

President's Cancer Panel Meeting

Meeting Minutes

Decision Making Based on Quality of Care Guidelines and Their Impact

October 6, 1998
Buffalo, New York

Overview

The President's Cancer Panel was chartered to monitor and evaluate the development and execution of the National Cancer Program and to report to the President on barriers to Program implementation. This meeting, the last in a series of three focusing on the meaning of quality of care and quality of life, explored issues in decision making based on quality-of-care guidelines and their impact on the delivery of cancer care.

Nineteen speakers presented testimony to the Panel on the role of Federal agencies in clinical practice guideline development, as well as the guideline-related activities of leading oncology professional societies, professional organizations, health care organizations, and health care regulators. Speakers offered specific recommendations for improving the development and implementation of cancer care guidelines in the evolving health care environment.

Meeting Participants

President's Cancer Panel: Harold P. Freeman, M.D., Chairman; Paul Calabresi, M.D.; Frances M. Visco, J.D.

National Cancer Institute: Otis Brawley, M.D., Assistant Director, Office of Special Populations Research, National Cancer Institute; Maureen O. Wilson, Ph.D., Assistant Director, NCI, and Executive Secretary, President's Cancer Panel

Speakers:

Dr. Cynthia Ambres, Chief Medical Officer, Blue Cross/Blue Shield, Buffalo, New York

Dr. David Asch, Executive Director, Leonard Davis Institute of Health Economics, University of Pennsylvania

Dr. Otis Brawley, Office of Special Populations Research, National Cancer Institute

Dr. Gregg Broffman, Medical Director, Health Care Plan, Buffalo, New York

Dr. Steven Clauser, Director, Quality Measurement & Health Assessment Group, Health Care Financing Administration

Dr. Michael Cropp, Medical Director, Independent Health Association, Buffalo, New York

Dr. Stephen Edge, Director of Breast Services, Roswell Park Cancer Institute, Buffalo, New York

Dr. Terry Hammons, Assistant Vice President, Quality and Managed Care Standards,

American Medical Association

Dr. David C. Hohn, President and CEO, Roswell Park Cancer Institute, Buffalo, New York

Dr. George J. Isham, Medical Director and Chief Health Officer, American Association of Health Plans

Ms. Linda Krebs, President, Oncology Nursing Society

Dr. William T. McGivney, Chief Executive Officer, National Comprehensive Cancer Network

Dr. James Schibanoff, Editor-in-Chief, Milliman & Robertson Healthcare Management Guidelines, Milliman & Robertson

Dr. Cary Sennett, Executive Vice President, National Committee for Quality Assurance

Dr. Lisa A. Simpson, Deputy Administrator, Agency for Health Care Policy Research

Dr. Dixie Snider, Associate Director for Science, Centers for Disease Control and Prevention

Dr. Mark R. Somerfield, Director, Health Services Research, American Society of Clinical Oncology

Dr. Max S. Wicha, President, Association of American Cancer Institutes, University of Michigan Comprehensive Cancer Center

Dr. Rodger Winn, Chief, Section of Community Oncology, M.D. Anderson Cancer Center

Opening Remarks

In opening the meeting, Dr. Freeman congratulated the Roswell Park Cancer Institute on the occasion of its 100th anniversary and stated that:

- This is the last in a series of three meetings to consider the meaning of quality in the context of cancer care. The Panel believes that defining and delivering quality care is essential to achieving the goals of the National Cancer Program to alleviate the burden of cancer in this country. The first meeting of this series, held in April 1998, focused primarily on how we define, measure, and improve quality cancer care. Testimony presented at that meeting highlighted clearly the difficulty in agreeing on a uniform definition of quality cancer care. Perceptions of quality vary significantly depending on who you are and what you have experienced.
- Cancer care is a continuum, from prevention through diagnosis, treatment, and

palliation, and even following death, when social support and bereavement counseling for family members are needed. We must examine the notion of quality care in each of these areas.

- The second meeting of this series, held in June 1998, focused on the special health care needs of cancer survivors, and the need to enhance research on survivorship and end of life issues. Cancer survivors, who now number more than 8 million, are rightfully demanding not merely new cancer treatments, but improved cancer care and a better quality of life following diagnosis through the end of life.
- This meeting is to examine the role that guidelines play in determining our approach to and understanding of quality cancer care. The use of guidelines in medicine is not new. Standards of care and clinical pathways for diagnosis and treatment of cancer are accepted resources for health care providers to make recommendations on the best course of cancer care for patients. However, rapid changes in our health care system, particularly the evolution of for-profit managed health care, have raised new issues regarding the development, application, and impact of guidelines. Reasonableness of cost has been added as a measure of quality in consumer evaluations of health care delivery organizations, yet the cost and quality of care are often perceived as competing priorities. It is important to evaluate the impact of these changes and how we can best develop and apply guidelines that promote quality care in a cost-cutting environment.
- The impact of cancer care guidelines has not been well studied. Cancer, as a spectrum of chronic diseases with long-term outcomes, does not lend itself to conventional quality measurements applied to the treatment of other diseases.
- Key issues include but are not limited to: how we establish indicators of quality and of effective cancer care as applied to the general population; how we develop a process for evaluating guidelines; how we use information that is gathered about quality; and how this information will be used to refine our notions of quality cancer care. It is also important to consider how guidelines are communicated to the health professional community and to the public. New technologies, particularly the Internet, have increased access to and availability of a wide variety of research discoveries and evolving cancer care guidelines. It remains unclear how this information is affecting decision making and the delivery of care.
- Any discussion of cancer care guidelines must encompass investigational care, or clinical trials. Access to clinical trials is often equated with state-of-the-art or optimal cancer care. Guidelines incorporating cost as a measure of quality may promote quality standard care, but may in fact limit access to so-called optimal care, such as may be available in clinical trials.
- The National Cancer Institute (NCI) has worked with several organizations to ascertain the cost differentials between standard care and care in clinical trials. These analyses will be made available in the future.
- It has been asserted that every person waging a personal war against cancer needs timely access to the best therapies available to fight his or her disease, and assurance that medical knowledge and care will be applied appropriately. The difficulty is in determining on what basis we establish guidelines for care, and assuring that appropriate care is delivered under appropriate circumstances in a

cost-effective manner. In the war against cancer, we must be concerned not only with the effectiveness of treatment but with its quality as perceived by patient, family, and practitioner. We must also be concerned with its appropriateness—whether more treatment was provided than necessary or at higher cost than required, or whether the treatment provided was ineffective. How we deliver health-related messages and provide services can have a significant impact on individual perceptions of quality of care. Further, technical definitions of quality must take quality of life into account, both during and after treatment, and at the end of life when cure is not possible. We cannot say that we are delivering quality care if the patient does not feel that the care is of high quality or that life is worth living.

NCI Report

Representing Dr. Richard Klausner, Director, NCI, Dr. Brawley indicated that:

- The NCI, principally through the input of expert panels from the extramural research community, has identified four areas of extraordinary opportunity in cancer research: cancer genetics, preclinical models, imaging technologies, and molecularly based detection and diagnosis. The Institute has also been working to enhance the infrastructure for research and foster collaborations among the cancer centers throughout the country.
- NCI and other studies have shown clearly that equal treatment yields equal outcome in cancer care, and that race is not a factor in cancer outcome. Patterns-of-care studies, however, show that cancer treatment is not applied equally in the United States. Factors shown to influence outcome include socioeconomic status (SES) and comorbid conditions; many special populations in this country have both lower SES and greater numbers of comorbid conditions. Regional and racial differences in prostate cancer treatment have been demonstrated and have been used to question the efficacy of the common treatments for the disease. Within race, however, regional mortality rates are nearly identical. Disparities in quality of care have also been demonstrated among white Americans of different socioeconomic strata.
- Similar patterns have been identified in the treatment of breast cancer. One-half of the difference in the breast cancer death rates among black and white women is due to later removal of the tumor following diagnosis in black women.
- Treatment guidelines are an important vehicle for applying research findings in the population, but a key question is how to effectively disseminate the guidelines to the physicians and hospitals who treat patients.

PRESENTATION HIGHLIGHTS

ROSWELL PARK CANCER INSTITUTE

Key Points

- Cancer centers face multiple strategic challenges in the current health care environment. Necessary tactics for survival include the ability to standardize and predictably implement care not only within the institution, but within the community. Delivering care to a whole population is going to be a major challenge in cancer care, and for cancer care management, in the decade ahead. Cancer centers face difficult challenges because the care they provide is subspecialized and often more expensive; justifying the value in that added expense can be difficult, and the ability of the centers to subsidize their greater expenses from nonclinical income streams is becoming constrained.
- Increasingly, simpler cases are being treated in the community, while the more complex cases are being sent to the cancer center. Without guidelines and accompanying data defining this greater case acuity and the associated differential cost, the center will not be reimbursed by payers and will jeopardize its ability to fulfill its academic mission.
- Another strategic decision is the choice to compete or collaborate. Some cancer centers have moved to the competitive model, establishing satellite facilities throughout their service areas to capture patients and ensure the quality of care. This model is difficult to support in the Buffalo area; as a result, Roswell Park is moving toward the collaborative, or network model, bringing community physicians to the cancer center. To do so, however, it is necessary to define what care is provided through guidelines, and how it is done through clinical pathways.
- The cancer center must also maintain alignment with the area's health care systems. Guidelines and clinical pathways help the center define for these health care systems what the center does and also helps protect its academic mission. The cancer center should serve as the hub in a hub-and-spoke relationship that supports the delivery of high-quality care to a regional population.
- Declining earned income is a continuing issue; the center is now negotiating contracts for care based more on market price than a more precise accounting of cost for the care provided. Guidelines should lead to a methodology for better cost accounting and the ability to negotiate fair, honest, value-oriented managed care contracts. Such contracts should enable the center to generate sufficient margin to support the academic mission. Revenue issues are also endangering investigators' protected time for research.
- Guidelines and pathways offer opportunities to more precisely determine clinical costs, reduce costs for inappropriate care, promote educational collaborations between physicians and other cancer care providers, develop disease-site panels to set guidelines, reduce legal risk by reducing variability in care, and measurably enhance quality of care.
- Challenges to the development and use of guidelines include difficulty in achieving physician consensus, implementing guidelines, monitoring outcomes

- appropriately at the level of the individual provider, influencing behavior change in physicians whose practices differ from those prescribed by the guidelines, and maintaining the confidentiality of physician-specific outcome data.
- Though guidelines have been developed for the treatment of most cancers, few have been implemented systematically. A simple, user-friendly, networked computer system is essential to support wider use of guidelines. Progress is being made toward this objective, notably by the National Comprehensive Cancer Network (NCCN), and also by the M. D. Anderson Cancer Center, which has developed an editable online disease management system that enables the physician to print out guidelines, patient education materials, and preformatted order sets and consent forms. Such approaches are needed if physicians are to embrace rather than resist the use of guidelines.
 - In addition to their missions in research, education, prevention, and patient care, cancer centers need to more clearly define and actively pursue their roles in setting and maintaining the standard of cancer care in the community. The development and implementation of guidelines at the community level is the best way to accomplish this mission. Standard care guidelines must be evidence based, clearly defined, easy to use, and widely accessible to health professionals, payers, and patients. Raising the quality of care in the community will best be achieved through partnerships between cancer centers, payers, and community physicians. An informed public can help promote this revolution in the way we practice medicine and can help set the agenda for raising the quality of care.

ROSWELL PARK CANCER INSTITUTE

Background

The Roswell Park Cancer Institute, Independent Health Association (a health care payer in western New York), and a board of community physicians are engaged in a partnership to develop a breast cancer practice guideline and use the guideline to establish a regional total quality management program. The first phase of the project involves a retrospective quality review of breast cancer care in 1995 and 1996 in western New York, to be benchmarked against the NCCN breast cancer practice guidelines. The second phase is the development of a prospective quality improvement program, using prospective ongoing data collection and educational interventions using local peer experts and ongoing involvement of community physicians.

Key Points

- Breast cancer care varies widely in the United States. These variations are seen in biopsy techniques, the use of x-ray staging tests, rates of breast-conserving surgery and radiation therapy, use of adjuvant chemotherapy, and patient followup and treatment of recurrences.
- Measures of quality are difficult to develop. Cancer recurrence and survival are the ultimate measures of quality, but acquiring data on these endpoints may take many years. Single measures (e.g., mammography or breast-conserving surgery

utilization rates) may serve as useful quality benchmarks, but may not get at the heart of the quality issue; in contrast, practice guidelines may provide that opportunity.

- Roswell Park conducted a retrospective analysis of its breast cancer care and compared the findings to practice guidelines developed and updated annually by the NCCN. The comparative analysis revealed a high rate of compliance with the guidelines, as well as areas of variation and areas in which guideline updating seemed indicated. Roswell Park now conducts ongoing guideline benchmarking for all breast cancer care at a monthly conference of the breast cancer staff.
- In the first phase of the Roswell Park/Independent Care/community physician project, insurer claims data will be used as the source of practice data. The advantage of using these data is that care provided in any venue is captured. Patients will be identified from procedure and diagnosis codes, and data will be collected on identified patients for all care provided in the 6 months following biopsy or a surgical procedure. It is recognized, however, that claims data have disadvantages, including the lack of cancer staging data and possible clerical coding errors. In addition, claims data by definition do not include care provided to the uninsured. Moreover, in the western New York market, most Medicare beneficiaries are not enrolled in managed care; as a result, data on care provided to the elderly population will be incomplete. Other methods will be used to obtain information on care provided to this population. Independent Health will collect the pathology and operative reports, from which cancer staging data will be obtained. Practice patterns will be reviewed and benchmarked against the NCCN guidelines. Oversight is being provided by a multidisciplinary panel of community physicians.
- Preliminary results of the claims review indicate that the process is identifying both cases and procedures with 99 percent or greater accuracy. The optimal positive rate for breast biopsy ranges from 25 to 40 percent, depending on the population being studied. A low positive rate means that many women undergo unnecessary breast biopsy without benefit and experience needlessly the anxiety that accompanies the procedure. Though surgeons who performed a high volume of excisional biopsies with needle localization (EBNLs) had a consistently higher positive rate than those who performed few such procedures, the same was not true for radiologists who placed the needles.
- For women with breast abnormalities detected by mammography, the ideal is to have only one surgical procedure performed on the breast. This reduces both cost and anxiety, and produces the best cosmetic result. Repeat surgeries (re-excisions required because of unexpected findings) should not exceed 20 to 25 percent of cases). In the Independent Health study, women who had EBNLs had far higher re-excision rates than women whose biopsies were performed by fine needle aspiration (FNA) or stereotactic core needle biopsy.
- Claims data review, in conjunction with staging data, provides detailed practice review data that may be useful for practice guideline benchmarking. The methodology developed by Dr. Cropp and colleagues is applicable to other cancer types and other payers. Such evaluations must be provider based; i.e., they must be directed by providers and be quality-driven to promote provider acceptance

and provide real quality improvement.

INDEPENDENT HEALTH ASSOCIATION

Key Point

- As a payer, Independent Health views quality of care broadly. It works with its provider partners to enhance health-promoting behaviors in the community and thereby reduce future cancer incidence among members. Cancer screening demonstrated in the literature to have a positive impact is provided to as many members as possible. Independent Health believes members need to become more aware of the early signs and symptoms of cancers. A major concern of members is the quality of the provider network available through the plan.
- The health plan strives to ensure that diagnostic care is accurate and expedient, and that treatment is effective, appropriate, coordinated, and compassionate.
- The plan's physician partners expect Independent Health to provide them with information on patients' status, including information on health maintenance and screening procedures. In addition, the plan now provides physicians with information on the status of their patient populations to encourage them to ensure that more of their patients receive recommended screenings. Information is also provided about "best practices" for both screening and treatment.
- Community physicians also want access to a network of quality institutions at which they can provide direct services or to which they can refer patients with confidence that they will receive excellent care. Independent Health looks to the Roswell Park Cancer Institute to help enhance community standards of care and to provide services either directly or through community collaborations.
- In the care of its patients with cancer, Independent Health considers population-specific measures of value, including quality of care, quality of service (e.g., timeliness, patient-friendly delivery), quality of life, and cost.

BLUE CROSS/BLUE SHIELD

Key Point

- Unless efforts to determine how to enhance the health of the community are collaborative, such efforts are likely to fail.
- It is important that payers are participants in consensus building and guideline implementation, but also that they are facilitators rather than barriers to care. Blue Cross/Blue Shield, in collaboration with Roswell Park and other providers and physicians in the Buffalo community, hopes to be a prototype for the Nation in this regard.

HEALTH CARE PLAN

Key Point

- Noting that "many are stubborn in pursuit of the path they have chosen; few in pursuit of the goal" (Nietzsche), Dr. Broffman cited the work of Drs. Cropp and Edge in breaking down artificial barriers to quality care in the community and advancing the common goal of improving community health. Health Care Plan welcomes the opportunity to collaborate on practice guidelines and related efforts.

COST, QUALITY, VALUE, AND PATIENT CHOICE IN CANCER CARE

Key Points

- It is often perilous to talk directly about health care costs; even people whose job it is to reduce cost do not like to be allied explicitly with that role.
- When people talk about clinical guidelines, they usually are referring to ways to standardize clinical management. The movement toward guidelines grew out of several decades of health services research that demonstrated wide variation in clinical practices. Such variation provides an agenda for standardization, especially if health care is viewed as a commodity product and health care delivery is viewed from industrial models. A key question, however, is: What is standardization through guidelines expected to accomplish? The possible answers include: to direct patients to optimal care; to direct clinicians to provide care that provides the best value; to direct care to conform to patients' preferences; to direct patients to a concept of the most appropriate care; or to direct patients to care that will be reimbursed by insurers. The stated goals of guidelines may include one or more of the following: reduce high costs, provide high-quality care, provide cost-effective care, or provide appropriate care.
- In a choice between two screening tests, in which one test is slightly more sensitive but significantly more expensive than the other, a fully insured and fully informed patient would be expected to want the more sensitive test. It clearly offers the highest quality. Which test offers the best value, however, depends on how one values the added benefit of the more sensitive test relative to its higher cost. The clinician's selection of one test or the other may be based on a desire to provide the highest quality care, but in the current health care environment, may include other goals, such as value or cost containment. The cost perspective of the patient may depend in part on what insurers will reimburse; moreover, insurance payments can become a standard against which physicians judge their practices, and, in the extreme, may define those practices.
- Eliminating unnecessary procedures or ineffective care is good for everyone. Quality can sometimes be improved and money saved at the same time, but, often, better clinical approaches cost more. Techniques such as cost-effectiveness analysis provide a framework for understanding value, but the highest quality is still the highest quality (however quality has been defined). The real challenge facing patients, clinicians, and policymakers is deciding when cost-increasing

- improvements in quality are not worth their added expense.
- When we talk about seeking value in health care, we are really talking about compromise; i.e., we are saying that we are willing to accept something we believe is of lesser quality because we believe the added benefit, compared to another alternative, is not worth the additional cost. Physicians make these compromises routinely in clinical practice and have become comfortable with a notion of value (versus quality) by disguising it in one or more of several ways:
 - By thinking beyond the individual patient; i.e., considering the effects of a more expensive alternative on overall social welfare. In this case, the tension between the cost of the alternative and its benefit is overt, though displaced from a single patient to a wider field. This kind of thinking is often embedded within hospital policies and other kinds of clinical guidelines.
 - By appealing to the "standard of care," even though the standard may not represent the highest quality care. Cost does not immediately appear to be part of this argument, but the standard of care is itself often influenced by cost (i.e., if the higher quality test cost less, the standard of care might be different). Appealing to the standard of care is one way of saying that we believe more value is more important than a certain amount of quality.
 - By displacing responsibility for the decision; e.g., the health plan's formulary restricts the prescription of certain medications in certain situations. Similarly, a patient's request for a less expensive and less effective medication or treatment does not erase the provider's responsibility, since the patient may not be informed about the existence or higher quality of an alternative.
 - By rationalizing making do with less than the best. This compromise involves comparing the best with the good. A shorthand assessment of quality in such cases might be: Would you recommend this approach (or this physician, or this practice) to a relative?

By using the "best treatment" only after others fail. In some cases, physicians are not aware that they are making these compromises, which are embedded in practice patterns, policies, and guidelines.

- In contrast to the typical rhetoric of organized medicine, many physicians are comfortable tolerating lower quality care if it is seen as providing good value. Cost is important, understood by physicians, and recognized as meaningful in clinical decision making.
- One of the most important roles for guidelines is in setting a target for physicians, who use the strategies above to balance their sometimes conflicting goals of providing high quality and good value. Guidelines can help physicians decide whether quality or value is the goal.

Discussion

Key Points

- One of the issues we face in trying to use health care resources wisely is not only using them wisely in each individual case, but making sure that resources are distributed fairly across a population. A major problem in cancer prevention and screening is that some populations, for a variety of reasons, are not getting recommended screening tests. In general, the cost of any test can be reflected by the opportunity costs of using those resources elsewhere. One of the most efficient strategies is always to make sure that the things that work get to the people who need them. However, in the case in which a reasonably good, lower cost test has been distributed to the entire population, the decision would again arise as to the added benefit of moving to a higher quality, more expensive test. Dr. Asch noted that his comments referred principally to the health economics questions surrounding the latter point, rather than the social health questions reflected in the difficulty getting services of any quality to currently underserved populations.
- In comparing the total health care costs associated with one screening test versus another, the lifetime costs of care for patients whose cancer or other condition is missed by a less sensitive but less expensive test must be taken into account. Likewise, lost earnings and other human capital considerations should be assessed. At the same time, we cannot say that no cost is too high to save a human life, since we would then devote all of our resources to saving lives, and go bankrupt. Absent an infinite amount of money, choices must be made. These choices include whether resources saved in using a less sensitive screening test (that would result in some missed diagnoses) should be diverted to public health improvements (e.g., better bicycle helmets, clean water for more of the population) that will impact significantly on health and quality of life.
- Currently, we lack the physician and payer data to establish and measure quality as determined by outcome. These data are crucial if we are to truly measure cost-benefit.
- Employers impose some constraints on health plans as to what treatment will be covered; however, it is up to the health plan to ensure the most appropriate distribution of the employer's health care dollar.
- Also at issue within the framework of guidelines and quality of care is the designation and responsibility of decision makers. For example, is the provider responsible for communicating choices (and related issues of quality and value) to the patient, or is the provider responsible for making the choice and providing care accordingly? How are these considerations to be incorporated into guidelines?
- In the theoretical scenario which focuses on providing a more expensive, more sensitive test to a smaller population versus applying the cost differential between that test and a less sensitive, less expensive test to provide the lesser test to a larger number of poor people (and by doing so, find more cancers and save more lives), society has decided that the lives of the undiagnosed poor people are

- expendable.
- Multiple tiers already exist within the health care system, though often not explicitly. Individuals at the uppermost tier(s) may, for example, choose to pay out of pocket for care not covered by their insurer. This may be more of a political issue than a medical issue. In terms of the appropriate allocation of health care dollars across a population, the issue of societal benefit versus individual benefit remains. In addition, when insurance premiums (most of which are paid by employers) rise because of increased utilization and/or utilization of more expensive care options, less money goes to wages, stockholders, widows and orphans, and others. Ultimately, therefore, when prices rise, we all pay. Dr. Asch suggested as an analogy the situation in which individuals at a restaurant tend to order more if the check is to be shared equally, but tend to order more conservatively if there will be separate checks.
 - Many factors are operant in the treatment differences by race described by Dr. Brawley. In some cases, people are afraid to be treated or may have cultural reasons for not accepting treatment. Much of the difference may reflect socioeconomic issues (e.g., treatment is unaffordable, there is no source of free treatment, treatment is not offered at a time or in a place that is accessible). Disparities in receipt of radiation therapy following lumpectomy are not due to comorbidity, but are more likely due to the quality of the physicians available to poorer populations. The NCI is interested in funding more studies of these disparities.
 - Health plans have a responsibility to fully disclose and educate prospective members prior to enrollment as to the treatment that will and will not be covered. Similarly, physicians and other providers must be educated concerning the plan's structure, policies, and reimbursements. Health plan members and patients should be included more fully in medical policy decision making that will govern coverage under the plan.
 - Referring to the issue of using health care dollars to make screening available to populations currently not receiving it, a participant noted that some of those dollars (or additional monies) are needed for outreach and for taking the services to individuals in the community.

THE FEDERAL ROLE IN GUIDELINES TO CARE

Agency for Health Care Policy Research

Background

The Agency for Health Care Policy Research (AHCPR) was created in 1989 from the former National Center for Health Services Research. Its mission is to enhance the quality, appropriateness, and effectiveness of health care services through a broad base of scientific research. While research is the primary product of AHCPR, it recognizes that translation and dissemination are critical to achieving its mission. The Agency has three main goals: (1) to support improved outcomes through outcomes research and the development of outcome measures and instruments; (2) to strengthen quality

measurement and improvement; and (3) to improve access, foster appropriate use of services, and reduce cost. In addition to research, AHCPR also produces data sets and tools for decision makers. Its audiences are public policy decision makers at the Federal and State levels, systems policymakers, and clinical decision makers (including both clinicians and patients).

The AHCPR's initial guidelines program, which existed between 1992 and 1996, produced 19 guidelines, of which two focused on cancer-related issues (cancer pain and quality determinants in mammography). All of these guidelines were generated by multidisciplinary expert panels that included patient and consumer representatives. They used an evidence-based methodology to weigh, synthesize, and summarize the evidence. The guidelines were influential both because of their content, which was widely adapted and adopted, but also because they improved the methodologies and raised the level at which evidence-based guidelines are developed. The guidelines also were controversial (to be expected if the evidence indicates that some aspects of current practice are ineffective) and expensive, due to the labor-intensive nature of the process. In light of all of these factors, the guidelines development process was redesigned in 1997 and is now known as the Evidence-Based Practice Center Program.

Key Points

- Concerning guidelines, AHCPR sees itself as having five important roles:
 - Developing the evidence base upon which to create guidelines. This evidence base includes effectiveness research, research on cost-effectiveness analysis, and research into better methods for doing this kind of study.
 - Synthesizing all of the available evidence.
 - Establishing partnerships to increase the adoption and use of guidelines.
 - Conducting research to advance understanding of the use and impact of clinical practice guidelines.
 - Providing a feedback loop as to research that is still needed.
- With the establishment of the 12-center Evidence-Based Practice Center Program in 1997, AHCPR created a structure to facilitate its activities to synthesize available evidence and develop reports related to various aspects of medical practice for use in the development of guidelines. The evidence reports can also be used to develop performance measures and to inform or set priorities for quality improvement programs.
- Some of the evidence reports are intended to be used to inform coverage policies and decision making in both the public and private sectors. For example, AHCPR evidence reports are used by the Health Care Financing Administration (HCFA) in its administration of the Medicare program. AHCPR sees the users of the evidence reports as quite varied (e.g., providers of care at both individual and system levels, researchers, purchasers of care, policymakers, consumers).
- In addition to producing evidence reports, the 12 Evidence-Based Practice Centers also will have the capacity to perform advanced analyses, conduct research, improve methodologies for evidence synthesis, and work with private-

sector partners in implementing guidelines. Federal partners include the NCI, other institutes within the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Social Security Administration. Both private- and public-sector partners have been involved from the early stages of report development to ensure that the issues are defined and addressed appropriately.

- The hallmark of the evidence reports is the methodologically driven, systematic, and thorough approach to their development. Once drafted, the reports are peer reviewed. The first set of reports developed under the new process is now in review. The second set of reports has recently been commissioned; one of these will be an update of the cancer pain guideline developed in the early 1990s. It is hoped that the reports will be published and distributed within 12 to 18 months of commissioning; this represents a significant improvement over the prior program, which often took 2 to 5 years to produce a guideline.
- The evidence reports will also include an extensive bibliography and a recommended research agenda addressing identified gaps in the evidence for the area in question. Of the first 12 reports commissioned, two are cancer related (cervical cytology and testosterone suppressant treatment).
- The U.S. Preventive Services Task Force, established in 1984, is another quality-related activity of the AHCPR. The Task Force makes recommendations on clinical preventive services, including screening (including cancer screening), immunizations, counseling, and chemoprophylaxis, and like the Evidence-Based Practice Centers, uses an evidence-based and systematic methodology to review what is known about the effectiveness and cost-effectiveness of various tasks. Recommendations of the Task Force were first published in 1989; its most recent publication (1996) covers more than 200 topics. It is widely circulated and is used by many managed care organizations to guide coverage and payment decisions for clinical preventive services. The Task Force has recently been reappointed, and will receive technical support from two of the Evidence-Based Practice Centers. New or updated reviews will be made available online to expedite distribution. These products will also be linked to the Agency's dissemination and implementation agenda, entitled "Put Prevention Into Practice."
- The National Guideline Clearinghouse, now under development, will be an online service operated by AHCPR (in partnership with the American Medical Association [AMA] and the American Association of Health Plans [AAHP]) to disseminate guidelines and help clinicians and health care systems sift through the multiple guidelines in existence to identify those most appropriate for their populations and needs. It is also expected to help patients and their families make informed diagnostic and therapeutic choices. In addition to structured abstracts of the individual guidelines, tabular data will compare multiple guidelines for the same condition or aspect of care. The full text of the clinical practice guidelines will be available when possible; otherwise, hot links will be established to other sites at which the guideline or ordering information is available. Further, links will be provided to discussion groups, and to annotated bibliographies for those who wish to access the supporting literature for a given guideline. The Clearinghouse is expected to become operational in December 1998.

- Guidelines are a tool for improving quality of care, but research has shown that simply mailing a guideline to a provider will not precipitate a change in practice. Implementation strategies are crucial; this is an area in which more research is needed to identify effective strategies that best promote behavior change. AHCPR is working in partnership with the National Committee for Quality Assurance (NCQA) to facilitate the integration of evidence-based guidelines into the quality measurement activities of NCQA.
- To better understand the impact of guidelines on the quality and outcomes of care, AHCPR is funding jointly with the American Association of Health Plans a \$7 million initiative to study the role of various features of managed care. Use of guidelines will be one of the factors studied.
- AHCPR also supports a portfolio of investigator-initiated research. Part of its agenda for the future is a continued, and possibly expanded, investment in research and demonstrations to help understand how to better translate research findings into practice. The role of guidelines and their appropriate use is an item on this research agenda.

Initiatives for Quality Improvement: Cancer Care and Quality of Life

Key Points

- The Health Care Financing Administration does not itself develop practice guidelines, but relies on AHCPR and professional associations to do so. HCFA uses those guidelines to improve its programs.
- Two years ago, HCFA reorganized with the goal of becoming a value-based purchaser. The Agency has a long history of building financial considerations into its decision-making and operational processes; the reorganization was designed to also build quality considerations into these processes.
- HCFA believes performance measures should at a minimum be highly evidence based and built on the best available clinical science, but the Agency recognizes that performance measures alone are not necessarily practice guidelines. Guidelines can serve a variety of purposes, depending on the ability to measure the elements of which they are comprised.
- HCFA's goal is to use performance measurement in a data-driven strategy to serve as the benchmark for all of its quality improvement initiatives. Among the interventions now considered part of the portfolio of opportunities to improve care under Medicare and Medicaid are enforcement of the Agency's traditional regulatory responsibilities, providing technical assistance to providers, providing information and assistance to consumers, using payment and coverage to advance quality goals, and rewarding superior performance.
- As part of its traditional regulatory functions, HCFA sees itself as a protector of beneficiary health and safety. This role is carried out by setting minimum standards or conditions for provider participation in Medicare and Medicaid. With managed care providers responsible for the care of a growing number of beneficiaries, these conditions increasingly are being applied to provider contracting arrangements. In addition to traditional clinical performance and more

qualitative measures, HCFA is now trying to supplement these data with process and outcome information based on performance measures derived from well-established guidelines. One of the challenges in this endeavor is to determine how to link quality improvement with HCFA's regulatory requirements.

- In its relatively new role as an extraordinarily large purchaser of care, the Agency is recognizing that regulatory strategies are only one of many possible tools to promote quality of care. It is now exploring how best to use its leverage in the marketplace to try to improve quality of care.
- Through initiatives such as the 1993 Government Performance and Results Act (GPRA) and the Vice President's National Performance Review, HCFA has been challenged to select specific, measurable improvement goals for the Medicaid and Medicare programs. To meet these goals, HCFA has worked to establish collaborative relationships with its contractors and encourage participating providers to accept some of the accountability implicit in the goals.
- HCFA's quality improvement strategies each focus on a particular program area with a focused clinical goal for a given population. For example, breast cancer screening is a national priority for the Agency; in response to the GPRA Act of 1993, HCFA has established the goal of increasing by 5 percent between 1997 and 1999 the proportion of female Medicare beneficiaries aged 65 and older who receive a screening or diagnostic mammogram in a 2-year period. To meet this and other quality improvement goals, HCFA develops measures of quality of care using comparable and accurate measures, audits the data for accuracy, and examines community variability. These data are to be fed back to providers so they can monitor their performance relative to HCFA's benchmarks; the data would also be available to beneficiaries to educate and help them make informed choices of providers and services. These steps in the quality improvement process are intended to stimulate improvement in care, provide remeasurement and evaluation, and enable the program to make changes in the delivery process and medical advances.
- It is not always clear, however, what the goal (e.g., 60 percent of female Medicare beneficiaries receive mammograms annually) of such quality improvement programs should be, or when data analyses produce conflicting results, which data should be used. Similarly, the unit of accountability for intervention may vary, or a variety of strategies may be needed. HCFA continues to research these issues, which tend to be easier to assess in the managed care setting.
- HCFA has re-engineered its peer review organization (PRO) program, which has previously been locally based, to support a more national focus on quality improvement. Six clinical priority areas have been selected for emphasis; one of these is breast cancer screening. The PROs will be held accountable for improvement in rates on a statewide basis, and HCFA will provide contracting incentives for the PROs to build voluntary partnerships between hospitals, physicians, and managed care organizations to try to achieve the desired results. In managed care, HCFA is establishing a mandatory quality improvement initiative (Quality Improvement Standards for Managed Care, QISMC) for both Medicare and Medicaid. Clinical priorities have yet to be set for this program.
- Performance measurement is still in its infancy, though it is developing rapidly.

- Partnership-involving the professional communities, beneficiary communities, and purchasers of care-is essential to success. Challenges include developing meaningful performance measures and encouraging scientifically based decision making at all levels.
- Many activities to promote quality improvement and partnership are under way. HCFA is, through the Vice President's Forum, involved in discussions with many large private employers. In addition, Federal agencies including HCFA, AHCPR, the Department of Defense (DoD), and the Veterans Administration have been working together through the Secretary's Quality Improvement Interagency Council to coordinate strategies. HCFA is also involved in activities of the Joint Commission on Accreditation of Health Organizations (JCAHO), the AMA, American Hospital Association (AHA), and NCQA.
 - Other HCFA quality improvement initiatives include efforts in collaboration with AHCPR to link preventive practice guidelines to coverage criteria for these services; beneficiary education efforts; and continued research on performance measures for cancer treatment, quality of life for nursing home patients (focusing particularly on pain management), and the link between specific cancer treatments and functional status.

Additional Research Needs and Other Recommendations

- Expanded collaboration is needed between the public and private sectors in the area of cancer care and quality of life.
- Efforts should be supported to translate evidence-based medicine in all aspects of cancer care into clinical quality improvement.
- Partnerships with consumers should be fostered to identify their needs, learn what they are experiencing, and provide them better choices for quality health care.

Centers for Disease Control and Prevention

Background

CDC's mission is to promote health and quality of life by preventing and controlling disease, injury, and disability. The agency accomplishes its mission through research, public health surveillance, outbreak investigations, evaluation of interventions, public health capacity building, and national leadership.

CDC is primarily a public health agency; as such, it takes a community perspective, identifying the community as the patient, and seeking to identify community interventions to solve community health problems. CDC strongly emphasizes prevention, an area to which only 1 percent of national health care expenditures are devoted, and, in particular, primary prevention. In addition, because of the value it places on social justice, the agency takes an egalitarian view on resource allocation issues.

Issues of principal concern to the CDC include maternal and child health, chronic diseases (including breast and cervical cancer screening programs and smoking-related

cancers), environmental health, occupational health, and injury prevention and control. CDC supports State and local health departments in conducting public health surveillance, including surveys for behavioral risk factors for cancer. In addition to other national surveillance efforts through the National Center for Health Statistics, CDC trains public health workers in a variety of areas, such as response to public health emergencies.

CDC's scope of responsibility has been expanding over the years. Current areas of emphasis (and guideline development) include infectious diseases associated with cancer, such as hepatitis B, hepatitis C, human papillomavirus (HPV), and others. In the United States, approximately 10 percent of cancers are estimated to be associated with preventable infections.

Key Points

- CDC maintains on its website more than 300 guidelines of various types. The agency develops guidelines because it hopes to accomplish its mission by influencing people to take actions that will reduce preventable morbidity and mortality. CDC frequently develops guidelines at the request of its State and local health delivery partners, community organizations, and academia. Guidelines may be developed in response to an emerging health problem, the development of a new technology, the availability of new epidemiologic data, the results of research studies, or any combination of these.
- The target audiences for CDC guidelines may include State and local health department officials; other Federal, State, and local public officials; school officials; public safety officials; community-based organizations; hospital administrators and staff; laboratory personnel; physicians and other health providers; management and labor officials; and the public.
- CDC's approach to guideline development varies. For some guidelines, a standing Federal advisory committee exists that is responsible for issuing the guideline. In other cases, a guideline may be developed by an ad hoc committee, or by scientific staff at the agency. It is CDC's policy to involve in the guideline process those who will be involved in implementing the guideline. Decisions as to how a guideline will be developed may be influenced by how quickly it is needed, but generally follow the approach outlined in "CDC Guidelines: Improving the Quality." Generally, this approach includes: a statement of the problem; literature review; review of other available scientific data; ascertainment of the relevance, generalizability, and quality of the data; review of the recommendations of other groups; and consideration of practical and feasibility issues (e.g., acceptability of the recommendations to providers, community, and patients; impact of the recommendations on health care delivery systems; distributional effects in the population; other social, legal, and ethical concerns). Public meetings normally are held to solicit the views of the general public on the proposed guideline; if a topic is controversial, guidelines will be published in the Federal Register for comment.
- When the data permit, CDC guidelines are based on rules of evidence; when data are absent or inadequate, expert opinion is used without hesitation. In these cases,

expert opinion may be gathered through Delphi or nominal group techniques, and meta-analyses, systematic reviews, and economic analyses are used as appropriate. In addition, since many of the guidelines must address policy as well as technical issues, formal policy analysis is encouraged.

- In establishing priorities for guideline development, CDC considers the prevalence and incidence of disease, the burden of illness, the cost of the illness, the cost of the intervention, the availability and quality of data, the availability and quality of existing guidelines, and the feasibility of implementing any recommendations.
- CDC's guideline development and dissemination process could be improved by reducing the length of time now required to develop and publish a guideline, updating guidelines more systematically, improving the process for obtaining input, and broadening dissemination.
- The extent to which CDC guidelines are followed varies. The agency assesses the impact of its guidelines by using its surveillance systems, special surveys, or other special information systems. Overall, the guidelines are believed to be influential; this is due in part to the agency's institutional culture, which values scientific integrity, openness, competence, accountability, and the involvement of constituents in the development process.
- State health departments frequently translate CDC guidelines into regulations. Similarly, many of the recommendations in CDC guidelines are consistent with managed care goals and have been incorporated into measures such as HEDIS (Health Plan Employer Data and Information Set).
- All participants in the health care system will be challenged in the future by changes in health care providers and technology. Genetic testing and population screening for genetic predisposition to disease, including cancer, will be especially challenging to ensure that people do not experience discrimination or other adverse consequences due to loss of privacy.

Discussion

Key Points

- Guidelines are being developed by numerous Federal agencies and professional organizations with little coordination among these efforts, which may overlap or offer conflicting recommendations. To address this issue, CDC has established advisory committees for certain areas (e.g., immunizations) through which it attempts to "harmonize" divergent recommendations and involve all of the major participants in that aspect of care. HCFA has taken a somewhat similar approach to develop consistent measures for diabetes care. It is hoped that the National Guidelines Clearinghouse will help identify overlapping guidelines and areas in which no guidelines now exist.
- Issues related to practice guidelines are complex. Standards of care may be developed for which insurance reimbursement is available, yet physicians may know that a higher level of care is possible. Appropriate variation from a standard due to shared decision making and the tailoring of care to the patient's

- circumstance can be difficult to distinguish from inadequate care when a body of evidence is being reviewed.
- The National Guidelines Clearinghouse will be an online service. To disseminate information to those without online access or with limited online resources, Clearinghouse information will be "wholesaled" to professional associations, consumer groups, and others that will reach a broad spectrum of the population. CDC relies on partnerships with community groups, churches, and others to help disseminate guideline information. Discussants agreed that no one organization can fully support the expense of information dissemination through multiple media.
 - It is anticipated that guidelines from many public and private sources will be available through the National Guidelines Clearinghouse, either directly or through "hot links." Guidelines developed by the Department of Defense, however, are unlikely to be included. It was noted that the Quality Interagency Task Force described by Dr. Clauser is considering issues of quality across programs, including the DoD, Veterans Administration, Federal employees health benefits program, and programs of the Department of Health and Human Services (DHHS) and Department of Labor (DOL).
 - In addition, the DoD has recently concluded an effort to adopt a single set of breast cancer treatment guidelines to be implemented in all DoD hospitals. With the help of a consultant, 43 sets of guidelines were collected and rated on 12 key attributes, and a single set of guidelines was selected. The decision is now being reviewed at the topmost ranks. A participant suggested that implementation will be challenging, noting that adherence to the widely accepted cancer pain management guidelines is only about 39 percent.
 - Though reimbursement, or lack of it, can be used to motivate providers not to do something, it is harder to motivate them to adopt new behaviors or practices. Recent summaries of available literature on motivating adherence to guidelines suggest that no single strategy is sufficient, and that depending on the setting, population, and type of clinician, the combination of strategies required will vary.
 - Tools are lacking to help the public evaluate medical evidence and practice guidelines or to determine who is to be considered the authority on various aspects of care. It is hoped that abstracting and presenting in tabular form multiple guidelines on a given topic will assist practitioners and the public in evaluating existing guidelines. In addition, tools are needed to facilitate shared decision making, since each person weighs risks (including side effects) and benefits differently. The development of such tools is challenged by the science literacy level of the public relative to the vast amounts of information available through various media.
 - The dissemination and implementation of practice guidelines is also complicated by political forces that may be difficult to sway. It was observed that some people or organizations may become so invested in the path they have chosen with respect to guidelines that they may lose sight of the goal-reduced cancer incidence, morbidity, and mortality. The Nation must resolve philosophical questions as to how and by whom guidelines should be developed and managed, and the appropriate limits of public policy or Congressional mandate in these

- areas.
- Even when a guideline is developed by a representative group of constituents, local or regional groups tend to want to modify the guideline to accommodate cultural or other local values. This situation reflects our ambivalence about national standards of medical practice for various conditions. We want a guideline to ensure quality care, but we want the flexibility to tailor it to local needs.

PROFESSIONAL SOCIETIES AND ORGANIZATIONS

National Comprehensive Cancer Network

Background

The National Comprehensive Cancer Network (NCCN) is an alliance of 17 major cancer centers across the United States. Since 1995, NCCN has supported the basic missions of these institutions to provide the highest quality of care to the greatest number of patients in need, and to advance the state of the art in cancer care through research. NCCN also was initiated to help make member institutions more competitive in the evolving health care marketplace.

Activities of the Network have been based in the guideline development process. In just under 3 years, NCCN has completed guidelines that cover over 90 percent of all cancer patients, in over 1,000 pages of algorithms and text developed predominantly by expert panels. Presently, more than 500 physician experts in various fields are involved in 38 expert panels. A decision was made 15 months ago to also involve patients in the development of NCCN guidelines. NCCN has recently reached an agreement with a major partner to begin the translation of its guidelines into patient information.

Key Points

- The trend toward outcomes-based decision making has been a major change in the health care system over the past 10 to 12 years. Accordingly, NCCN takes an evidence-based consensus approach to guideline development. The process includes outcomes data review, integration and consensus by expert panels, solicitation of input from member institutions and other constituencies in the health care community, multidisciplinary review at member institutions, and finalization by the expert panel. The guidelines are living documents, and the entire guideline process depends on continual updating.
- The NCCN guideline process seeks to restore authority in determining appropriate practice and decision-making autonomy to practicing oncologists.
- NCCN guidelines have been published in *Oncology* and disseminated to its circulation of 32,000 individuals. The Network has encouraged and supported the efforts of other oncology centers and oncology groups to adopt and integrate the guidelines into their practices.
- The NCCN process has addressed four common deficiencies in guideline development: (1) lack of timeliness, (2) lack of specificity, (3) failure to update

- guidelines regularly to reflect clinical advances, and (4) poor implementation.
- Implementation is achieved by monitoring the performance of individual practitioners. To facilitate performance measurement, an oncology outcomes database is being developed by NCCN. The ultimate goal is to collect uniform, comprehensive, sociodemographic, clinical treatment, outcome, and cost data on all patients with the common cancers treated at NCCN member institutions. The database was initiated in July 1998 at five member institutions for the collection of data on breast cancer patients. By the end of 1998, another six institutions will be added. The effort will continue to be expanded over the next few years; it is anticipated that by the end of 2001, the oncology outcomes database could be collecting extensive data on patient treatment and outcome for approximately 50 percent of all cancer patients (people with breast, prostate, colorectal, or lung cancer together comprise approximately 50 percent of all cancer patients).
 - The database will be used to evaluate the level of practice conformance with NCCN guidelines within member institutions, and to evaluate the clinical and relevant nonclinical (e.g., days lost from work during specified time periods following diagnosis) outcomes of treatment. It is expected that these data will provide a foundation for establishing partnerships with various constituencies in the health care community.
 - A 224-element data dictionary in breast cancer was developed directly from the NCCN breast cancer guideline. It includes sociodemographic data and a focused set of outcomes. The database is multidisciplinary in approach and the information collected, and permits severity adjustment across patient populations. In addition to monitoring general conformance with the guideline, the database can be used to address controversial issues that arise in the expert panels during the discussion of guidelines, compare performance across institutions, and serve as a benchmark for practices across the country.
 - NCCN is about to launch a partnership with a large managed care company to implement NCCN guidelines across its oncology network. It is expected that all centers will begin reporting to the NCCN database within 24 to 30 months.
 - All of NCCN's data forms are available on the Internet. NCCN can collect and receive data, and can structure and maintain databases accessible through a data coordinating center website.

Additional Research Needs and Other Recommendations

- Practice guidelines implemented through performance measurement is the model for continuous quality improvement in cancer care.

Clinical Practice Guidelines

Background

The American Medical Association's guideline activities center on its role as a coordinator and conveyor of information, and on setting attributes or criteria for guideline development and dissemination. AMA works with national medical specialty societies,

methods experts, government, and other private-sector organizations in these efforts. As part of its activities in these areas, AMA has established a coordinating entity, the Practice Parameters Partnership and Forum. The Practice Parameters Partnership, composed of the 13 large medical specialty organizations, the American Hospital Association, AHCPR, the JCAHO, and HCFA, focuses principally on policy development. The Practice Parameters Forum includes more than 80 specialty societies and other organizations and functions as a broader source of expertise and an information dissemination mechanism.

The AMA has for 10 years published the *Directory of Clinical Practice Guidelines*, which includes information on approximately 2,000 guidelines from a variety of physician organizations and Government entities, including the NIH, the American Cancer Society, the American Heart Association, and others. The *Directory* is updated annually; the new edition will have about 100 oncology-related guidelines from approximately 20 organizations.

Key Points

- Guidelines are strategies for care and decision-making support. They define the process of care with the goal of achieving the best possible outcomes. Since guidelines typically provide the rationale for recommendations made, they also serve as summaries of knowledge and its application in clinical care. Clinical practice guidelines can also be used in continuing professional education, and as key information when adding or refining critical pathways or protocols in the care process.
- Guidelines are also useful in deciding what to measure about care or outcomes to assess whether the intended process of care is being delivered and the intended outcomes are being realized. Thus, guidelines are useful for designing measurement systems and review criteria.
- Guideline development at the American Medical Association began about 15 years ago. Early emphasis was on developing and disseminating sound guidelines. It was assumed, however, that thorough dissemination alone would yield changes in practice and better patient outcomes. AMA has since learned that dissemination is not enough to ensure implementation. It has become clear that implementing or embedding guidelines in thought and action requires motivation (not limited to financial or professional incentives) and capability to improve, measurement and feedback to enable clinicians to see improvement, and organizational support.
- The AMA is piloting a new project, the Clinical Practice Guidelines Recognition Program. Its purpose is to identify guidelines developed with a sound process and broad representation, and having recommendations based on evidence from the literature.
- AMA has emphasized that guidelines must be implemented flexibly, with respect for clinical judgement by the physician and for the patient's particular needs. Reflecting this emphasis, AMA has recently initiated the American Medical Accreditation Program (AMAP), a program to accredit physicians and engage them in measuring the care they provide and the results they achieve for their

patients. This program, which will incorporate measures for oncologic conditions, will provide feedback to physicians to support improvement. To become accredited under the program, physicians will be required to satisfy a number of standards. One such standard will initially encourage and later require participation in measurement, feedback, and care improvement related to the physician's patient population.

- AMAP will establish criteria for measurement systems and measures, for effective feedback, and for protecting patient and physician confidentiality. In addition, AMAP will develop core measure sets for 50 to 80 specific conditions and populations (including oncology populations). Physicians may initially participate in programs measuring their performance only against core measures, then progress to a more extensive measurement system.
- AMAP is leading the oversight of accreditation development and the measurement systems to support it. Individuals from national and State medical societies and methodological experts are working with AMA in advisory committees and work groups in these efforts.
- AMAP has also established the Performance Measurement Coordinating Council (PMCC) with NCQA and JCAHO. Through the PMCC, the three accrediting bodies seek to bring commonality and rationality to their measurement and feedback activities. In this way, measurement at the physician level regarding a particular condition will be consistent with what hospitals are measuring about that condition, and consistent with health plan measures through HEDIS.
- As part of its work to disseminate information on performance measurement, the AMA will this year publish the *Clinical Process and Outcomes Measurement Directory*, which will contain approximately 250 examples of work from varied sources. The *Directory* replaces the *Outcomes Resource Guide*, which focused only on outcomes. The new directory recognizes the need to measure both process and outcome.
- To augment measurement, feedback, and improvement efforts, AMAP will provide one-on-one support for physicians to help them understand program data and guidelines and how these relate to the individual provider's practice, as well as to share ideas for improvement.
- In addition to oncology guidelines in the *AMA Directory* and oncology measures included in the AMAP, the PMCC will facilitate an integrated approach to measurement across time, space, and organization. It will enable clinicians to link activities occurring in the physician's office with those occurring in the hospital, the rehabilitation facility, and in home care.
- AMA's initiatives in clinical practice guidelines and clinical performance measurement have the potential to speed the application of advances in the knowledge, diagnosis, and treatment of cancer.

Clinical Practice Guideline: Progress, Pitfalls, and Prospects

Key Points

- Since 1993, when its Health Services Research Committee was formed, the American Society of Clinical Oncology (ASCO) has published four practice guidelines in its *Journal of Clinical Oncology* (JCO). Another 10 guidelines are in progress. The published guidelines are on: (1) use of hematopoietic colony-stimulating factors (CSF), (2) tumor markers in breast and colorectal cancer, (3) breast cancer surveillance, and (4) treatment of unresectable non-small-cell lung cancer. Each is being updated, in some cases for the second or third time. Updates are also published in the JCO. ASCO is also developing consumer versions of the guidelines; those for breast cancer surveillance and advanced non-small-cell lung cancer are nearing completion.
- Most of the ASCO guidelines are boundary guidelines, which define the appropriate use of novel and often expensive technologies. These guidelines are distinguished from path or algorithm guidelines that describe the current standard of care for a single disease.
- In addition to practice guidelines, ASCO recently has undertaken technology assessments, defined as the establishment of a process for determining if a procedure, device, or test is appropriate for broad-based conventional usage (i.e., when it is no longer considered experimental). A technology assessment has been initiated on the use of tamoxifen and raloxifene for breast cancer prevention. The working group for this activity will complete a systematic review of the evidence and provide guidance to the clinicians who are responsible for discussing risks and benefits of these preventive agents with healthy women. It is hoped that a document will be ready to be presented to the ASCO Board in February 1999.
- A paradox of evidence-based guideline development is that guideline topics selected on the grounds of practice variation do not lend themselves to evidence-based guidelines, to the extent that practice variation is the result of limited or inconsistent evidence.
- Two of the more common criteria for selecting a guideline topic are that: (1) significant variation in the practice exists; and (2) suitable data on the practice are available. The availability of consistent randomized trial data, however, does not necessarily lead to changes in practice. In such cases, one purpose of guidelines is to put existing evidence into concrete, formal recommendation form, and thereby serve as a catalyst for translating evidence into practice. The most common scenario is one in which there is some evidence, but it is insufficient in both quantity and quality. The challenge, then, is to ensure that the guideline consumer clearly understands the strength of the evidence supporting the recommendation.
- ASCO has adopted two methods for characterizing the strength of evidence contributing to guidelines. The first method, adopted from the American College of Chest Physicians, employs a combination of levels of evidence and grades of

recommendations. In this method, five levels of evidence are defined:

I. Evidence obtained from meta-analysis of multiple, well-designed, controlled studies; randomized trials with low false-positive and low false-negative errors (high power).

II. Evidence obtained from at least one well-designed experimental study; randomized trials with high false-positive and/or false-negative errors (low power).

III. Evidence obtained from well-designed, quasi-experimental studies such as non-randomized, controlled single-group, pre-post, cohort, time, or matched case-control series.

IV. Evidence from well-designed, nonexperimental studies such as comparative and correlational descriptive and case studies.

V. Evidence from case reports and clinical anecdotes.

The recommendations are graded as follows, reflecting the consistency of available evidence:

A. There is evidence of type I or consistent findings from multiple studies of types II, III, or IV.

B. There is evidence of types II, III, or IV and findings are generally consistent.

C. There is evidence of types II, III, or IV but findings are inconsistent.

D. There is little or no systematic empirical evidence.

- The second method employs three categories of guidelines defined by the evidentiary support for or against a given clinical practice:
 - Recommendation: Reserved for guidelines that are based on level I or level II evidence.
 - Suggestion: Used for guidelines that are based on level III, IV and V evidence; this implies panel consensus on the interpretation of this evidence.
 - No Guideline Possible: Used when there is insufficient evidence on which to base a guideline. This conclusion implies that: (a) little or no evidence exists on the practice in question; and (b) the panel lacks

consensus on the interpretation of existing evidence.

This second categorization method was developed to address the perception that the levels of evidence and grades of recommendations under the first method were being misconstrued by the readership (e.g., every guideline seemed to carry the same amount of weight).

- It is hoped that the "No Guideline Possible" category will help ASCO's expert panels resist the temptation to venture guidelines in instances where none are warranted. This has been referred to as the "right to refrain from making recommendations," based on the contention that society may be better served at times by having expert groups admit that there is considerable uncertainty.
- ASCO has completed two membership surveys on the use of growth factors; key findings were that: (1) use of CSF growth factors was related to physician practice setting (physicians in fee-for-service settings were more likely to use growth factor than those in managed care or academic settings); and (2) practice across settings is in line with many of the growth factor guidelines, but not with others. The surveys do not reveal why publication of the guideline on growth factors has not led to wholesale changes in practice. The problem is believed to be due in part to limited implementation efforts beyond publication in the JCO. Some have argued that in rationing resources for clinical practice guidelines, 10 percent of the effort should be spent to develop the guidelines, with the remainder allotted to implementation. For example, implementation of a preauthorization requirement for the use of CSF resulted in a marked overall decline in use (and related cost) at one institution, but no change in use for indications described in the ASCO guideline.
- To better assess the impact of ASCO's guidelines, the Health Services Research Committee established a working group on guideline evaluation. The working group concluded that, ideally, an evaluation would assess whether guidelines are of high quality, whether ASCO members are aware of and satisfied with the guidelines, whether payers and providers are using the guidelines, if practice is changing in accordance with the guidelines, if guidelines are changing practice, and if guidelines are leading to improved patient outcomes. The working group decided that, initially, ASCO should focus on the first four items. Efforts are now under way to assess these parameters relative to ASCO's four published guidelines. ASCO recognizes, however, that all of the assessment items must be addressed to realize the full potential of clinical practice guidelines for improving the care of individuals with cancer.

ONS Position on Quality Cancer Care

Background

The Oncology Nursing Society (ONS) is the largest oncology-related health care organization in the country, with more than 27,000 members. ONS is entering its 24th year of existence, and is dedicated to making a difference in the care and well-being of

people experiencing cancer. ONS has been active in guideline development for some time, particularly in the areas of chemotherapy administration and safe handling, venous access device management, and standards of oncology nursing education and practice at both the advanced and basic levels. The goal of achieving quality is the cornerstone of ONS' strategic plan and a focus of its mission to promote excellence in oncology nursing and quality cancer care.

Key Points

- Quality cancer care means timely access to specialty cancer care, insurance coverage for specialty care, a comprehensive approach to cancer care, involvement of all relevant disciplines (including social workers, nurses, pharmacists, chaplains, and others) on the treatment team, and equal and active inclusion of the patient and family on the treatment team.
- Quality cancer care is a continuum that includes prevention, early detection, treatment, supportive care, long-term followup, and end-of-life care. Prevention means helping others learn about cancer risks and lifestyle changes that can decrease the chances of developing cancer. Early detection includes screening activities that result in early detection of cancers, when they are most curable; these services should be covered by the patient's health plan. Treatment means timely access to the range of treatments best suited to treat the specific cancer affecting each patient.
- Supportive care includes timely access to resources in the community that can augment the self-care and home care abilities of the patient and family. With increasing levels of cancer treatment now being provided on an outpatient basis, families are being asked to be health care providers without the education or resources to complete those tasks safely and effectively; this is a major burden for these individuals. Thus, supportive care also includes helping patients and families learn about cancer treatment and side effects of treatment, and how to cope with them.
- Long-term followup includes rehabilitation services and followup by oncology specialists for all cancer survivors. In many communities, rehabilitation is not occurring, or it is not being provided by oncology specialists who can monitor survivors for long-term sequelae of cancer and its treatment.
- End-of-life care means access to services that preserve and assure the quality of life when long-term survival is no longer possible. This includes competent and comprehensive symptom management, emotional support of patients and families, hospice care, and bereavement counseling.
- Quality cancer care is also culturally competent, ethical, and cost-effective. Further, it is coordinated and delivered by competent cancer care providers. Many hospitals and other agencies do not believe cancer patients require specialized nursing care. ONS believes accountability and coordination of quality cancer care is best accomplished by registered nurses (RNs) educated and certified in oncology nursing. ONS further maintains that there is a moral obligation to make decisions guided by quality, rather than by cost alone, in all health care restructuring efforts.

- To promote the ideas above, the ONS has adopted an active health policy agenda advocated at the local, State, national, and international levels. Among the specific positions being advanced by ONS are adequate pain management for cancer patients; RN workplace identification (currently denied nurses in many settings); expanded roles for nurses in genetic testing and risk assessment counseling; reasonable hospital stays for breast surgery, as determined by the woman and her physician; assurance of proper nursing credentials for those administering chemotherapy; and strategy development for decreasing the worldwide burden of tobacco use. Other positions include: care of individuals with HIV, rehabilitation of people with cancer, and ensuring safeguards (e.g., cardiopulmonary resuscitation and advanced life support capability, or "crash carts") in outpatient oncology treatment settings.
- In addition, ONS is collaborating with the Association for Oncology Social Workers on end-of-life care issues, and has recently developed a patient bill of rights.
- Future plans of the ONS include: collaborating in the development of a quality cancer care consumer brochure; conducting outcomes research to evaluate and define the role of the oncology specialty nurse in the delivery of cost-effective quality cancer care; and developing positions and forming partnerships that will promote the Society's strategic goal of quality cancer care.

American Association of Cancer Institutes

Background

Organized in 1959, the American Association of Cancer Institutes (AACI) is a forum for cancer organizations to exchange information on research, education, administrative, and financial policies. AACI represents the national cancer centers, both those designated by the NCI and those actively working to achieve that designation. The AACI has more than 100 members representing all regions of the country, and collaborates on cancer issues with NCI and many other organizations in the cancer community.

AACI's mission includes providing the best possible scientific base for cancer research, improving cancer prevention and education programs, promoting the highest quality of treatment and care for cancer patients from diagnosis through survivorship, taking an active role in public-policy-making issues, and cooperating with cancer and patient communities to further mutual goals.

Key Points

- Academic centers have a role in the three principal domains involved in clinical practice guidelines-development, dissemination, and implementation.
- Key attributes of a system of oncology practice guidelines include completeness (i.e., following the entire course of the disease), comprehensiveness (i.e., covering all cancers), relevance to the majority of patients with a particular cancer, formal processes for guideline development, and scheduled updates.

- Guideline development must be structured, and one of several processes are used. Informal consensus involves bringing together a group of experts who apply their opinion to the review and assessment of the available data and develop the guideline. The formal consensus process, used by NIH, brings together a set of experts who are provided a formal set of data that they may use as they wish in developing a guideline. Evidence-based guideline development is the current gold standard; it involves a rigorous delineation of the data; however, in many cases the evidence does not exist. Explicit guideline development, the goal for the future, is a quantitative model that attempts to assess the cost, percentage, and probability of outcomes.
- One study of decision points in a set of guidelines for hematologic/lymphatic cancers concluded that high-level randomized clinical trial evidence was available to support only 24 percent of decisions. Single-arm trial evidence supported 20 percent of decision points; for the remaining decisions, no real evidence existed. These findings suggest that one role of the academic centers is to develop their expertise in interpreting the quality of high-level trials, resolving inconsistencies in data from such trials, assessing the importance of single-arm trial findings, providing rational guidance based on experience, deriving guideline logic, and assessing evidence and providing specific recommendations.
- If a guideline is to conform to the clinical decision-making process, it must be logical. Because of its complexity and heterogeneity, cancer does not always conform to the algorithms typical of path guidelines, yet appropriate models are not too complex to be practical.
- In the current managed care environment, primary care physicians and nurses will be involved in providing oncologic care. Guidelines will be very important in helping perform these tasks well.
- Reliability (reproducibility) is a problem in the use of expert opinion. Reproducibility means that given the same evidence and method of development, two separate consensus groups would produce essentially the same guideline. A comparative study of ASCO (narrative) and NCCN (algorithm) guidelines for advanced non-small-cell lung cancer found that recommended workup, treatment, and followup were highly similar or identical. The two guidelines were produced by different groups using different methods, but yielded reproducible products.
- Academic institutions can manage bias by taking a multidisciplinary, multi-institutional approach, and ensuring that the spectrum of clinical approaches is represented. It is also important to include geographic diversity on the expert panel. Multiple iterations and feedback loops are also essential for eliminating bias in guideline development.
- It is important to bear in mind that guidelines developed at academic institutions may not always be generalizable to community care, since treatment at academic centers tends to be more aggressive and focused on clinical trials. Communities may lack the technology, surgical or other expertise, and access to trials necessary to conform to such guidelines.
- Academic centers are no longer ivory towers; they are community affiliates, hospital network members, and managed care participants. Many academic centers are developing disease management systems, including guidelines-

- monitoring systems and quality improvement systems. Through these, they will have a broad impact on how care is delivered.
- Websites and interactive programs will be essential future keys to guideline dissemination. Effective implementation will be aided by education, the participation of respected leaders, feedback mechanisms, administrative and regulatory mechanisms, and positive and negative incentive systems.
 - Guidelines are being used for quality improvement, resource utilization control, and provider profiling. They will be used as quality indicators; in oncology, it will be necessary to use process indicators rather than outcome indicators for some time. Since guidelines are process maps, adherence to a guideline that has been validated to predict for favorable outcomes should be a good measure of quality.

Discussion

Key Points

- The ASCO guideline development process typically involves a methodologist; some of the panels include consumers, but primary care physicians and public health experts have not been included. The NCCN process did not include consumers initially. A decision was made approximately 15 months ago to include consumers in every new panel (typically composed of 8 to 12 individuals from varied disciplines). Currently, approximately half of the NCCN panels have a consumer representative.
- NCCN does not charge for its guidelines; they have been disseminated through the JCO. Totalling more than 550 pages, the most recent set of guidelines was distributed to more than 32,000 subscribers, including all U.S. oncologists and others.
- All of the guidelines and guideline-rating processes are works in progress. Guideline evaluation is an iterative process; its value will grow as guidelines are refined, and where question marks exist, trials may be done and more evidence collected. The ethical pitfalls exist principally in the areas where the evidence is unclear. The improvement process for guidelines should be continual; cyclic review and updating are important. Updating processes should include consumers.
- Though it currently conducts some activities focused on the public policy-oriented issues associated with cancer care and clinical guidelines, NCCN has decided for the near term not to engage in public policy development or specific legislative lobbying. Instead, NCCN will maintain its focus on developing comprehensive guidelines and integrating them with its database. In part, this decision stems from one of NCCN's missions-to develop programs to enhance the competitive position of member institutions in the marketplace. Voicing a personal perspective, Dr. Freeman suggested that NCCN's leadership has the opportunity and authority in the cancer community to have a substantial impact on public policy issues such as access to care and insurance coverage.
- In the guideline development process, it is necessary to balance the need for specificity with the need for flexibility in making treatment decisions for the individual patient. This is a delicate balance. When guidelines lack specificity

(and when they are not based on good scientific evidence), their usability and utilization drop significantly. At the same time, the guideline algorithm must present reasonable options for physicians and patients. Dr. McGivney expressed his view that physicians in the late 1980s lost an important opportunity to have substantial input into coverage development processes at major managed care companies because of their reticence to take stands on important issues; this is an opportunity that NCCN member organizations do not want to miss again.

- Though it is possible that by freely distributing its guidelines to community oncology practices, NCCN may actually create competition for its member institutions, NCCN is working toward key partnerships and affiliations and a growing role in consultation, evaluation, and referral with community oncology groups that follow its guidelines. In addition, it is anticipated that member institutions will hold seminars to support implementation of updated guidelines. In time, the outcomes database will also be a resource for significant education and collaboration in improving both clinical and nonclinical (e.g., days lost from work, patient satisfaction, financial impact) outcomes. This potential for interactive and constructive relationships is perceived to be of greater value than could be achieved through a more proprietary stance.
- Good guidelines should improve care at all levels; they should not just be a "vacuum cleaner" to pull care in one direction or another. The appropriate role of guidelines includes trying to provide guidance as to when particular types of care are unwarranted (i.e., avoidance of overtreatment). Unfortunately, the needed evidence to provide such guidance is woefully lacking; in many cases, we are still using response rates rather than survival or quality-of-life data to inform these recommendations.
- Guidelines must be constructed carefully, since once guidelines are set, payers, the Government, and the medical community will respond. The history of treatment advances suggests that guidelines based on clinical experience may reflect what is known at that point, but may be wrong. For example, the radical mastectomy was the established standard of care for breast cancer for decades, yet time has shown that lumpectomy plus radiation offers the same survival benefit with fewer side effects and less disfigurement. Discussants pondered whether current guidelines may pose barriers to the next generation of researchers and clinicians who question currently recommended clinical care, or if collecting and using outcome data from nonrandomized trials in guideline development will discourage the conduct of needed controlled studies. It was suggested that guidelines actually point out deficiencies in existing evidence and encourage the design and conduct of needed trials. It was also observed that because of the existence and widespread implementation in the United States of guidelines on mammography screening for women aged 40 to 49 years, it is now virtually impossible to conduct a randomized controlled study on the efficacy of screening in this age group in this country. A similar phenomenon is occurring with respect to prostate cancer screening guidelines and their implementation.
- Participants further suggested that guidelines leading to overly aggressive care (e.g., mastectomy for breast carcinoma *in situ*) may have a perfect outcome (e.g., the patient is a survivor), but have prescribed the wrong care. The ethic should be

to question everything, and to strive continually to improve on standard care rather than allow "fossilization" around guidelines. Unless standard care is totally curative, it is never good enough. Cancer centers and academic centers should take the lead in this endeavor.

- *Ad hoc* investigational care is a difficult issue because it contributes nothing to the body of knowledge, even though it may satisfy the patient. It may even delay the day in which we have the answer. One strategy for discouraging *ad hoc* investigational care is to provide coverage for the costs of well-defined, rigorous clinical trials that will advance knowledge.
- Local tailoring of national guidelines is inevitable; recognizing this, NCCN sees its guidelines as templates and is seeking ways to make sure that adaptations remain consistent with the guidelines.
- Particularly in cancer, in which nearly half of patients (excluding basal- and squamous-cell skin cancer patients) die of their disease, the lack of explicit links in most guidelines to clinical trials is disturbing. Since standard care is clearly inadequate for many patients, this linkage to participation in trials should be explicit to prevent denial of insurance coverage.

HEALTH CARE AND RELATED ORGANIZATIONS

American Association of Health Plans

Background

The American Association of Health Plans represents more than 1,000 health maintenance organizations (HMOs), preferred provider organizations (PPOs), and other similar health plans. Together, member plans provide coverage for more than 140 million Americans. There is tremendous variety among these plans in terms of structure and organizational behavior. This variation has led to AAHP developing a philosophy of care that: (1) emphasizes active partnerships between patients and their physicians; (2) maintains that comprehensive health care is best provided by networks of health care professionals who are willing to be held accountable for the quality of their services and the satisfaction of their patients; and (3) is committed to high standards of quality and professional ethics, and to the principle that patients come first.

Key Points

- AAHP defines clinical practice guidelines as systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific circumstances. They are designed to close gaps between current and optimal practice. Thus, clinical practice guidelines are recommendations for clinical interventions and are not designed to replace the judgment or experience of clinicians. Guidelines vary in their degree of flexibility and are broad strategies for patient management within the limits of accepted clinical practice. Narrower types of guidelines exist that are specific clinical pathways defining the specific sequence of clinical events, often linked by timeframes, specific conditions, care

processes, and expected outcomes. In addition to practice guidelines, other guides or policies are used in reimbursement and accrediting decisions; these are used in concurrent or retrospective utilization management.

- AAHP has no guidelines of its own-it is neither a medical professional society nor a care delivery organization. Health plan members of AAHP formulate and disseminate derivative guidelines based on AHCPR or professional society guidelines. The result of the process of developing these derivative guidelines is not necessarily different from what is seen in many professional guidelines. Most health plan guidelines, however, are based on broad population factors, resulting in a different perspective on clinical practice.
- Over a 2-year period, representatives from a number of AAHP member health plans have met to identify problems or other areas in which guideline development might be warranted. Such issues included practice variations, the availability of evidence, the frequency of occurrence in a population, cost differentials, and whether external concerns exist about the quality of care. Reflecting defined attributes of a well-developed guideline, health plans choosing to develop a guideline in response to a problem are following an evidence-based process. This process typically includes problem identification, data acquisition, multidisciplinary review of the literature with evaluation based on a criteria set similar to the U.S. Task Force for Clinical Preventive Services, two cycles of draft and comment, pilot testing, finalization, and dissemination. The guideline, which should be clinically flexible (to allow for exceptions and patient preferences) is presented in easily understood language for each of the intended audiences, and in patient versions. A committee is kept in place to be responsible for updating the guideline in response to new literature or other issues that may arise. The committee meets at least annually to determine if updating is required. In terms of evaluation, data are collected to assess changes in practice, before/after studies are conducted, administrative systems are used to collect data, and qualitative information is gathered from clinical practice to assess the effect of the guideline.
- Key strategies for implementing clinical guidelines in managed care settings include identifying clinical and academic leaders who will champion the guidelines; sharing with practitioners the synthesis of evidence that informs the guideline; offering practitioners effective implementation tools (e.g., education, resources, support systems); employing logic, discussion, and incentives rather than exhortation; and engaging practitioners and other stakeholders in an ongoing, interactive process of improvement.
- Effectively engaging physicians in guideline implementation includes involving them in guideline development and implementation activities to ensure that the guideline fits their needs, providing information to clinicians about their practice patterns, using academic detailing to investigate and discuss reasons underlying current practices where change is suggested, and recruiting opinion leaders to promote the cause in unstructured situations.
- Educating physicians about clinical guidelines is important; it is particularly effective to provide continuing medical education (CME) credit for these educational efforts. Small-group sessions on narrow, specific topics work well.
- Tools to support decision making consistent with guidelines include flagged

- laboratory slips, pharmacy alerts, tags on charts, standing orders (e.g., immunization orders for nurses), and administrative policies.
- Managed care systems are in a unique position to promote clinical guidelines development and use, since they have a broad, multidisciplinary approach to health care, access to levels of empirical data necessary to create and improve guidelines, and an infrastructure for educating providers on guidelines.
 - AAHP has joined AHCPR and AMA in sponsoring the National Guidelines Clearinghouse, which AAHP believes will promote better guidelines by providing an authoritative, easily accessed resource for guideline developers.

Optimizing the Impact of Guidelines on Medical Decision Making

Background

Milliman and Robertson is a consulting company founded more than 50 years ago. Growing out of its health care consulting practice in the late 1980s, the company has developed a set of health care management guidelines that now encompass seven volumes, with another two volumes in progress. These guidelines span a range of health issues that includes acute care, worker compensation, ambulatory surgery, home care, and primary care. Some of these guidelines (e.g., acute, subacute, and home care) are utilization management guidelines focused on quantitative issues of efficiency.

Milliman and Robertson's guidelines related to oncology are limited to diagnostic issues that face primary care physicians, and referral, hospital admission, and length of stay issues. Its guidelines on ambulatory mastectomy have earned the company a degree of notoriety. Milliman and Robertson does not develop guidelines for chemotherapy or radiation therapy, leaving these to the expertise of practitioners in those fields.

Key Points

- Guidelines have been called "the battlefield of cost and quality" (D. Eddy). It may be more accurate to say that guidelines are where issues in defining efficiency meet issues of quality. Issues of efficiency may be implicit in that a certain course of therapy is prescribed and another is not. These issues also may be explicit, such that the efficiency issue is quantitated, or specific items are not recommended.
- Issues of quality are best conceptualized as in the Institute of Medicine's Roundtable on Health Care Quality report published in the *Journal of the American Medical Association* in September 1998. The report describes quality problems in three general areas: (1) underuse (i.e., failure to use a treatment or a procedure that could benefit the patient, and for which the benefit far exceeds the risk); (2) overuse (i.e., using a procedure or treatment when the risk of harm significantly exceeds benefit); and (3) misuse, which could include complications of surgical or diagnostic procedures.
- Overuse issues include questions of appropriateness; in such cases, cost and quality issues are the same. Similarly, in the area of misuse, by reducing complications, quality is improved and cost is reduced. In issues of underuse, cost

and quality considerations may be synchronous (for example, the use of beta blockers after myocardial infarction), or asynchronous (e.g., cases in which certain preventive services are more costly than the outcome being prevented). Overall, however, Milliman and Robertson sees cost and quality moving in the same direction.

- The ideal guideline development process would consist of an outcomes research project on a specific issue that could be converted directly into a guideline. Current guideline processes, however, consist of the review of evidence by expert clinicians, who make judgments about the evidence and develop a guideline based on those decisions.
- Milliman and Robertson concurs with the statement that "evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients" (Sackett, *British Medical Journal*, January 1996). Its guideline efforts categorize evidence as follows: Level 1-randomized controlled trials (RCTs); Level 2-observational studies published in peer-reviewed journals; and Level 3-expert opinion (often informed by unpublished data as well as clinical experience). Published studies, especially RCTs, are relatively rare, particularly those addressing efficiency issues. In the best systems, practice innovation that improves quality and efficiency occurs continuously, but this information generally is not published. Much knowledge comes from sources other than RCTs. For example, there are multiple instances of institutions sharing best practices that lead to significant improvement in outcomes and lower cost. Such efforts are not documented in the literature because it is the institutions' ethic to care for patients rather than to publish. The RCT may be the last step in closing the loop of evidence rather than the first.
- Milliman and Robertson uses the available literature in its guideline development process, but also uses other sources of data. These include the expertise of clinician and academic partners; specialty societies; its own healthcare management consultants and actuaries; data purchased from national, State, and private sources; chart reviews; site visits; and feedback from guideline users.
- Actuaries develop aggregate data that help make guidelines meaningful. These data are used by clinicians to write the practice guidelines. This approach reflects a move from the consideration of one patient at a time to consideration of aggregate groups of patients, and a shift from minimally acceptable standards to benchmarking and process improvement.
- Guidelines have an important educational role in that they synthesize the evidence for the physician and present it in a form more readily usable to practitioners than individual articles in the published literature. Guidelines are not cookbooks; rather than replacing clinical judgment, they require it. Moreover, guidelines do not apply to every patient, and must be updated regularly. Local review of guidelines, now required by NCQA, is necessary so that local modifications can be made as indicated. Guidelines are best when they describe the best practice benchmark rather than an average; this is particularly true of length of stay-average length of stay does not lead to improvement, whereas benchmarking optimal length of stay gives an organization a target for a future period.

- Milliman and Robertson perceives guideline implementation as having several key components: (1) the availability of appropriate infrastructure to support implementation; (2) appropriate incentives for participants; (3) information that can be fed back to physicians to motivate change; (4) integration of all parts of the organization; and (5) involvement of the local practice community. Utilization management is critical, but should be proactive and collaborative rather than retrospective and punitive.
- Outpatient modified radical mastectomy has been controversial; however, it is possible to perform this procedure in a manner that provides control of pain and nausea, includes adequate home care, and incorporates patient choice.

Improving Care for Patients with Cancer: The Role of NCQA

Background

The National Committee for Quality Assurance (NCQA), a non-Governmental, independent, not-for-profit organization, is headquartered in Washington, DC. Its mission is to improve the quality of health care service in America by providing information that changes how people choose their health care and how organizations provide it.

Key Points

- The public wants health care competition based on value; at present, most health care plans are competing based on price. To move to a market that is competitive based on value, we need information about the other elements in the value equation (e.g., quality, performance). By providing this information to those who use health care, provider organizations will be motivated to deliver high-value care, and a marketplace will be created in which competition leads to improvement.
- NCQA's approach to evaluating health plans combines a review of systems (structure and process) with a review of outcomes. These evaluations are limited by the available technologies, but NCQA is committed to using the best possible technology, and to advancing the state of the art in health plan evaluation. NCQA accreditation is the Nation's standard in health plan evaluation, and it relies on an assessment of the strength of the core systems upon which high-quality care and service depend. Beginning in 1999, performance results as measured by HEDIS will be incorporated into the accreditation program, with 25 percent of the overall score dependent on demonstrated performance (half coming from clinical performance measures and half from member satisfaction).
- HEDIS is a broad set of measures designed to assess performance in key areas important both to those who purchase health benefits and those who use them. The more than 70 HEDIS measures are precisely specified to ensure comparability and are supported by a specialized infrastructure. HEDIS measures comprise the core of most of the health plan "report cards" and are also used by the lay media. Though they are imperfect measures, a process is in place to ensure their continuing evolution and improvement. Oversight of this evolution is the

- responsibility of a broadly constituted Committee on Performance Measurement (CPM). The CPM is intended to bring the public's voice and the perspectives of all stakeholders in quality measurement and improvement into NCQA's work.
- The process of developing HEDIS measures involves the explicit use of criteria designed to ensure that to the extent possible, measures are supported by available science. The criteria address the relevance of measures, their scientific soundness, and the feasibility of implementing them. In the last 18 months, Measurement Advisory Panels (MAPs) have been established to bring clinicians more directly into NCQA's work; the MAPs are working with NCQA to address the gaps that still exist in the HEDIS measures.
 - HEDIS was introduced in late 1993, with results first reported in 1995. Despite this limited experience, NCQA has learned that there is striking variation in the performance of health plans related to screening and treatment for a wide range of conditions (including cancer), that this variation has a real impact on the health and satisfaction of the public, and that there is demand for, and increasingly widespread use of, the HEDIS data.
 - Relative specifically to the evaluation of cancer care, some screening and treatment HEDIS measures exist, and additional measures are in the testing phase. A MAP has been established to work with NCQA on cancer-related measures.
 - Health plan evaluation is a work in progress that is still far from completion, but we are moving incrementally and regularly toward more numerous, better, and more robust techniques for evaluating the quality of care delivered in health plans (principally HMOs). At this point, little information is available about care delivered in PPOs, other managed care arrangements, or fee-for-service plans. Further, little or no comparative information exists on institutional performance, and institutional performance is critical to the delivery of high-quality care.
 - The availability of information is restricted both by limitations in the science of medicine and in the science of measurement. In the area of measurement, some of the limitations are profound and relate to the long time lines associated with some measures. Moreover, the small denominators involved (i.e., populations in the average health plan) result in low statistical power, and the science also is limited with respect to risk adjustment. The high cost of data collection is another constraint reflecting limitations of the environment, including lack of standardization and disincentives to invest in information systems. Such investment is seen as wasteful by those whose focus is on medical loss ratio. In addition, there is a limited market for quality; until organizations are rewarded for providing higher value care, this will not change.
 - Public information can stimulate and enable real improvements in health care. Though the information needed to do this is currently limited, information volume is increasing, as is the rate of information production. Overcoming the barriers to creating and using information will require concerted action and coordination among all who wish to move this agenda forward.

Discussion

Key Points

- According to Dr. Schibanoff, approximately one-half of the purchasers of Milliman and Robertson's guidelines are payers, while the remainder are primarily providers (e.g., hospitals, medical groups, and Independent Practice Associations). He also clarified that in an ideal guideline development process, outcomes data from RCTs would be the basis of the guideline.
- It remains unclear exactly how incentives should be structured, but rewards should flow to individual and organizational providers and to health care purchasers who show by their performance or decisions that they value higher quality or higher value care.
- Currently, health plans that participate in clinical research do not get higher performance scores. The MAPs have indicated that clinical trials participation is important; whether a measure in this area should be developed may be explored by NCQA.
- Regarding the guideline concerning outpatient mastectomy, Dr. Schibanoff indicated that it was implied that the patient's choice as to whether or not to undergo the procedure as an outpatient would take precedence over cost and reimbursement issues. He stated that this would be made explicit.
- There was general agreement among the discussants that the prevalent public perception that health plans are forcing mastectomy patients out of the hospital prematurely reflects the behavior of a minority of health plans. It was also noted that it is not good to keep a patient in the hospital longer than she wishes to be there. It is necessary to put the patient in control, and disconnect the economics from the achievement of a good outcome and patient satisfaction. This may become easier as we move from per diem as a payment methodology to case rates.
- Outpatient mastectomy, assuming the patient's agreement, can only be successful if the patient and family are properly educated and prepared well before the procedure. Care must be taken to ensure that the patient and family will be able to handle the postoperative care, both emotionally and in terms of skill. If they cannot, nursing home or hospital care must be provided.
- In some instances, health plans may not provide care consistent with clinical practice guidelines if the purchaser of care (public or private) restricts coverage for a particular aspect of care.

Closing Remarks

In his closing remarks, Dr. Freeman highlighted aspects of the day's presentations and indicated that:

- Our society will have to grapple with the conflict between public health considerations that may favor dispersing health care resources across a broader population, and the medical approach that seeks the best possible care for the individual patient.
- Standards of care, which tend to become the standards for payment, have the potential to stifle medical progress by denying support for experimental/investigational care.
- Issues must also be resolved as to who should have the authority to make decisions on the care provided to a patient. This has traditionally been the purview of the physician, but this is no longer so. Some of this authority is being taken over by payers and is influenced by political decisions.
- We believe people should be treated according to the evidence, with the highest level of evidence being the clinical trial. Yet most of what is done in medicine has not been proven in clinical trials. Thus, the standard of care typically is based on lesser evidence which may never be challenged by controlled research studies.
- The Panel will be need to address all of the complex issues raised today in its report to the President.

I certify that this summary of the President's Cancer Panel meeting on Decision Making Based on Quality of Care Guidelines and Their Impact, held on October 6, 1998, is accurate and complete.