ASIM) has taken the position that board certification does not measure physician characteristics such as listening ability, time spent with individual patients, availability to provide care, and so forth. In lieu of required board certification, the ASIM suggests consideration of continuing medical education, peer review, patient satisfaction, standing in the community, hospital privileges and outcomes measurement.

A recent survey found that in 62 managed care organizations, 70+% accept other standards that "would demonstrate competence in internal medicine as a minimum qualification for participation," including more than 65% that accept completion of training alone (i.e., qualification for board examination or mere completion of residency).

The Health Care Finance Agency (HCFA) advocates the most current HEDIS criteria (HEDIS 3.0) with the omission of board certification as a credentialing measure for primary care physicians under Medicare. When extended to specialty care

by cardiologists, these measures of quality, access and utilization focus on prevention and treatment of coronary artery disease (CAD). The FACCT's performance measures similarly focus on CAD. The CONQUEST data set contains information on the treatment of acute myocardial infarction, unstable angina and congestive heart failure. However, because this information has not been readily available, the use of performance criteria for participation has not been adopted by the insurance industry for general participation.

The process of granting the authority to provide specific patient care services is called "privileging." For hospitals, the JCAHO requires that privileging "be based on assessment of applicants against professional criteria specified in the medical staff bylaws." Physicians must demonstrate individual competence for each area of activity. Privileging by most HMOs, however, relies on hospitals to police the granting of competency and imposes no criteria beyond the hospital. Some HMOs have adopted the ACC/AHA volume criteria for the credentialing of physicians to perform cardiac catheterization and percutaneous vessel remodeling. Other major insurers have established "centers of excellence," largely based on outcome measurements that have been established and/or data generated by the National Cardiovascular Network. One HMO has included a cardiac catheterization film review as a minimal requirement to perform diagnostic cardiac catheterization. That same HMO has even provided financial incentives for the achievement of related performance outcomes, including groin complications, sequencing of diagnostic and therapeutic catheterization and restenosis rates.

Because there are conflicting comparable volume criteria (16,17), an attempt by one HMO to set minimal volume requirements for the performance of open heart surgery ignited a vehement protest (18).

Although there are published guidelines for echocardiography, nuclear cardiology and electrophysiology, the controversy that has resulted from the catheterization guidelines has impeded the implementation of or the application of criteria to either laboratories or subspecialists. Recently, the American Society of Nuclear Cardiology has published suggested guidelines for the performance and credentialing of nuclear cardiology (19).

### *What Do HMOs Currently Do?*

In a report published in the *New England Journal of Medicine* in 1995, Gold et al. (20) reported the results of a telephone survey, sponsored by the Physician Payment Review Commission, that was conducted in 1994 by Mathematica Policy Research. They found that, among 108 plans in 20 metropolitan areas, plans emphasized "careful selection" of physicians (71%) as opposed to "prune later" (18%) or "as broad as feasible" (11%) when forming a network. Thirty-eight percent of the plans were "tightening the network" (subtracting physicians), while 43% were "widening the network" (adding physicians). In general, HMOs were more demanding with requirements for board certification or eligibility, network

hospital privileges, volume requirements (agreement to take a predetermined number of patients) and exclusivity (not to practice outside of the plan).

Regarding economic patterns of care for selection, 61% of the plans responded that physicians' previous costs or utilization of resources had little influence on their selection; 26% said these factors had a moderate influence; and 13% said that they had a large influence. Although reliance on quantitative information was modest, 63% of the plans took qualitative information (professional reputation, patterns of care) into account for initial credentialling.

Virtually all plans verified license and credentials, and all screened for prior disciplinary actions, substance abuse or similar actions. More IPAs visited physician's offices to review the facility and charting and medical care delivered through a chart review.

### *Recredentialling*

Most HMOs recredential their specialist physician networks on a schedule as short as yearly and as long as five years. The basic process is similar to the initial credentialling process, and may be limited to a verification of license, hospital affiliation, an NPDB query and the validation of professional liability coverage. The inclusion of measures of patient satisfaction, performance and outcomes are becoming the rule rather than the exception. Included in many instances are cost measures intended to determine cost-effectiveness.

The simplest and least sophisticated measures are strictly utilization parameters, such as 1) prescribing and referral patterns; 2) number and type of noninvasive studies ordered per unique member; 3) average total costs for care for each patient seen; 4) average length of stay in general and by specific diagnosis; and 5) readmission rates. Other recredentialling parameters may include such measures as 1) member and referring physician satisfaction; 2) a review of grievances and member complaints; 3) contract adherence, which may include target utilization and quality measures; 4) philosophy of managed care and cooperation with the health plan; 5) billing practices beyond pure utilization (e.g., fraudulent billing, overcoding); and 6) focused chart reviews (e.g., for aspirin use after myocardial infarction or angiotensin-converting enzyme [ACE] inhibitor use in congestive heart failure).

Several recent reviews of performance measurements and "report cards" (7,21-23) indicate the need for physicians to be involved in the development, interpretation and implementation of these tools and for data to be population based and adjusted for case-mix and severity.

Regardless of the scope of the process and the measures adopted, the concept of "without cause" must be eliminated, so that a plan is required to provide the reasons for not recredentialling a physician or physician group. All parameters for the process must be shared and should result from an interplay between the health plan and physician advisory groups both for quality assessment/improvement and credentialling. A well

defined appeal process must be accessible for rejected physicians.

### *Databases*

An HMO is somewhat limited in assembling databases that go beyond purely administrative measures. The practitioner is able to collect and store more detailed clinical information that will help establish needed case-mix adjustment, while measuring variables that are not within the reach of the HMO. For example, even a sophisticated HMO that can capture laboratory and pharmacy data along with bills and encounter data cannot measure the use of aspirin in acute myocardial infarction. The latter reflects a measurable quality of care issue that clearly may separate practices according to behavior.

There is, of course, a cost to collecting data, but the major outlay is not so much in funding as in a mental and philosophical appreciation of the worth of the process. This important component of practice is worthy of the dedication of resources and personnel to gather, enter, track and analyze the data. The value of a national database (e.g., the Society of Thoracic Surgery [STS] or ACC database) cannot be overemphasized.

### *Other Issues*

The credentialling/recredentialling process becomes even more complicated where physicians assume financial risk and, therefore, the development and maintenance of the network. NCQA accreditation is dependent on the continued oversight of this process. The role of credentialling verification organizations also remains to be defined in the current environment. The latter represents an attempt to streamline the process, provide uniformity among various insurers and reduce the administrative burden and cost to physicians.

### *Future Efforts*

Physicians who deal with managed care organizations on credentialling and other issues should 1) understand the environment and appreciate the direction of local HMOs; 2) develop databases to track key performance measures; 3) measure individual performance in group practices so that performance of procedures is restricted to cardiologists with satisfactory training and outcomes; 4) make communication between HMOs and cardiologists a high priority; 5) understand business and financial issues; 6) explore the use of nonphysicians to improve care and overall work flow; 7) develop proactive disease management programs; and 8) be involved in decision making with the major local HMOs.

Credentialling is the first step in a relationship with a managed care organization. It is a misunderstood and underutilized resource in building a quality system that should never become an end in itself.

### Role of Professional Societies in Developing Credentialing Guidelines

Medical professional organizations have developed practice guidelines for clinical competence in procedural skills for a variety of reasons, the foremost being to sustain high-quality patient care. This can provide reassurance to patients undergoing procedures deemed to require certain skills and experience. Also, hospitals and other institutions providing clinical privileges to physicians cannot assume that residents or fellows have received even the minimum training required to perform certain procedures (24). Clinical competence statements endorsed by reputable professional organizations are welcomed by hospitals and managed care companies to guide them in establishing a fair and valid credentialing process for physicians seeking privileges to perform procedures.

Medical organizations also get involved in the guideline process for credentialing for competence because members demand such involvement to sustain a high procedural success rate with a low rate of complications and good long-term outcomes. Guidelines generated by medical professional organizations are also educational: They are consensus documents summarizing indications and contraindications; anticipated complications, with information on how to manage them; and how results should be interpreted. In order not to appear self-serving (i.e., limit the number of operators to reduce competition), members of specialty organizations base guideline methodology on published scientific data and expert opinion that will be beyond criticism by those excluded by their inadequate training.

### History of ACP/ACC/AHA Guidelines

From June 1990 to May 1995, a task force consisting of representatives of the ACC, the AHA and the American College of Physicians (ACP) published a series of guidelines for clinical competency for a variety of cardiovascular procedures. These were published simultaneously in the *Journal of the American College of Cardiology*, *Circulation* and the *Annals of Internal Medicine* as “ACP/ACC/AHA Task Force Statements.” These guidelines were intended to define the minimum education, training and experience required to attain the cognitive and technical skills necessary for the competent performance of these procedures. Whenever possible, these procedure-specific guidelines were based on published data. When data were lacking, a consensus of expert opinion was undertaken.

The procedures addressed by the ACP/ACC/AHA Task Force were hemodynamic monitoring, adult echocardiography, PTCA, exercise testing, electrocardiography, ambulatory electrocardiography and elective direct current cardioversion (25-31).

### Background

Prior to this joint effort of the three societies to develop guidelines for clinical competency, the ACP published a series of Statements on Clinical Competence developed by the

**Table 3.** Pathways to Procedural Competence\*

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- A physician who completes an accredited residency or fellowship program may achieve certification in the respective specialty, which implies that the physician’s procedural skills and competence have been documented in writing
  - A physician may successfully complete an accredited residency or fellowship program in which procedural competence may be documented, independent of certification
  - A physician may successfully complete an accredited residency or fellowship program in which the procedure is taught, but the physician’s procedural competence is not documented in writing, necessitating special evaluation by, for example, inquiry to the program directors or direct observation of such skills by the credentialing institution
  - Due to changes in practice or technology, a physician may become skilled in a procedure subsequent to his or her formal training
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\*From reference 32.

College’s Clinical Privileges Project Steering Committee. In 1987, the ACP published a position paper entitled, “Guide for the Use of American College of Physicians Statements on Clinical Competence” (32). In this guide, the ACP declared that the Statements of Clinical Competence were intended to “set forth the minimum criteria necessary for competent performance of specific procedures and . . . to facilitate assessments of physician competence during the course of privilege delineation decisions” (32).

Table 3 summarizes the four alternative pathways to procedural competence proposed by the ACP in the published guide for use of the ACP statements (32).

In its guide for the use of the clinical competence statements (32), the ACP was careful to point out that the statements may need to be modified over time, particularly when research better defined the relationship between procedural competence and physician education, training and experience. Furthermore, it was emphasized that the number of procedures performed should not be the sole criterion to attain competence, but “rather should be considered along with cognitive skills and educational experience.” The latter is reflected by the “qualities of the educator” and the “educational milieu” in which experience with the procedure was acquired. The guide acknowledged the concept that some physicians may require considerably more experience to achieve procedural competence than others due to differences in manual dexterity. It also noted that the statements cited are minimum, suggested standards for attaining competence. Finally, the ACP said that the guidelines were intended to be applied on a “case-by-case basis in the context of well-defined privilege delineation and peer review processes.”

In an accompanying editorial (33), Eugene Hildreth, who chaired the ACP committee that commissioned the clinical competence statements, wrote that the procedural competence guidelines were to be neutral as possible in terms of medical specialty, geographical location and type of practice. He stated that the ACP’s position was that the guidelines were intended to “describe minimum competence for the beginner doing the

procedure in the average patient." Guideline development involved a search of pertinent literature and obtaining expert opinion, both from those using the procedure in academic settings and from clinicians. The ACP also sought "cooperation" with other organizations sharing their "common goals." Interestingly, Hildreth suggested in this editorial published in 1987 that other organizations, such as "managed care health systems," would find the guidelines of value.

The initiative between the ACP and the ACC and AHA naturally followed the ACP activities for developing guidelines for clinical/procedural competence. This earlier effort by the ACP did not include cardiovascular procedures. The rationale cited for developing guidelines for cardiovascular procedural competence by the three organizations was that selective granting of clinical staff privileges to physicians continued to be one of the primary mechanisms used by institutions to sustain the quality of care.

Each set of guidelines was written by either a single lead author or a writing group of no more than two or three authors. The Task Force members provided critical editorial review, after which the statements were sent to outside experts for further comments. Ultimately, the competency statements were approved by the ACC Board of Trustees, the AHA Steering Committee and the ACP Board of Regents. They were then published for use by the ACC membership, each hospital staff responsible for clinical privileges and the medical profession as a whole.

### *Strengths of the ACP/ACC/AHA Guidelines*

The positive features or strengths of the joint guidelines are that 1) they include a descriptive "overview" of the given procedure; 2) indications, contraindications and complications of the procedure are succinctly detailed, often in tabular form; 3) a justification for the recommendations is presented; 4) training in the acquisition of cognitive skills as well as in the technical skills for the procedure is deemed important; 5) trainees learning to perform a procedure are required to be supervised by an effective teacher who is considered an expert in the *clinical use* of the procedure; 6) completion of a fellowship by itself is not acceptable in guaranteeing competency in the procedure; 7) physicians in private practice are permitted to achieve the necessary experience to gain competency in a new procedure by attending courses, workshops, completing preceptorships and undergoing "supervised practical experience"; 8) they suggest that cognitive and technical skills of candidates be confirmed in writing by the training supervisor or by observation of the candidate doing the procedures by a physician considered an expert teacher; 9) they encourage trainees to keep logs during training, documenting the date of the procedure, patient identification number, indications, findings and signature of the supervisor; 10) they provide recommendations for numbers of procedures that are required on an annual basis for ensuring continuing competency; 11) they suggest that quality assurance programs randomly sample certain procedures (e.g., echocardiograms)

done by a physician be reviewed periodically to confirm that indications were appropriate, that the examination was adequate for interpretation, that the interpretation of test of procedural data was accurate and that the results were accurately recorded and shared with other physicians; 12) they recommend ongoing correlation of results of certain procedures with results of other techniques and the patient's clinical course; 13) they recognize that not all training or practice environments are the same and that a greater or smaller number of procedures other than the number recommended in the guidelines may be deemed appropriate by a local credentials committee; and 14) they encourage timely institutional reviews of patient outcomes after therapeutic or invasive procedures.

### *Weaknesses or Limitations of the ACP/ACC/AHA Guidelines*

Some weaknesses or limitations of the ACP/ACC/AHA Task Force statements have also been identified. Perhaps the most controversial aspect of the procedural guidelines is related to lack of objective data from the literature at that time to support the numbers of procedures that were recommended as the minimum to attain competency or the numbers judged as the minimum to sustain competency. (More data are now emerging which do suggest a link between procedural volumes and outcomes.) Also, the ACP representatives often proposed lower numbers of procedures to serve as the minimum to attain competency, compared to the higher numbers recommended by representatives of the ACC and AHA. This resulted in delay in approving certain statements and ultimately required agreement on a compromise number. For example, many cardiologists perceive that the 800 ECGs recommended for interpretation by the Task Force is too low for attaining true competency, but this was the compromise number that was ultimately published (31). A similar difference occurred in determining the minimum number of exercise stress tests deemed necessary.

Numbers have also been controversial in guidelines directed solely to cardiovascular specialists. This is best illustrated by disagreement over the recommendation that 75 coronary angioplasty procedures should be performed annually for continuing competency (27).

Another limitation of the guidelines is that they conflict at times with recommendations made by other professional organizations, particularly those of the subspecialty societies, which often state higher numbers of procedures for achieving competency. This leads to provider and institution confusion. Certain guidelines that relate to procedures performed solely by cardiologists should perhaps be generated jointly by the ACC, AHA and the relevant subspecialty society whose members are identified as predominantly performing the procedure under study.

Local institutional credentialing committees often ignore the recommendations outlined for competency since the major aim of a hospital administration is to have as many physicians

on its staff as possible. Many hospitals do not use the Task Force recommendations for competency in granting privileges.

Another limitation of the ACP/ACC/AHA guidelines is the failure to articulate the need for an adequate case-mix during physician training (34). This can lead to suboptimal training, even when the requisite number of procedures was performed by the trainee during training. Eisenberg et al. (34) suggest establishing minimum criteria for defining an adequate case-mix for physicians being trained in advanced procedures.

### Procedural Guidelines

Procedural guidelines should be, as much as possible, data driven. Established therapies with support of randomized trials or overwhelming clinical evidence should be publicized, and compliance should be measured. Where data are lacking, there is no choice but to develop guidelines from broad experience, with the help of the social sciences best efforts to measure behavior and uncontrolled outcomes.

Guidelines should be just that; inappropriate use of guidelines as minimum standards should be discouraged.

Developers of guidelines should be representative of both expertise in the field and of practitioners representing the field broadly.

#### *Should Societies Participate in the Development of Guidelines for Procedure Volumes for Clinical Competency With Respect to Individuals and Institutions?*

Because guidelines will be developed with or without specialist participation, it is incumbent on societies to evaluate the evidence and make reasonable judgments on behalf of its membership—if only to counterbalance guidelines developed by others.

Institutional and individual volume measures are better established for some procedures than others. For some rapidly changing technologies, it may be impossible to obtain data to support volume requirements for related procedures. Volume requirements should be general requirements for subspecialty areas and not for specific procedures, such as number of stent placements, number of Swan-Ganz catheter insertions or number of pericardiocenteses. Guidelines to establish volume measures should be aimed at improving patient outcomes, both short and long term, while allowing adequate accessibility.

#### *Is There a Relationship Between Procedure Volumes and Outcomes for Institutions and Individuals as Has Been Established for Surgery?*

Data suggesting a relationship between institutional and operator volumes and outcomes of interventions are accumulating (35-41). Institution-specific data have suggested that less than 200 cases/year are associated with a higher risk of emerging coronary artery bypass graft surgery (CABG) (36) or major complications (35) or mortality (37). Operator-specific

data from single institutions (38,39), the Medicare database (40) and high volume centers (41) show that complications of intervention are higher among the lower volume operators. Ellis et al. (41) showed that, as a group, operators performing less than 70 angioplasty cases/year in high volume academic centers had a higher complication rate. In complex lesions, the lowest complication rate was achieved by operators performing more than 200 cases/year. Jollis et al. (40) found a correlation between operator volume and complications in the Medicare database and suggested that a volume of >100 procedures/operator per year was significantly associated with lower death or bypass surgery rates. However, in these studies not all low volume operators had the least favorable results. The data available have been obtained in a rapidly evolving field, and more observations are clearly needed.

#### *What Should the Mechanisms Be for Credentialing Procedural Skills, Both Initially and With Respect to Ongoing Competency?*

The ACC has issued two sets of recommendations for initial training related to PTCA and catheterization; the Society for Cardiac Angiography and Interventions (SCAI) has also made recommendations. At least one year of training for those entering interventional cardiology in 1996 and beyond has been recommended. The ABIM has approved, and the ABMS has endorsed, a certificate of added qualification (CAQ) for interventional cardiology. This will set minimum training standards for eligibility to take board certification and recertification examinations. It is likely that the ACC will accept these standards, because the College and the SCAI were the sponsoring organizations for this action. Electrophysiology has already gone through this process, and a CAQ is in place.

Regarding specific techniques or use of specific devices, industry currently provides training and certification for selling instruments for use by approved physicians. This consists in all cases of one day or less of instruction, followed in some instances by proctoring for one to three cases by someone already credentialed. This is obviously not adequate training for competency. The ABIM training programs may provide training in specific devices for those already practicing and certainly must provide such training for those in the formal training program. Industry will continue to be involved, and the role of the ACC in collaborating with industry on training in new devices needs to be defined.

#### *How Should Database Registries Be Used for Benchmarking for Procedural Guidelines With Respect to Outcomes?*

The key here is to arrive at common definitions, accurate and complete data collection and wide participation in databases. The ACC database is best structured to study these subjects. Risk adjustment and local requirements can be considered in benchmarking. Use of the data to improve patient outcomes for all constituents of the College must be

appreciated by the participants for this effort to succeed. If left to those for whom economic imperatives are central, benchmarking may look quite different. The recently reported adverse outcome for intensive care patients receiving Swan-Ganz catheterization is an example of outcomes research that caused major confusion. The interpretation of this study raises important issues regarding the danger of sweeping conclusions being drawn from incomplete data (42).

### Physician-Specific Report Cards

In order for patients, referring physicians and payers to make appropriate quality-based selections of health care, and for physicians to demonstrate accountability for the care they provide, information concerning the performance and outcomes of individual practicing physicians is essential (21,43,44). In addition, objective criteria are needed to guide managed care programs and other payers in their selection and rejection of physicians; the current selection is driven primarily by economic considerations (45,46). Furthermore, in order to develop objectivity in the credentialing and recredentialing process necessary and standard at many hospitals, accurate data are required to benchmark physician staff in relation to their own colleagues as well as in relation to regional and national standards (47). Physician outcomes are presently measured by governmental agencies (i.e., the NPDB, HCFA, New York State and Pennsylvania Departments of Health), by managed care companies, by professional societies, by proprietary companies and by hospitals and institutions (48,49).

Traditionally, the results of procedural physicians have been scrutinized, used for credentialing and, in some instances, reported in the public domain (10,18,50-52). A focus on procedures has developed because of a perception that these activities have higher costs, morbidity and mortality (specifically, for cardiac surgery and interventional cardiology). Recently, HCFA/Medicare and managed care plans have also been concerned about physician utilization of diagnostic procedures (e.g., nuclear and ultrasound imaging and cardiac catheterization), as well as the evaluation of physician profiles related to the costs of managing specific conditions, such as chest pain and acute myocardial infarction. In fact, Medicare/HCFA and some managed care systems have developed comparative though non-risk-adjusted profiles, which can provide an analysis of the billing practices of individual physicians (46). Physician profiles of humanistic outcomes as well as clinical outcomes are of increasing interest to patients. Yet, managed care administrators and physicians with increasing financial risk may continue to be more interested in economic outcomes (53).

The Cooperative Cardiovascular Project (CCP) has attempted to measure quality of care by studying the performance of groups of hospital physicians by reporting the use of aspirin, beta-blockers and ACE inhibitors, as well as the time to reperfusion in patients with an acute myocardial infarction (54). In addition, the frequency of the use of anticoagulant therapy in patients with atrial fibrillation has been analyzed.

Critical pathways have been developed, using practice guidelines, to guide the management of patients with congestive heart failure, myocardial infarction and unstable angina. Assessment of an individual physician's use of practice guidelines and the subsequent effect on length of stay and utilization of resources will be measured. Of concern is potential overregulation of the complex process of clinical decision making, which could override clinical judgment in the management of an individual patient.

Medical outcomes are often difficult to measure, and certain end points are subjective (e.g., the incidence of myocardial infarction, procedural success following coronary angioplasty) and are susceptible to manipulation (7,55). The predictive capacity of various models, for example, to assess differences in physician outcomes following coronary angioplasty, have been modest (55). Furthermore, the low incidence of adverse end points following coronary angioplasty inhibits the ability to accurately assess the relation between a poor outcome and procedural volume, particularly for those physicians with a low volume of cases (7,55).

In the past, outcome measurements have focused primarily on early and, in some instances, late freedom from adverse clinical events. In addition, evaluations of the cost of care, patient satisfaction, appropriateness and utilization of resources and quality of life measures are of increasing interest to the medical industry (56). Longitudinal analysis of outcomes may be particularly important in comparing one physician's results with another's (7). Assurance that patients are not deselected for appropriate care because of the disincentive policies of managed care programs needs continued surveillance. High-quality outcome data are essential; volunteer reporting without auditing has inherent problems with bias and potential misrepresentation. Methods to standardize risk adjustment for severity of illness must be refined (7). In order to assure clinical relevancy and accuracy, careful medical peer review of data is essential.

Report cards have been released for public scrutiny and information by New York State and Pennsylvania, with the laudable goal of improving quality of care (48,49). Criticism and justification of the New York State method of public disclosure have been published (56,57) and at times sensationalized by the media. Critics have questioned the validity of the data, accuracy of reporting and interpretation of results (56). In addition, fears of "gaming the system" by upcoding, avoiding the treatment of high-risk patients (by referring them out of state, which could promote a defensive medical posture practice), misuse of the data by the media and premature release of the data before careful peer review have been of concern (56).

However, proponents of the New York State program have made the compelling argument that the statewide mortality following CABG has in fact improved significantly, with a 41% decline in risk-adjusted operative mortality from 1989 to 1992 (57). In New York, the public release of information detailing risk-adjusted operative mortality—both for patients and institutions when compared with the state average—has been

viewed as one part of a strong oversight program that includes active consultation and advice to outlier programs identified as performing poorly. There is clearly a continuing need to educate the public and media in order to prevent misuse of the data and to prevent sensational or misleading interpretations.

## Recommendations

### Certification processes:

1. The ACC should recognize and support the importance and requirement of appropriate training in RRC approved programs as essential to the certification process.

2. The ACC should work with ABMS Boards wherever possible and with appropriate subspecialty societies to provide standardized, objective assessment of skills (cognitive, interpretive, procedural) where needed.

### Local-level physician credentialling:

1. The ACC should take a leadership role in developing recommendations for the credentialling and recertification process to assist hospitals or other institutions. The goal is to better guide those responsible for local credentialling toward more objective and effective means for assessing quality of care delivery in the short and long term (i.e., education as to the how and why of data collecting systems and other benchmarking techniques in measuring physician-specific performance).

2. Prospective studies or surveys should be conducted to assess whether formal, rigorous credentialling processes utilized by certain hospitals or networks yield better patient outcomes for diagnostic and therapeutic cardiovascular procedures.

3. The ACC should encourage the development of a database/registry in order to facilitate credentialling by the use of audited, objective risk-adjusted data.

### Credentialling by HMOs:

1. The ACC should encourage collaboration with the health care industry in the development of valid performance measures to credential practicing physicians.

2. The ACC should take a leadership role in helping physicians and institutions provide valid data in order to measure their performance.

3. Credentialling and recertification by the insurance industry should be based on a combination of objective, case-adjusted measurements of outcome rather than on economics.

### Role of professional societies in developing credentialling guidelines:

1. The ACC, in collaboration with the AHA and the cardiology and cardiovascular surgery subspecialty societies, should remain engaged in the development and revision of guidelines for clinical competence in procedural skills.

2. The ACC should utilize its database information and published literature to generate standards of care, which should include minimum expected procedural-related mortality and morbidity rates and other risk-adjusted outcomes. This will permit dissemination of objective criteria for institutional QI programs related to operator credentialling.

3. Guidelines for clinical competence should include indications and contraindications for procedures as well as expected success and complication rates.

4. The ACC should work with those subspecialty societies (e.g., NASPE, ASNC, ASE, SCA and SCAI) which seek to enhance quality of procedural performance and interpretation of data with examinations to test knowledge and skills in the given procedural field.

5. The ACC should continue to work with program directors of fellowship programs and the ABIM Cardiovascular Board to develop guidelines for trainees, including recommending numbers of procedures and numbers of months required to attain initial competency.

6. It is not necessary that the ACC, the AHA and the subspecialty cardiovascular societies publish joint competency guidelines with generalist organizations for cardiovascular procedures predominantly or exclusively performed by cardiovascular specialists. However, endorsement of such guidelines by those organizations would be desirable.

7. The ACC should continue to collaborate with noncardiology physician organizations to develop credentialling requirements for those cardiac procedures also performed by noncardiologists. The minimal volume criteria for attaining or sustaining competency for such procedures by noncardiologists should not be lower than those established for cardiologists.

### Procedural guidelines:

1. The ACC and AHA should develop guidelines for performance of procedures done by cardiologists only. The ACC and AHA with the cardiovascular specialty societies should cooperate with broader representation for performance of procedures by other physicians.

2. Research to evaluate the effect of procedure volume on risk-adjusted outcomes should be encouraged.

3. Health care organizations may use board exams and CAQs as a measure of excellence. Although these exams are not a measure of minimal competence, they could serve as a benchmark for setting standards.

4. Criteria utilized for assessment of ongoing competence in procedures by the local credentialling body should include the ACC/AHA Guidelines.

### Physician-specific performance measures

The conferees recognize that it has become increasingly important for hospitals and others to evaluate both institution and physician performance. Yet it was also recognized that the process needs further refinement in view of its present imperfections and limitations, including the need to develop longitudinal measurement of quality. Conferees further recognize that data must be risk-adjusted and validated by reliable audits and must remain confidential. We therefore offer the following recommendations:

1. The ACC should take a leadership role in the development and facilitation of methods to evaluate physician-specific and institutional performance. This is necessary so that the process can be studied in order to understand whether these techniques are in fact a reliable method to measure quality.

2. The ACC is encouraged to develop a National Database Registry, so institutions and physicians can benchmark their performance against national peer-reviewed data.

3. It is appropriate that physician-specific data be used by hospitals, health care plans and government agencies to credential and benchmark physicians—provided that the data are carefully audited, risk-adjusted and verified by appropriate medical review.

4. The ACC should encourage research on quality outcome measurements, including methods to monitor managed care organizations and others who measure physician performance.

5. The release of institutional physician-specific data from any source must be appropriate, impeccably accurate and used to educate physicians regarding their performance, in order to promote improved outcomes.

6. The ACC should continue to develop practice guidelines in order to enhance the clinical practice of cardiovascular medicine and surgery and to enhance the development of indicators to more accurately measure outcomes. These guidelines should serve as a standard for clinical practice and for evaluating physician performance.

7. The ACC should collaborate with the STS to develop methods to evaluate physician performance.

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## Task Force 4: Referral Guidelines and the Collaborative Care of Patients With Cardiovascular Disease

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Published referral guidelines are rapidly becoming a significant factor in the complex equation that determines the flow of patients between primary care physicians and specialists such as cardiologists. This task force explored several aspects of referral guidelines, including the challenges of creating and implementing them, their potential impact on collaborative patient care, and their legal implications.

Ideally, referral guidelines should encourage primary care physicians to refer appropriate patients to specialists in a timely manner to improve short-term and long-term clinical outcomes. They should also help prevent unnecessary referrals that can increase the cost of medical care. It is evident that managed care organizations are more likely to adopt guidelines that restrict or delay referral, and specialists are more likely to develop guidelines that encourage prompt referral. Despite significant shortcomings in the commercial referral guidelines that are available at the present time, they are being used in many health care markets and practice settings. The topic of this task force is timely, because interest in creating and using referral guidelines is increasing.

### Historical Perspective

Physicians have collaborated in the care of patients since antiquity. The Hippocratic writings, dating from about 400 B.C., address this important aspect of professional relations: If a physician finds himself "in difficulties on occasion over a patient . . . he should urge the calling in of others, in order to learn by consultation the truth about the case. . . . For when a diseased condition is stubborn . . . one must not be self-confident . . . it is no mistaken idea to call in a consultant" (1).

In 1889, Baltimore physician Webster Cathell (2) encouraged America's doctors to "ask for a consultation in all important cases in which knotty problems are presented, or where there exists any doubt as to the diagnosis . . . and in all cases where you think either the patient's interest, his protracted lack of improvement, or the appearance of fresh or puzzling symptoms, or a division of responsibility demands it; then another eye and a different mind may be of great service."

The practice arrangements and referral patterns that have evolved during the past century reflect a multitude of scientific, technological, social, and economic influences. Eventually, these forces led to the development of cardiology as a specialty

and the transformation of general practice into family medicine (3,4). Historically, most Americans have been able to choose their personal physician and to see a specialist if they so desired. In 1927 Chicago internist James Herrick (5) noted the “tendency on the part of the laity to demand and secure firsthand, i.e., over the head of the family doctor the services of the expert, i.e., what in their view are the best services.”

Many managed care plans restrict access to specialists in an effort to control cost, and concerns about the economic implications of consultation and patient-initiated self-referral are not new. Boston internist Francis Peabody (6) explained in 1930 that “the modern layman of the educated, and often of the comparatively uneducated classes . . . has attempted to get the best care, without regard to cost.” Because less than 10 percent of Americans had health insurance at the time, most patients paid for the care they sought. Anticipating the managed care paradigm, a writer in the *New England Journal of Medicine* (7) complained the same year that “over-specialization is unnecessary and costly to the public, particularly where self-diagnosis and selection of specialists is practiced by the patient.” The challenge was to develop a model that would encourage meaningful collaboration and improved outcomes—and would be acceptable to patients and their doctors.

Although the term gatekeeper was added to the medical lexicon only recently, the concept was described in the United States during the Great Depression, when specialization was growing rapidly and concern about the cost of health care was increasing. The Committee on the Costs of Medical Care (a multidisciplinary panel of 48 medical practitioners, public health physicians, hospital administrators, nurses, social scientists, and lay persons) concluded in 1932 that “Many patients now go directly to independent specialists without first consulting a general practitioner. This practice increases the complexity and the cost of medical services” (8). The committee recommended that every American city with a population of more than 15,000 should have one or more “medical centers” where health care services would be delivered in a coordinated manner. “Preventive medicine would receive special emphasis. . . . Within the medical center, the role of the family practitioner would be prominent and respected. . . . Each patient would be primarily under the charge of the family practitioner of his choice. . . . The patient would look to his physician for guidance and counsel on health matters and ordinarily would receive attention from specialists only when referred to them by his physician” (8). The committee’s report was largely ignored, “swept aside in the rush of technological breakthroughs, the growth of specialism, and the increasing affluence that followed World War II,” according to health policy analyst Anne Somers (9).

The Millis Report, published in 1966, helped set the stage for the modern managed care movement. It summarized the findings and recommendations of the Citizens Commission on Graduate Medical Education, sponsored by the American Medical Association (AMA). The report catalyzed the reinvention of the general practitioner as a primary care

*specialist* and the creation of the American Board of Family Practice. The commission championed a new type of doctor, the “primary physician” who would be “competent and willing to offer comprehensive and continuing care.” This doctor would “serve as the primary medical resource and counsellor to an individual or a family. When a patient needs hospitalization, the services of other medical specialists, or other medical or paramedical assistance, the primary physician will see that the necessary arrangements are made, giving such responsibility to others as is appropriate, and retaining his own continuing and comprehensive responsibility” (10).

As concern about the availability and cost of health care increased during the late twentieth century, Congress passed several laws designed to enhance access and control the growth of federal spending on health care. One of these laws, the Health Maintenance Organization Act of 1973, stimulated the growth of the managed care industry (11–13). Managed care plans have been successful in the marketplace mainly because they promise short-term savings to employers and other purchasers of health insurance. Today, most cardiovascular specialists in the United States have some affiliation with one or more managed care organizations (14).

Because controlling access to technology and specialists is an important factor in managed care’s cost-savings equation, more than 90 percent of health maintenance organizations (HMOs) contract primary care physicians to serve as case managers or gatekeepers (15). Some primary care physicians have expressed concern about the gatekeeper model that requires them to control access to specialists, certain diagnostic tests, therapeutic procedures, and inpatient care. Somers (9) explains: “The gatekeeper role, if appropriately discharged, is obviously complex, requiring a great deal of knowledge and many different skills.”

In many practice settings, family physicians are not the only primary care providers: most general internists and many internal medicine subspecialists also perform this function. The Federated Council for Internal Medicine recently established a high standard for general internists: “As a specialist in the care of adults, the general internist combines the characteristics of a humanist clinician, diagnostician, primary care physician, consultant, and expert in disease prevention, health promotion, continuing care, and the management of patients with advanced disease” (16–18).

The Pew Health Professions Commission predicted recently that primary care in the future would not be dominated by physicians because “nurse practitioners, nurse mid-wives and primary care physician assistants deliver care that is of a high quality and responsive to patient needs for access and consumer satisfaction” (19,20). It remains to be seen what types of physicians or physician extenders managed care organizations will prefer as primary care providers as this health care delivery model matures (21,22).

**Table 1.** Specialties Most Frequently Consulted by Family Physicians (in decreasing order of frequency)\*

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General surgery
Orthopedics
Obstetrics/gynecology
Otolaryngology
Ophthalmology
Urology
Neurology
Dermatology
Cardiology
Psychiatry

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\*From Rakel (26).

### Referral Guidelines as a Method for Defining the Complementary Roles of Primary Care Physicians and Specialists

Payers and providers use guidelines, critical pathways, and care maps to help them steer patients through the increasingly complex world of health care delivery more efficiently. The challenge is to prove that these new generic approaches achieve the desired result: high quality care that is necessary and is delivered by the appropriate provider in a timely manner in the optimal setting at a reasonable cost. Many managed care organizations have purchased or developed referral guidelines to help them rationalize the use of consultants, technologies, and therapies. Because these referral guidelines were developed mainly to reduce expenses by limiting what managed care administrators and others have defined as unnecessary services, they have caused concern among specialists, their patients, and organizations that view themselves as advocates for specialists and patients (23). The American Heart Association (AHA), a voluntary health organization, supports the mission of the Patient Access to Specialty Care Coalition "to ensure that prompt and direct access to medical and surgical specialists is available for the vast majority of the US population" (24).

Staff at the American College of Cardiology (ACC) have concluded that "one of the most troubling developments for cardiovascular specialists in the evolving health care delivery system is the deliberate attempt by managed care organizations to control and/or limit referrals for specialty care" (25). It is understandable that many physicians and patients dislike policies that restrict primary care to specialist referrals and prohibit patients from seeking specialty care directly. In many markets, the threatened loss of patient-initiated self-referrals is problematic since family physicians refer fewer than 3 percent of patients they see to another doctor. They consult cardiologists less often than many other specialists (Table 1) (26). Moreover, referral rates fall if an approval process that requires review by colleagues is instituted (27).

Theoretically, referral guidelines attempt to describe an interface between primary care physicians and specialists (28). The "first-generation" referral guidelines created in the early 1990s have approached the problem by attempting to define

the scope of practice for the primary care physician. They specify what conditions he or she should diagnose and treat independently and what circumstances justify referral to a specialist. It is widely acknowledged, however, that available referral guidelines oversimplify clinical practice and the dynamic and complex process of referral.

Traditionally, primary care physicians have referred their patients to specialists to help establish a diagnosis, define and/or provide optimal therapy, and participate in follow-up care as needed. Several factors determine the threshold for specialty referral, including the severity and acuity of the illness, the patient's (and family's) wishes, the availability of diagnostic procedures, access to specialists, and the primary care physician's degree of confidence in dealing with the problem at hand (including interpreting various signs, symptoms, and laboratory tests as well as initiating and evaluating the response to therapy). The threshold for referral therefore depends on a variety of objective and subjective contextual factors, most of which are not addressed in referral guidelines.

Individuals or groups seeking to create referral guidelines face many challenges, including (but not limited to) significant variations in the knowledge, training, and experience of the primary care physicians who are expected to use them. It is difficult to create a generic document that acknowledges the uniqueness of each patient and each physician, the educational value inherent in collaboration, and the significance of the medical and social interaction among two doctors and a patient that a referral triggers. Just as patients vary in their sophistication and expectations, each practice setting and community has a culture and context that may influence the implementation and effectiveness of referral guidelines. For this reason, any referral guidelines must be adapted to the specific regional or local context.

Referral guidelines do not address many important aspects of the ongoing process of collaborative care. Physicians sharing responsibility for a patient have obligations to each other and to their mutual patient, including timely communication of pertinent information—from the referring physician to the consultant and back to the referring physician. The consultant should avoid serial referrals to other specialists without concurrence of the primary care physician. He or she should return the patient to the primary care physician for ongoing management when the clinical condition warrants it.

There is no standard method for developing referral guidelines or assuring that they will be adopted or used appropriately. Understandably, the content of referral guidelines reflects the opinions and interests of their creators. Robert and Suzanne Fletcher (29), former editors of the *Annals of Internal Medicine*, recommend that guidelines should be created by "experts," but they acknowledge the potential for conflict of interest. "Experts in the content area—for example, subspecialists in the disease in question—have much to contribute, but they also have vested interests that may color recommendations that bear on their customary thinking, prestige, and remuneration." Meanwhile, "economists give costs their due

**Table 2.** Parties Interested in the Content of Referral Guidelines

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Patients
Primary care physicians
Specialists
Families
Payers (e.g., employers)
Managed care administrators
Clinic and hospital administrators
Nonphysician medical personnel
Government officials
Medical malpractice lawyers

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but may be insensitive to quality and simply assume that the lowest-cost care is best.”

Referral guidelines should reflect accepted medical practice as delineated by national consensus (such as the ACC/AHA practice guidelines on congestive heart failure and acute myocardial infarction). Ideally, representatives of the several interested parties should have input into their content (Table 2). Although such an inclusive approach to guideline development is impractical, it is important to acknowledge and blend the opinions of the main groups whose interests often define the extremes. At all levels (national, regional, and local), the group or committee that develops or refines referral guidelines should include primary care physicians and cardiovascular specialists in addition to managed care administrators.

Reimbursement strategies such as capitation can influence the behavior of physicians and their attitudes toward practice and referral guidelines (30). Various types of financial and nonfinancial incentives may encourage or discourage referrals. Most doctors practicing in capitated groups have voluntarily adopted utilization management policies and procedures that many physicians practicing in a fee-for-service environment perceive as intrusive. In a recent study of 94 physician groups that were part of a large network HMO in California, Kerr et al. (31) found that they all used gatekeepers and required preauthorization for certain referrals or tests. The authors concluded that “capitation at the group level has influenced physicians to devise their own management systems to contain costs.” They predicted that “as managed care expands, physicians in other states will probably face the challenge of capitation and will respond with utilization management strategies” (31).

Patients have a right to know what economic and noneconomic incentives their health plans use to influence participating physicians to make certain choices with respect to resource utilization such as specialty referral (32,33). David Orentlicher, director of the AMA’s Division of Medical Ethics, emphasizes the undesirable effects of economic and noneconomic incentives designed to discourage primary care physicians from making referrals. Under certain circumstances, these doctors “might assume responsibility for care that should be referred to more expert and more expensive specialists” (34–36).

Marcia Angell, executive editor of the *New England Journal of Medicine*, explains that some HMOs “withhold a portion of

doctors’ salaries if they refer patients to specialists too often or use too many tests and procedures. These doctors become ‘agents’ for the HMO and have a direct incentive to undertreat their patients, just as in the fee-for-service system they have an incentive to overtreat them” (37,38). Because the traditional fee-for-service reimbursement model is predicated on paying physicians for each service they provide, it can encourage them to deliver more care and use more resources than might be necessary. The challenge in creating and implementing referral guidelines is to find the proper balance between altruism and self-interest, both individual and corporate (39,40). Ideally, from the physician’s perspective, the referral process should be financially neutral and free of other incentives. Referral guidelines should not encourage inappropriate referrals to a colleague at financial risk or restrict referrals by a physician whose patient would benefit from them.

### The Creation of Referral Guidelines: Two Examples

Milliman & Robertson, Inc. (M & R) an actuarial and health care consulting firm founded in 1947, has been the main source of referral guidelines in the United States. This Seattle-based firm employed approximately two dozen physicians and nurses to develop practice guidelines in recent years. They proposed the 24-hour length-of-stay for normal childbirth that caused concern recently among women, potential parents, health care providers, and others. A public outcry led to legislation that requires insurers to pay for at least two days of hospitalization. In this context, medical writer Farah Kostreski (41) predicted that “in 1996 the lightning-rod issue is expected to be the company’s referral guidelines, especially those for cardiology.”

Richard Doyle, M & R’s senior health care management consultant, has played a major role in developing their guidelines since 1988. He has had a longstanding interest in resource utilization and became convinced that “we needed to stimulate more efficient care.” M & R did so by setting ambitious targets, termed “best practice,” with respect to the need for hospital admission, the duration of hospitalization, and the indications for specialty referral (Doyle RC, Fye WB. Personal communication, 1996).

The M & R referral guidelines are very succinct—they do not include references to support their recommendations. Most physicians view them as very restrictive. One example from the cardiology guidelines illustrates the point: “Primary care physicians should treat angina medically with risk factor/lifestyle modification and with nitrates, beta blockers, calcium channel blockers, and other medications as appropriate. Consult for angina occurring despite maximal medical treatment with maximally tolerated doses of nitrates, beta blockers, and calcium channel blockers” (42,43).

The M & R referral guidelines reflect the firm’s belief that primary care physicians should assume major responsibility for managing most of their patients’ health care needs. Although

their guidelines acknowledge that “the skills and interests of physicians with responsibility for primary care are variable,” the “protocols assume that primary care physicians will provide successful cognitive care for most patients.” They also state that “those primary care physicians who achieve optimal health care status for their patients by decision-making of moderate and high complexity, as well as appropriate use of diagnostic and performance of some therapeutic procedures, are more valuable than those who do not” (43). Doyle explains that they are “more valuable because you are not going to need to use the cognitive or procedural specialists as often” (Doyle RC, Fye WB. Personal communication, 1996).

Although their guidelines are designed to discourage referrals, M & R explain that “it must be understood that undiagnosed or intractable problems, in which the patient’s optimal health status has not been achieved or restored, should have consideration by another physician” (44). Many primary care physicians do not embrace the doctrine of late referral. There are social and scientific reasons for this. Academic family physician Robert Rakel (26) advises that “an early consultation is much less likely to damage patient confidence than a delayed one. The confident and secure physician who considers patient welfare to be of the utmost importance is not threatened and freely utilizes consultants at the appropriate, sometimes early, stage of a problem, before it has progressed to serious proportions that are more difficult to manage.”

In response to M & R’s referral guidelines, the California Chapter of the ACC published “Guidelines for Referral to a Cardiovascular Specialist” in July 1995 (45). The task force that developed them included fourteen college fellows: cardiologists (practitioners and academics) active in general cardiology and/or subspecialties such as echocardiography or electrophysiology. The California cardiologists, like many of the nation’s heart specialists (and other specialists), felt that M & R’s restrictive referral guidelines threatened their traditional role in the patient care and might result in delayed diagnosis, unnecessary testing, and suboptimal outcomes (45).

Writing on behalf of the North American Society of Pacing and Electrophysiology (NASPE), electrophysiologists David Benditt and Sanjeev Saksena expressed concern about the implications of restrictive referral guidelines (46). They and the California ACC task force argue that optimal referral guidelines should encourage effective collaboration between primary care physicians and specialists. “The consultation process,” Rakel (26) notes, “works best when two physicians work together as colleagues to solve a difficult patient problem. The process is usually a learning opportunity for the referring physician.”

The California ACC guidelines address seven clinical categories: hyperlipidemia, hypertension, congestive heart failure, arrhythmias, chest discomfort, cardiac murmurs, and children with suspected cardiovascular disease. They are more permissive than the M & R guidelines with respect to the indications for referral. But the mere existence of referral guidelines does not imply their acceptance. The California guidelines were sent to every HMO and insurance company in the state, but it

appears that few organizations have used them to this point (Goldschlager N, Fye WB. Personal communication, 1996).

Nine months after the California ACC chapter published their guidelines, Nora Goldschlager reported, “Although the guidelines have enjoyed wide popularity among specialists, primary care physicians have endorsed neither the concept nor the substance of the guidelines, nor have payers recognized the longer term cost reduction and medical prudence of the ‘referral guidelines’ when weighed against the (likely higher) up front costs.” Susan Hogeland, Executive Director of the California Academy of Family Practice, explained that family physicians who reviewed the California ACC guidelines thought they were too liberal with respect to the indications for referral (41).

It is apparent that the creation and dissemination of referral guidelines does not guarantee that they will be endorsed, formally adopted, or followed. Several factors determine how guidelines are used in a specific context, including their content, their relevance to local practice, and their economic implications.

## Outcomes Research in Cardiovascular Disease

One of the most problematic aspects of referral guidelines is their subjectivity. Increasingly, medical decisions are being based on various types of objective information, so-called evidence-based medicine. This trend reflects advances in research design, better statistical methods, and the impact of computers on science and medicine, but it is part of a larger cultural phenomenon. As consumerism increased in the United States in recent decades, patients and payers began to expect more from their doctors and hospitals. Attention is now being focused on managed care organizations—especially their policies and profits. Various interested parties are now asking them to demonstrate that their policies (including those that restrict access to specialty care) do not adversely affect outcomes.

Most would agree that it is intuitive that cardiologists, because of their additional focused training and experience, know more about the pathophysiology, diagnosis, and treatment of heart disease than primary care physicians. But in this era of managed care, specialists (and their professional societies) are beginning to realize that they need to prove that their unique expertise and technical skills improve outcomes and add value (47). If they cannot, their role in America’s health care delivery system will decrease even more than it is projected to under managed care.

Many controlled clinical trials have shown that specific cardiac treatments, such as early reperfusion and adjunctive pharmacologic therapy for acute myocardial infarction, prolong life and improve functional status (48). Studies evaluating interspecialty differences in the short-term outcomes of patients with acute cardiac disease are just beginning to appear in the literature, however. Some investigators are focusing on

interspecialty differences in clinical outcomes, while others are studying the cost of the evaluation and management process of patients with known or suspected heart disease. The American Society of Internal Medicine recently challenged managed care organizations to "evaluate the cost of subspecialist and primary care physicians by using severity-adjusted economic profiles and other measures of physician performance, rather than arbitrarily limiting subspecialists' scope of practice because of cost-effectiveness concerns" (49).

Schreiber et al. (50) studied the consequences of whether a general internist or a cardiologist directed the care of patients hospitalized with unstable angina. They found that those treated by internists were less likely to receive effective medical therapy or revascularization procedures and experienced a trend to poorer outcome. Schreiber et al. (50) concluded that their study "does not support a positive gatekeeper role for generalists in the treatment of unstable angina." Similarly, Ayanian et al. (51) found that "internists and family practitioners are less certain about key advances in the treatment of myocardial infarction than are cardiologists."

In a 1993 study of 39,256 cases of acute myocardial infarction, the Pennsylvania Health Care Cost Containment Council (52) found that "cardiologists had fewer patient deaths than expected and shorter lengths of stay than expected across all hospitals. Patients treated by physicians specializing in internal medicine stayed in the hospital longer than expected across all hospitals. Family medicine physicians practicing in hospitals *without* advanced cardiac services had more patient deaths than expected. Physicians practicing internal medicine in hospitals *with* advanced cardiac services had more deaths than expected."

Some research suggests that earlier referral to a cardiologist can reduce the overall cost of evaluating and managing a person with known or suspected heart disease. In a study of the appropriateness of radionuclide exercise stress testing, Stein et al. (53) concluded that while both cardiologists and noncardiologists overutilized these tests, noncardiologists were more likely to order tests that were not indicated. Referral to a cardiologist before ordering the test resulted in cost savings. (53). In a study of patients with a positive exercise stress test, Borowsky et al. (54) found that "the present study cohort was more likely to undergo medically necessary coronary angiography when a cardiologist was the regular source of care."

Cardiologist and health policy analyst Tom Lee (55) concludes that "common sense and recent research support the expectation that patients with serious cardiovascular syndromes benefit from subspecialty care." He suggests that "the real goal of an effective provider organization is not to keep patients away from subspecialists; rather, it is to keep the low risk patient away from inpatient nursing care and procedures from which that patient is not likely to benefit. This goal is consistent with a definition of quality of care that matches patients' needs with resources." Lee (55) advocates "strategies that allow rapid access to subspecialists for patients who are likely to benefit from subspecialty care and procedures."

Most persons with stable chronic heart disease are not followed regularly by cardiologists, and it is unlikely that this will change. The writing group of Task Force 4 of the ACC's 25th Bethesda Conference (56) concluded that "it is in society's best interest to have generalists give as much cardiologic care as they can give safely and effectively." Lee (55) agrees that "patients who are not likely to benefit from a subspecialist should receive their care from a primary care physician." The challenge is to decide just when an *individual* patient might benefit from seeing a cardiologist.

Managed care organizations are pragmatic and their guidelines reflect this philosophy. They have chosen to implement a spectrum of utilization policies in the absence of clinical outcome data. Although objective and reproducible data that demonstrate benefit at a reasonable cost should be the standard when new therapies or care plans are introduced, this is idealistic. After reviewing the various ways that doctors choose diagnostic and treatment strategies, physician and health policy analyst Clement McDonald (57) concluded "there will never be enough randomized trials or epidemiologic studies to guide every clinical decision."

Peter Dans (58), deputy editor of the *Annals of Internal Medicine* advises that "guidelines must be based on sound evidence, supplemented where necessary by truly expert opinion. Except where supporting data are incontrovertible, guidelines should be regarded as works in progress." Organizations such as the ACC and the AHA and the federal government should encourage and fund research that compares patterns of resource utilization and clinical outcomes of heart patients managed by cardiologists and noncardiologists.

## Medical Training and the Collaborative Care of Patients With Cardiovascular Disease

Board-certified cardiovascular specialists have extensive focused training that distinguishes them from board-certified general internists and family physicians. The American Board of Internal Medicine (ABIM) (59) "defines the certifiable cardiologist at the successful completion of required training as being competent to provide comprehensive, specialized care based on a high standard of demonstrated component skills." Referring to clinical judgment, medical knowledge, clinical skills, and other critical components of high quality cardiovascular care, the ABIM believes that the skills of the certifiable cardiologist "should clearly exceed those demonstrated by the certified internist" (59).

The content of cardiology fellowship programs has expanded dramatically in the past two decades. Moreover, the training process has become more rigorous, with higher expectations for both trainees and faculty (60). The ABIM requires a minimum of three years of cardiology fellowship training beyond a residency in general internal medicine before they will admit a candidate to their certification examination. A fourth year of specialized cardiology training is required to

take the certification examination for added qualifications in clinical cardiac electrophysiology.

Although primary care physicians receive much less training than cardiologists in the area of cardiovascular disease, they are being asked or required by managed care plans to play a more active role in the diagnosis and management of conditions that have traditionally been in the realm of specialists. For this approach to succeed in patients with heart disease, the primary care physician must have a cognitive and experiential knowledge base that permits him or her to accurately diagnose and appropriately treat common cardiac disorders.

Medical schools and internal medicine and family practice residency training programs provide a broad outline of specialty core knowledge, but there is no consistent approach with respect to who should be responsible for imparting this information to students and residents (61). Cardiologists should be actively involved in the educational process as it pertains to cardiovascular disease. The cardiovascular specialist, by virtue of his or her advanced training and focused experience, is usually the best person to instruct students and trainees in how to 1) obtain a relevant history; 2) perform a thorough cardiovascular examination; 3) choose the most cost-effective diagnostic tests; and 4) define the optimal treatment strategy (53,54,62,63).

Throughout medical training, clinical teaching at the bedside or in the outpatient setting must supplement classroom exercises to optimize understanding of the pathophysiology, diagnosis, and management of cardiovascular disease. Exposure to inpatients and outpatients is equally important. Specialists who have the opportunity to participate in the training and supervision of residents in family medicine and general internal medicine are the ones best able to assess the ability of these primary care physicians to evaluate and manage patients with cardiovascular disease.

The fund of knowledge and clinical expertise with respect to the evaluation and management of patients with cardiovascular disease attained by the end of the internal medical residency is highly variable (51,64,65). Because primary care physicians do not receive adequate training to interpret advanced cardiac diagnostic tests, such as echocardiograms and nuclear imaging studies, they should not be expected to do so in practice. Many primary care physicians interpret electrocardiograms and monitor and interpret standard treadmill exercise tests. They should be able to demonstrate competence in providing these services, however. The ACP/ACC/AHA Clinical Competency Statements provide guidance for many such procedures (see Task Force 3). It is inadvisable and unethical to expect or to permit individuals to practice beyond the scope of their training and experience.

### **Legal Implications of Referral Guidelines**

The legal implications of referral guidelines are beginning to receive attention. Only a small percentage of medical malpractice lawsuits result in a jury verdict, and a recent RAND study (66) found that plaintiffs won only 33 percent of

such suits. Failure to refer a patient to a specialist in a timely manner, however, has resulted in significant malpractice awards. Three of eleven recent verdicts against managed care organizations reviewed by the Medical Insurance Exchange of California involved failure to refer to specialists, and the awards ranged from \$500,000 to \$2,952,000 (67).

Perverse economic incentives and the increasing use of restrictive referral guidelines place primary care physicians in the untenable situation of having to choose between patient advocacy and financial reward. Juries are unsympathetic to this dilemma, and often recommend large awards that include substantial punitive damages. In one well-publicized case (*Ching v. Simi Valley Family Practice Inc.* [68]), death was attributed to delayed referral to a gastroenterologist. The plaintiff's attorney argued successfully that economic incentives played a significant role in the primary care physician's decision to delay referral to a gastroenterologist.

As referral guidelines are used more widely in managed care, they will be drawn inevitably into litigation as a subset of managed care policies. Recognizing the growing popularity of various types of clinical practice guidelines, the National Health Lawyers Association (69) has addressed a wide range of legal issues related to their development and implementation. In addition to discussing legal issues related to the creation, validation, and dissemination of guidelines, they report on the relationship of guidelines to standards of care, the physician's fiduciary responsibility, and quality issues.

Although referral guidelines are becoming an integral component of some managed care contracts, physicians cannot assume that they will insulate them from liability. Documenting patient advocacy is the physician's best defense against managed care liability. Primary care physicians should appreciate the concept of vicarious liability. If the approved panel of specialists available to a primary care physician is too restrictive, the primary care physician may be held vicariously liable for the inadequate care provided by the specialist (70).

The plaintiff and defense attorneys who attended the 1994 National Health Lawyers Association Colloquium agreed that although clinical practice guidelines would not have a major impact on malpractice actions, they would be used as evidence to define the applicable standard of care (69). Increasingly, plaintiffs are using guidelines to screen for potential liability cases. In the past, guidelines have been of greater value to plaintiffs than to defendants (71). This situation may change as a result of the Maine Medical Liability Demonstration Project, however, in which guidelines can be used only as an affirmative defense in malpractice suits. Some states now require managed care plans to disclose their referral guidelines to subscribers (68).

The Employment Retirement Income Security Act of 1974 (ERISA) increases the legal ambiguity of clinical practice guidelines, including referral guidelines. This Act was created to exempt self-insured companies from state regulations, including state malpractice statutes. More than 60 percent of Americans with health insurance participate in such self-insured plans. Plaintiffs suing self-insured medical care orga-

nizations are limited to contractual remedies that often provide insufficient compensation to an individual for harm that resulted from restricting care or professional negligence. Since physicians are always liable for negligence, they are attractive targets when patients suffer adverse results from a course of action dictated by the plan's utilization review and benefits policies.

The shifting of liability from health care organizations to physicians as a result of ERISA "Preemption" has been challenged recently. The concept of vicarious liability has been used against managed care organizations when plan administrators supervise physician behavior too closely. Furthermore, the recent precedent-setting *Dukes v. U.S. Health Care Inc.* case (72) suggests that state courts will be allowed to apply theories of liability to health plans in suits that involve tort damages in addition to contract damages now available under ERISA. AMA attorney Carol O'Brien thinks this is a "positive trend to the extent that HMOs that are supervising and actively involved in medical treatment can be held liable" (73). The application of state regulations in such cases underscores the increasing importance of local guideline implementation.

Many physicians, especially primary care physicians who are expected to serve as gatekeepers, feel threatened by the liability aspects of managed care. While the courts assume that physicians have discretion, and therefore liability, medical care organizations have undermined that discretion with gag clauses, practice parameters, and guidelines that restrict access of patients to specialists. The legal implications of guidelines may actually enhance the collaborative care of patients with cardiovascular disease. Concern about liability may result in more realistic referral guidelines that insure timely access to specialty care and acknowledge the expanding responsibilities of primary care physicians.

## Recommendations

**Recommendation 1.** Collaboration between primary care physicians and cardiovascular specialists should be encouraged. A bidirectional process that is enhanced by effective communication and collaborative care has traditionally been focused on diagnostic procedures, risk stratification, and treatment recommendations or procedures. Optimal collaborative care must go beyond these key elements, however, and should include shared responsibility for education, risk factor modification, and appropriate follow-up.

**Recommendation 2.** A joint ACC/AHA committee should develop referral guidelines as a template for the collaborative care of patients with known or suspected cardiovascular disease. These referral guidelines should be based on current clinical practice guidelines. The standard ACC/AHA classification system (i.e., class I, II, or III indications) should be adapted for use with the referral guidelines. An ACC state chapter or a local committee could then adapt the national referral guidelines to a specific regional or local context.

**Recommendation 3.** At all levels (national, regional, and local), the committees that develop or refine referral guide-

lines should include primary care physicians and cardiovascular specialists in addition to managed care administrators. Ideally, other interested parties should be represented, especially at the local level (see Table 2 for examples of potential participants).

**Recommendation 4.** Commercial referral guidelines that are currently available should be used with caution because they tend to oversimplify clinical situations, and their primary intent is to limit resource utilization in a population of enrolled persons rather than to ensure the best clinical outcome in an individual patient.

**Recommendation 5.** Organizations (e.g., the ACC and AHA) and the federal government should encourage and fund research that compares resource utilization and clinical outcomes of patients with cardiovascular disease managed by cardiologists and other providers (e.g., primary care physicians).

**Recommendation 6.** Guidelines must not be viewed as absolute. Managed care organizations should permit specialty referral despite their guidelines in situations where the primary care physician and specialist agree that it is in the best interest of the patient.

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## Task Force 5: Assessment, Approval, and Regulation of New Technology

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The development of clinical practice guidelines for most cardiac syndromes requires knowledge of the safety, efficacy, and cost effectiveness of cardiovascular technologies. Because new technology normally evolves through multiple iterations, it typically undergoes evaluation before and after it is made commercially available. In the 1990s there has been increasing disagreement about how technology approval and assessment should be structured to best meet society's needs. This Task Force describes the history of technology assessment, the current process of pre- and postmarket assessments, and the markedly different perspectives of the users. After consideration of the current limitations perceived by the users, the Task Force proposes a major change in the system used for technology assessment in the United States.

### History of the Technology Approval Process

The first law to protect the public from the unrestricted sale of potentially unsafe drugs was passed by Congress in 1902. In contrast, medical devices were marketed without review by the U.S. Food and Drug Administration (FDA). As medical devices became increasingly complex in the post-World War II period, the marketing of sophisticated medical devices without adequate testing became more frequent. Public disclosure of the shortcomings and failures of medical devices, such as heart valves, pacemakers, intrauterine devices and intraocular lenses, led the government to reconsider this unsupervised marketing of medical devices during the late 1960s.

Following President Nixon's October 1969 consumer message, the Secretary of Health, Education, and Welfare (HEW) established a Study Group on Medical Devices, chaired by Dr. Theodore Cooper, then Director of the National Heart and Lung Institute. The Cooper Committee considered and rejected the possibility of applying regulatory drug law to new medical devices. Instead, the Committee recommended two immediate steps: an inventory of all medical devices already on the market, and an initial classification of the risk associated with those devices. The Committee proposed that the degree of regulation by the FDA would then be based on the potential risk and benefit to the patient. In very ill patients with limited options, the degree of regulation could be less demanding.

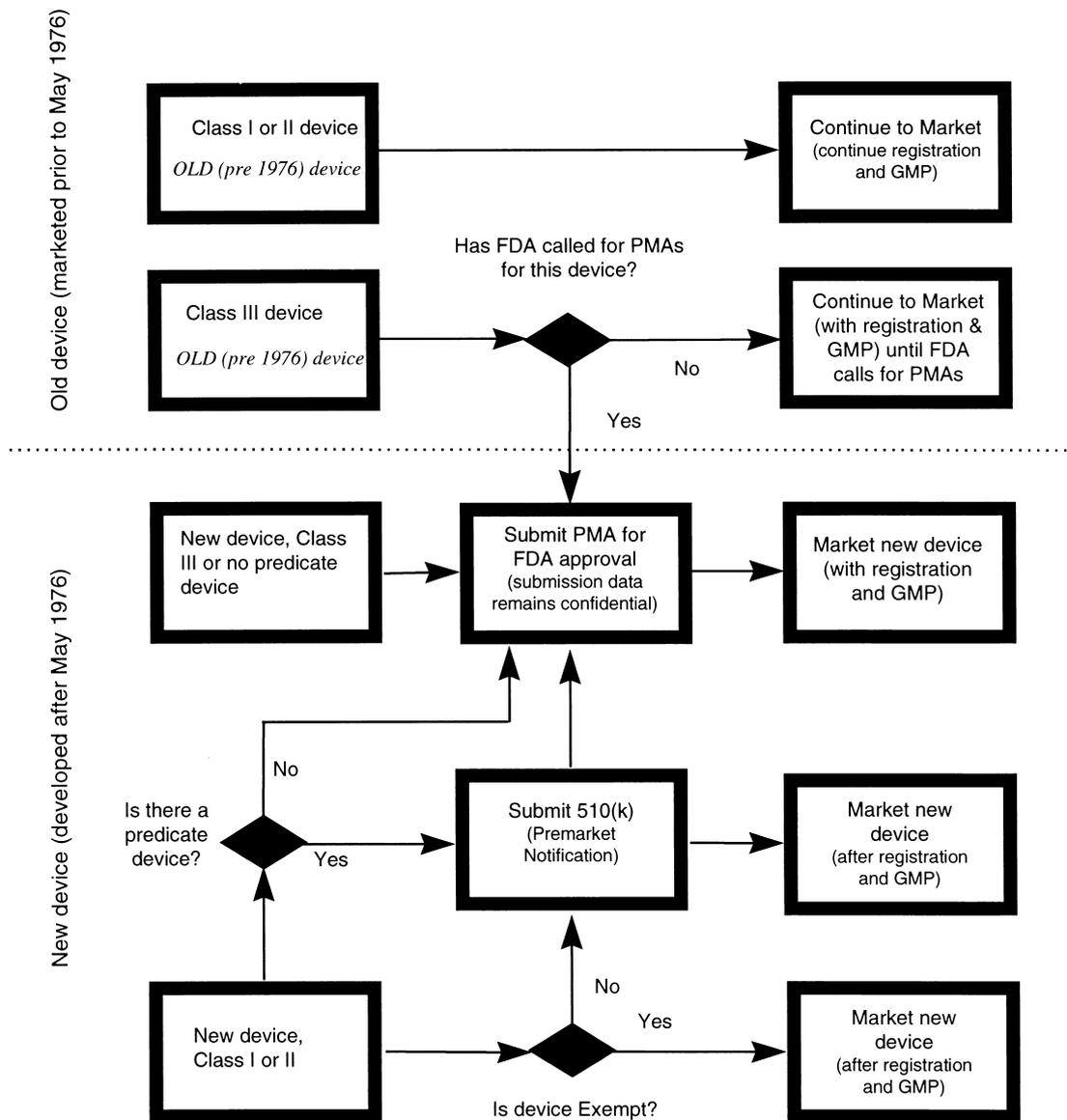
Conversely, the more hazardous a device, the more rigorous the regulation. This philosophy differed from the regulation of new drugs, where standards of safety and effectiveness were applied uniformly. The recommendations entered legislation as the Medical Device Amendments of 1976.

### The Current Regulatory Process

Figure 1 outlines the current regulatory process for devices. First, the device is classified as a Pre-Amendment device (or old device) on the market prior to the 1976 legislation, or a Post-Amendment device (or new device). Next, the device is classified by its degree of risk. Class I devices are only required to satisfy general controls which include registration and good manufacturing practice (GMP). Examples of Class I devices include tongue depressors and stethoscopes. Class II devices are subject to both general controls and performance standards. Examples include infusion tubing, monitoring equipment, and surgical masks. Finally, Class III includes devices that carry significant risk as well as potential benefit. Such devices include heart valves and stents. Class III devices cannot be marketed until the manufacturer demonstrates their safety and effectiveness to the FDA.

The evaluation and approval for marketing of new devices is generally by one of two avenues. For Class I and II devices, in the Premarket Notification, commonly referred to as a 510(k), the manufacturer demonstrates a substantial equivalence to a device with an existing 510(k) or a device that was marketed prior to 1976. The device must have the same intended use, same technological characteristics, and be at least as safe and effective as the one to which it is compared. Although the FDA may require additional clinical or laboratory studies, clinical data have not been included for 95% of devices marketed via this path. The vast majority (90%) of 510(k) submissions are approved.

The other route to market is via the premarket approval (PMA). This mechanism is used for Class III devices or for technology for which there is no existing equivalent. Demonstration of safety and effectiveness of PMA devices typically involves extensive safety and efficacy testing, including clinical trials.



**Figure 1.** Market access routes for medical devices. FDA = Food and Drug Administration; GMP = good manufacturing practice; PMA = premarket approval.

Clinical studies are carried out under an FDA investigational device exemption (IDE). As the name suggests, the IDE exempts the sponsor from commercial restrictions on unapproved significant risk devices in the United States. An IDE application includes laboratory and animal data, a clinical study design, hypotheses, procedure protocol, proposed statistical analyses, case report forms, informed consent materials, and proposed device labeling.

The IDEs, PMAs and 510(k)s fall under the authority of the Office of Device Evaluation, a section of the FDA's Center for Devices and Radiological Health (CDRH). This office received 16,978 submissions in 1995 (Table 1).

Supplements are requests for changes, either in the ap-

proved device or in the labeling, packaging, or manufacturing processes. For 510(k)s a supplement is required for changes in device design or manufacturing processes which could significantly affect safety and effectiveness or for a change in the indications for use. PMAs require a supplemental application for changes in device design or in manufacturing process which may affect safety and effectiveness, change in manufacturing facility, or change in indications for use, or change in labeling that may affect safety and effectiveness.

### The Process of New Technology Development

The development of new devices can be divided into four principal phases: preclinical development, early clinical development, trials to support marketing, and postmarketing trials. *Preclinical development* includes optimizing bioengineering design and preliminary bench and animal testing. As a general

**Table 1.** 1995 Submissions to FDA Office of Device Evaluation

PMA's	39 originals	499 supplements
IDEs	214 originals	210 amendments
510(k)s	6,056 originals	4,522 supplements
Total	6,309	5,231

FDA = Food and Drug Administration; IDEs = investigational device exemptions. PMA's = premarket approvals.

rule, the medical device industry has had little trouble meeting preclinical FDA requirements. *Early clinical development* under an IDE usually involves a pilot trial, after safety issues have been worked out on the bench and in animals. They are performed for the benefit of the developer or manufacturer. The pilot trial provides investigators with initial device experience, establishes an operator learning curve, permits an initial assessment of device design, addresses specific safety concerns, helps define the clinical protocol, estimates the potential therapeutic effect to permit calculation of a realistic sample size needed for a market entry trial, and focuses potential claims for the new device. *Market entry trials* in cardiology typically require a well defined research protocol, with specific inclusion/exclusion criteria, sample size estimates and defined endpoints. These trials involve multiple centers, and either data registries or randomization. The results of the trial are frequently reviewed by the FDA Advisory Panel. *Post-marketing trials* are conducted most commonly outside the FDA agency, although from time to time, the FDA makes changes in labeling based on such data. These trials typically involve analysis of technology performance in subgroups of patients who were not specifically identified in the premarket trials. The published data from these postmarket trials are used by professional organizations such as the American College of Cardiology (ACC) for ongoing technology assessment in clinical practice. Postmarketing surveillance studies are also required by the FDA for all long-term implants, such as pacemaker leads, implantable cardioverter-defibrillators, and heart valves.

### The Role of the FDA Advisory Panel in Device Approval and Assessment

The FDA Advisory Panel is a standing committee of experts representing the scientific community, which reviews selected PMA applications. In recent years, the Panel has increasingly taken the position that it needs randomized trial data to analyze the safety and efficacy of new devices. The precedent for this action comes from drug approvals, in which virtually all new medications are subjected to two placebo-controlled trials prior to FDA approval.

Prior to 1990, the FDA CDRH analyzed safety and efficacy by comparing a submitted data registry to historical controls. The precedent for more stringent analysis was established by experience with directional atherectomy. Although directional coronary atherectomy was approved on the basis of registry data analysis in 1990, a large-scale, multicenter randomized

trial comparing this technique with balloon angioplasty was initiated in 1991 after device approval. Completed in 1992 (1), the trial raised safety issues about directional atherectomy which were not noted by comparison of prior registry data to historical controls, included doubling of the rate of non-Q wave myocardial infarction, compared with balloon angioplasty (1,2). The feasibility of performing randomized trials prior to new device approval was then illustrated by two multicenter trials of the Palmaz-Schatz coronary stent, conducted in the United States and Europe, which led to FDA approval (3,4). Thus, methods typically used for postmarket assessment in the scientific community were brought to premarket assessment by the regulatory agency. Collection of multicenter randomized clinical trial data prior to commercialization represented a major precedent in the device approval process.

### Issues in Technology Approval and Assessment

There are a number of issues in technology approval and assessment that were identified by the Task Force (Table 2).

#### *The Long Duration of the Internal Review Prior to FDA Approval*

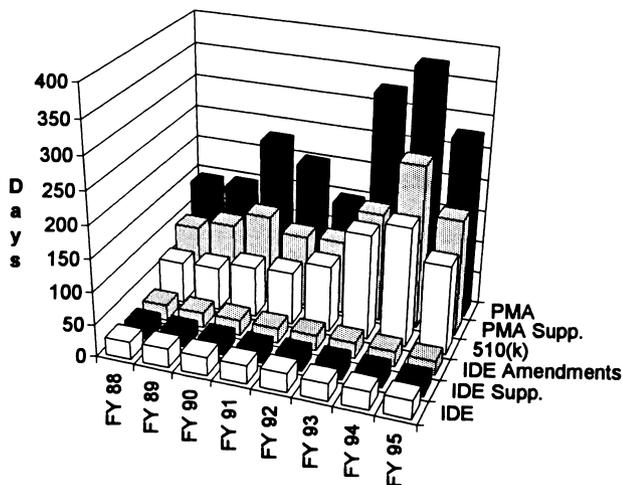
The duration of the *preclinical phase* (ending with IDE approval) depends on the complexity and maturity of the device. The time required for IDE review is relatively predictable. Under the Federal Food, Drug, and Cosmetic Act and FDA regulations, the agency has 30 calendar days from the date of receipt of the application to approve or disapprove an IDE submission. Over the last few years, the FDA has initiated a number of policy and procedure changes designed to improve the timeliness of device approvals. The average FDA review time for original IDEs was 29 days in both fiscal year 1994 and 1995, whereas the percentage of IDEs approved on the first review cycle increased from 30% in fiscal year 1994 to 57% in fiscal year 1995.

During the *preapproval phase* (under an IDE, and ending with PMA approval), the sponsor must develop and certify the manufacturing facility, complete the clinical trial and develop and package the necessary evidence of safety and effectiveness (file the 510(k) or PMA). The regulations permit the agency 90

**Table 2.** Current Problems in Technology Assessment

Long delays in FDA approval of new technology
Panel-mandated randomized trials that delay marketing
Increased cost of new technology development
Transfer of U.S. research money to Europe
Premarket trials not relevant to clinical practice
Limited availability of new technology for patients
Off-label use of technology by physicians
Payer uncertainty about reimbursement for non-FDA-approved devices
Little meaningful input from professional societies

FDA = Food and Drug Administration.



**Figure 2.** Average Food and Drug Administration review times. FY = fiscal year; IDE = investigational device exemption; PMA = premarket approval; Supp. = supplements.

days to complete the 510(k) review or 180 days to complete the PMA review and reach a decision. The agency may elect to present the information to the FDA Advisory Panel for independent assessment of safety and effectiveness. After obtaining the panel's recommendations, the FDA is required to approve the PMA, reject it, or request additional information. The average FDA review time for original PMAs was 276 and 374 days in fiscal years 1995 and 1994 respectively. The non-FDA component of review time, the time period when the document was being revised by the submitter, averaged 80 days during this time period.

The average total review time for 510(k) applications decreased from 216 days in fiscal year 1994 to 178 days in fiscal year 1995. Average FDA review times for 510(k) and PMA originals, amendments, and supplements from fiscal year 1988 to 1995 are shown graphically in Figure 2. Recent initiatives taken by the agency are expected to continue to improve or stabilize review times for an increasing volume of increasingly complex medical devices.

### *Delays Caused by Randomized Controlled Trials*

A second major limitation of the current technology assessment process is the time required to collect data required by the randomized trials that are mandated prior to device approval. Although the recent emphasis on premarket randomized trials evolved from successful application of this strategy for PMA of drugs, there are crucial distinctions between drugs and devices, which were made clear in the original Cooper Commission Report (5) (Table 3):

As a consequence, assessment methods that work well for drugs are not very effective for dealing with rapidly changing technologies. In addition to being insensitive to the iterative nature of new device development, randomized trials do not effectively capture the typical evolution of user skills and accessory improvements. While randomized trial data can be

extremely helpful in setting the boundaries of efficacy and safety, they are time consuming and expensive, costing several thousand dollars per patient. New technologies are typically first tested at a limited number of hospitals with considerable experience, making transferability to broad clinical practice questionable. Finally, to maximize the probability of approval, manufacturers design trials using the lowest risk patient subsets, knowing that "off-label" use after FDA approval will lead to much broader application in more complicated patient subsets in whom device safety and efficacy has never been demonstrated.

With these merits and disadvantages of randomized trials, their appropriate timing represents a key issue. Trials before FDA approval may be completed before the technology has matured, and before the learning curve of physicians has plateaued. Furthermore, the duration of a randomized trial substantially delays the FDA approval process. Without commercial revenue small companies cannot defray the cost of the trial. On the other hand, by deferring a randomized trial until after FDA approval, the potentially most accurate data about a new technology are not made available to the FDA Advisory Panel. These data may reveal a safety problem or lack of efficacy not evident in registry data. Performing a trial after FDA approval, however, allows for more sites and physicians to participate, a broader more relevant spectrum of patient subsets, more rapid completion of the trial, and an improved ability for extrapolating the data. To deal with these idiosyncrasies of device technology, PMA and postmarket assessment need to be viewed as a continuum (i.e., an effective system needs to be dynamic, not static).

### *Limited Availability of Effective Devices for Patient Care*

The consequences of the delay in new device approval is limited availability of new technology, and transfer of research and manufacturing dollars to Europe. The problem is illustrated by intracoronary stents, which improve early and late clinical outcomes in patients undergoing percutaneous revascularization for the treatment of coronary artery disease. More than 15 stents have been approved for clinical use in Europe, while in the United States the only 2 currently available stents were designed approximately 10 years ago and have not changed since that time. Both of these stents have important limitations. These include lack of radio-opacity which makes precise placement difficult, inflexible delivery systems which

**Table 3.** Differences Between Drug and Device Assessment

Factor	Drug	Device
Influence of physician technique on result	Low	High
Rate of technical change	Low	High
Ability to evaluate performance attributes in vitro	Low	High
Ability to visualize performance during and after use	Low	High
Effect of environment on performance	Low	High
Financial and personnel resources of developer	Large	Limited

limits their use to selected lesions, and the need for multiple balloons—one for predilation, one for stent deployment, and one for high pressure postdeployment inflation. In countries that have access to newer stent designs, these two older devices are rarely used. The newer stents are more flexible, and are mounted on high pressure balloons that obviate the need for use of separate balloons for deployment and high pressure dilation. Other stents are designed specifically for long lesions, for those with side branches, and for vein graft disease. New stents are coated to minimize subacute vessel closure. Until these newer stents are approved in the United States, selected patients will either not be able to benefit from stent application or will have suboptimal results, including the need for urgent coronary bypass surgery.

Another example involves pacemakers, cardioverters, and defibrillators. Models currently available in the United States have significant limitations in terms of flexibility, size, and programmability compared to versions available in Europe. In the past five years, smaller devices with less morbidity, and defibrillators requiring less energy have been used in Europe more than a year prior to their availability in the United States. Therefore both physicians and patients have been denied access to devices that may have reduced adverse outcomes.

### *Conflict of Interest Among Physician-Inventors and Developers*

Cardiologists with a significant financial interest now often play a key role in both the development and clinical trials of new technology. The increase in technology development is significant. In 1980 about 30 universities were engaged actively in technology transfer; at present about 200 are. In the period 1974–1984, 84 universities received just under 3,000 patents; now, about half that many patents are granted to universities each year (6). In 1986, U.S. universities reported aggregate licensing income of \$30 million; in 1994 U.S. universities reported aggregate licensing income of \$265 million (6,7).

Since October 1, 1995, the federal government has made institutions and investigators applying for National Institutes of Health (NIH) and National Science Foundation (NSF) grants or cooperative agreements subject to federal conflict of interest regulations (8). Since both new technology development and clinical trials are often supported by such funds, this new mandate is highly relevant to technology assessment. Institutions are required to define, disclose and manage conflicts of interest, including significant financial interests. Potential financial interest is defined as anything of monetary value, including but not limited to, salary, consulting fees or honoraria, equity, and intellectual property rights (e.g., patents, copyrights and royalties from such rights) (8). The regulations cover the manner in which data are collected, analyzed and interpreted; the hiring and supervision of staff; the procurement of materials; the sharing of research results; the choice of protocol; and the use of statistical methods. Neither the NSF, NIH nor other governmental agencies currently require submission of the disclosed material. Rather, the university must

advise these agencies that any conflicts are being appropriately managed. Nonetheless, an investigation by such government agency may require disclosure. The range of strategies which may be required include 1) disclosure only to the university; 2) disclosure in publications and to subjects in clinical trials; 3) research monitoring; 4) modification of the research plan; 5) disqualification of investigator; 6) designation of a co-investigator; 7) sale or transfer of relevant financial interest to a blind trust; and/or 8) severance of relationship with the sponsor.

Disclosure of conflict of interest to human subjects is also an issue in clinical trials. Informed consent is mandated by human subject protection regulations of the Department of Health and Human Services (DHHS). These human subject protection procedures are managed and administered by Institutional Review Boards (IRBs), the composition and operation of which are delineated in federal guidelines. Each institution files an assurance with the DHHS's Office for Protection from Research Risks, stipulating that the local IRB follows procedures substantially similar to those outlined in the federal regulations. Recent, well-publicized examples of scientific misconduct as well as heightened public concern regarding issues such as radiation exposure have increased the level of IRB scrutiny. Consequently, cardiologists and other investigators can expect steadily increasing regulatory requirements for human research. The information required for informed consent includes the risk (including the risk of loss of confidentiality regarding a real or suspected medical condition), potential benefits, potential new knowledge, alternative diagnostic or therapeutic choices, costs, and the potential conflict between financial gain for the investigator and scientific judgment. As in other situations involving the disclosure of potentially complex and arcane information to an individual not conversant with the field of endeavor, the burden of explanation falls on the investigator.

### *Payer Confusion Regarding Reimbursement for Experimental Procedures*

An additional major issue is the off-label use of approved devices for nonapproved indications. Current narrow clinical indications and highly specific product labeling have fostered off-label use which has potential legal and regulatory implications. Operators now fear punitive action when they use a device that is appropriate for their patients if the labeling does not recognize that indication.

The problem extends to Medicare/Medicaid reimbursement. Physicians and hospitals are reimbursed for medical services rendered to beneficiaries provided that the service is approved by the Health Care Financing Administration (HCFA). Pursuant to Section 1862 (a)(1)(A) of the Social Security Act, the HCFA is permitted to reimburse for medical services and procedures which are deemed reasonable and necessary for the diagnosis or treatment of an illness or injury. The Medicare program has historically interpreted the statutory terms *reasonable* and *necessary* to mean that a service or

medical device must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. If the procedure or device has not been approved, hospitals and physicians may not seek reimbursement from Medicare. Recently, however, even FDA approval has not been taken as a sufficient criterion for Medicare reimbursement. Historically, Medicare provided reimbursement for nonapproved FDA medical products on a case-by-case basis through recommendations made by Peer Review Organizations and various Medicare contractors.

The confusion over reimbursement criteria has been highlighted by the Office of the Inspector General's (OIG) investigation, begun in response to charges brought forth by a whistleblower in 1994. The OIG is investigating allegations that hospitals and physicians were wrongfully billing Medicare for nonapproved medical products and has issued subpoenas to 135 hospitals nationwide regarding the implantation of investigational devices in clinical trials under an IDE. Although the HCFA knew that hospitals were receiving payment for services found to be necessary and reasonable by Physician Review, Medicare based its interpretation of what is experimental solely on FDA action, excluding coverage of procedures involving non-FDA-approved devices as not reasonable and necessary.

Following the announcement of the OIG investigation, the HCFA sought to clarify existing Medicare policy for physician and hospital reimbursement. Under a new rule adopted by the HCFA on November 1, 1995, the FDA created a new categorization process to assist the HCFA in determining which medical services qualify for reimbursement under Medicare (9). Each device with an FDA-approved IDE is assigned to one of two categories: experimental/investigational (Category A) devices, or nonexperimental/noninvestigational (Category B) devices (10).

At present the OIG has agreed to limit its inquiry to nonapproved medical devices and dropped its plan to focus on nonapproved off-label uses. Additionally, the Federal District Court in Los Angeles has granted a summary judgment in favor of 25 hospitals that were under investigation by the OIG for billing Medicare for services which included a device not yet approved for marketing by the FDA. The Court ruled that the HCFA had not issued a clear policy statement governing payment for such medical products, therefore invalidating the OIG's investigation concerning non-FDA-approved devices. The government is currently appealing this decision.

## **The Divergent Perspectives of Technology Approval and Assessment**

### *The Perspective of the FDA*

The FDA perceives its mission as the promotion of the public health through timely approval of medical devices which are safe, effective and appropriately labeled. Therefore, it must base its regulatory decisions on valid scientific evidence from properly designed clinical trials that establish the safety and

effectiveness of the new device. As a regulatory body with a great deal of oversight from politicians, interest groups and journalists, the FDA is in the unenviable position of being criticized for making the smallest mistake, and never rewarded for taking risk. Its procedures are designed to withstand political criticism and tend to be long and detailed. From the FDA perspective, not every sponsor develops their device in a logical fashion. Many studies, conducted without prior FDA input, seem to lack scientific merit. Prospectively defined, objective endpoints that establish device effectiveness are often lacking. To better communicate requirements, the FDA urges early interaction with the sponsor and principal investigator. Such interaction should precede the IDE submission.

The FDA will support integrating premarketing and post-marketing activities, and earlier PMA, provided that the overall clinical plan is rational, safe, and has the appropriate balance between earlier public access and more detailed clinical data. In certain circumstances, PMA supplements with adequate preclinical data and appropriate postmarketing studies could be approved without premarketing clinical studies.

### *The Perspective of the Practicing Cardiologist*

The perspective of the practicing cardiologist is patient advocacy. The physician aims to optimize patient outcome with the minimum delay. When the pace of technologic change is rapid, cardiologists believe that both patients and society are not well served by the current approval and assessment system. The physician's view is that iterative changes of similar devices should have a facilitated approval process. In addition, cardiologists argue that it is wrong to deny Medicare beneficiaries access to the latest medical advances simply because the newer devices are waiting approval by the FDA. Finally they fear that if hospitals continue to limit clinical trials in response to the threat of fraud litigation, some devices may never reach the general market, forcing overseas development.

### *The Perspective of Industry*

Although industry perspectives are varied, in recent years there is a consensus that present methods for assessing and approving technology are excessively costly and time consuming, particularly in light of the lack of any evidence or cost/benefit analysis that public safety is being enhanced by the increasingly stringent requirements of the FDA approval process (11).

Industry also sees the issues of technology assessment as inextricably tied to the larger issue of health system reform, making the trade-offs between health care financing, delivery and quality more and more difficult (12). Manufacturers also feel that the managed care community has made it increasingly difficult to introduce new technologies or deviate from standards of practice. Industry sees the FDA and the academic medical establishment as unlikely supporters of managed care by insisting on rigorous scientific proof that a new device is more beneficial and cost-effective than the one it is intended to

replace. In industry's view, the benefits of greater scientific rigor and accuracy are more than offset by the liabilities of increased cost and time to develop new technology, and by the limited clinical relevance of scientific results that are obsolete by the time they are published.

### *The Perspective of Payers*

Payers want to know which tests and treatments should be reimbursed and at what level. Historically, acceptance of a new technology for reimbursement was based primarily on FDA approval. Payers see inherent contraindications when devices labeled as experimental are concurrently identified and utilized by the medical community as the standard of care in off-label applications.

These different views of technology assessment serve to illustrate the difference between safety (the potential to cause harm), efficacy (ability to produce the intended result), effectiveness (utilization in actual practice) and cost-effectiveness. FDA regulatory approval is based on the first two factors; physician and patient acceptance is influenced by the third and payer reimbursement by the fourth. The key to developing an effective method for technology assessment, therefore, is the phasing of information acquisition and analysis, and of approval and assessment. Device approval prior to marketing, which typically analyzes efficacy, must be linked to postmarket assessment of safety and effectiveness. At present, however, device approval is often the last rigorous step in technology assessment.

### **Technology Assessment: Meeting the Nation's Needs**

The flaws in the current system of technology approval and assessment are summarized in Table 2. The time required to bring effective new technology to patient care is far too long. The assessment of safety is conducted in highly selected, low risk subgroups that do not represent the patients subsequently treated in practice. The resulting off-label use of devices has created chaos among payers and providers. The postmarket analysis of device performance is inadequate. Research and development in the United States is transferred overseas. Finally, although not calculable, the cost of all these problems is undoubtedly in the billions of dollars. Solutions to the problems could lie in legislation or in restructuring the system. In this section, the Task Force considers these two alternatives.

### *Proposed Congressional Reform*

Throughout the 104th Congress, FDA reform was a primary focus of the congressional leadership. Senator Nancy Landon Kassebaum (R-KA) introduced the FDA Performance and Accountability Act of 1995 (S.1477) which was approved on March 28 by the Senate Labor and Human Resources Committee by a vote of 12 to 4 (13). The bill would amend the FDA Act and the Public Health Service Act to improve the

regulation of food, drugs, medical devices, and biological products. This bill would require the FDA to complete at least 95 percent of new product approval applications within set statutory deadlines; allow outside review boards to conduct product review under certain circumstances; expand access to experimental drugs and medical devices; reduce the quantity of data the FDA would require from industry during the approval process; and improve communication with regulated industries. An original provision of the bill would have allowed manufacturers to distribute information on off-label uses for medical drugs.

On the House side, the most notable bills were those proposed by the Chair of the legislative task force of Commerce Committee Republicans, Congressman James Greenwood (R-PA) (HR 3199, HR 3200, and HR 3201). These bills address the areas of medical devices, drugs and biologics, and foods. The bills would allow manufacturers to submit applications directly to a third-party review board if the FDA failed to meet the statutory deadlines, with private industry absorbing the cost of review. Although these FDA reform proposals received significant bipartisan support, all measures were unsuccessful in gaining approval during the 104th Congress. Republican members of Congress and administration officials have promised to reconsider FDA reform proposals in 1997.

On October 8, 1996, the FDA issued new guidelines on the dissemination of information by companies to health care professionals regarding off-label uses of their products. The guidance will allow industry to disseminate information on off-label uses through peer-reviewed journals and textbooks; however, industry representatives will not be permitted to promote information in the disseminated text that is not consistent with the approved labeling for a product. The information must clearly state that some data are for off-label use. The ACC commented favorably on this regulation when it was proposed but suggested that the FDA could go further in fostering the dissemination of new clinical information.

The ACC strongly advocates reform to decrease the complexity and length of approval time for pharmaceuticals and devices. The ACC recognizes the need for physicians and other health care professionals to have access to accurate and unbiased information about pharmaceuticals and medical devices. The ACC supports the exchange of public scientific information on off-label uses of pharmaceuticals and devices, while recognizing the publication of such peer-reviewed information must be handled with the utmost regard for patient safety. Many off-label indications of previously approved pharmaceuticals and devices are widely recognized as accepted by physicians but are not part of FDA-approved labeling. The ACC encourages the development of alternative mechanisms, including lengthy clinical experience, which would allow petitions for inclusion of a supplemental indication on FDA-approved labeling. The College supports the ability of the FDA to contract with qualified, non-FDA organizations for review of new pharmaceuticals and devices to facilitate the review process, if public safety is not compromised. The ACC is supportive of voluntary pilot projects to test the feasibility of

third-party reviews of low to moderate risk devices. Finally, the ACC is committed to providing unbiased professional guidance to both industry and the FDA.

Although the ACC believes that continued improvements are desirable, it does not support reforms that would mandate strict time frames for FDA approval unless additional funding is provided. Furthermore the ACC does not support complete transfer of the approval process from the FDA to private contractors. Finally, the ACC does not support changes that would require increased FDA responsibility unless the agency receives a commensurate increase in resources.

### Recommendations of the Task Force on Technology Assessment

The Bethesda Conference Task Force on Technology Assessment believes that major improvement in technology approval and assessment, meeting the needs of all users, can be readily accomplished within the current structure, which has many merits as well as the previously cataloged deficiencies. The Task Force proposes establishment of a new category of conditional approval for new technology. The proposed new category of provisional FDA approval would require acceptable data to demonstrate preliminary safety and efficacy, including bench testing, preclinical data, and pilot clinical studies. Provisional approval would give limited labeling (i.e., a narrow indication), but there would be prestipulated conditions of final approval, including

1. Completion of a comprehensive clinical trial in a specified time frame. The trial would include a wide spectrum of patient categories and indications, reflecting anticipated use in clinical practice.
2. Marketing of the device by the manufacturer only for the limited label.
3. Full acknowledgment that the new device approval could be rescinded if the data generated do not support its use or if the data were not available in the designated time period.

The advantages of this new structure are that it will:

1. Provide far better insight on true efficacy and safety in a broad population of patients.
2. Limit off-label use, by expanding the patient subsets in which new technology is tested.
3. Provide early access to promising new technology and extend safety and efficacy analysis to postmarket approval.
4. Allow more rapid introduction of new devices into clinical practice.
5. Improve global competitiveness in the United States for new technology assessment.
6. Achieve this within the confines of preexisting legislation.

To facilitate this process, the ACC would agree to work with the FDA in technology assessment in the following ways:

1. Participate in defining criteria for provisional device approval.
2. Advise FDA on Advisory Panel membership, including ad hoc membership.
3. Advise the FDA and the Advisory Panel on design of clinical trials.
4. Periodically draft Position Statements on the need for trials.
5. Conduct postmarket technology assessment using FDA-mandated clinical trial results and other data published in scientific journals.

The Task Force proposes, and the Bethesda Conference unanimously supported, this plan as an optional alternative to the conventional approval pathway. While the intent of provisional FDA approval is directed toward enabling devices to reach the U.S. market in a more expeditious manner, the Task Force also recognized that it is uncertain whether this proposal requires new legislation or whether there is sufficient latitude in the current FDA IDE regulations to allow immediate implementation. Consequently, the Task Force also recommends continued dialogue between the FDA, the ACC and the organizations representing patients, physicians and the business community to determine the legality and practicality of its proposal, and to explore all possible avenues for improvement in the system for approval and assessment of medical devices in the United States.\*

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\*Members of the FDA participated in the Bethesda Conference. At the conclusion of Task Force 5 deliberations, the FDA members drafted the following statement: "While the intent of a 'provisional' FDA approval is directed toward enabling devices to reach the U.S. market in a more expeditious fashion, the legality and practicality of this proposal needs further intensive development and review. In the interim, FDA would like to encourage the American College of Cardiology to actively dialogue with FDA so that (1) the ACC can become more familiar with current device development options, and (2) both parties can continue to explore new ideas and strategies for efficient device development in the United States."

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