

President's Cancer Panel Meeting

Meeting Minutes

Defining "Quality" for Cancer Care
April 23, 1998
Los Angeles, California

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 first in a series of three focusing on the meaning of quality of care and quality of life, explored issues in defining quality in cancer care from prevention through palliation.

Fifteen speakers presented testimony to the Panel on defining and assuring quality of cancer care; quality-of-life issues; policy and research perspectives on quality of care; cancer prevention in healthy, at-risk, and minority populations; cancer control; cancer care and survivorship; and diagnosis and treatment. Speakers offered specific recommendations in these areas for consideration by the Panel.

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, Executive Secretary, President's Cancer Panel

Speakers:

Dr. Roshan Bastani, Associate Director, Division of Cancer Prevention and Control Research, Jonsson Comprehensive Cancer Center; Associate Professor, School of Public Health, University of California, Los Angeles

Dr. Laura Esserman, Department of Surgery, University of California, San Francisco Mount Zion Medical Center

Dr. Patricia Ganz, Director, Division of Cancer Prevention and Control Research, Jonsson Comprehensive Cancer Center, University of California, Los Angeles

Dr. Judith Gasson, Professor of Medicine and Biological Chemistry; Director, Jonsson Comprehensive Cancer Center, University of California, Los Angeles

Dr. David Kleiner, Chief, Post Mortem Pathology, Division of Clinical Science, National Cancer Institute

Dr. Mitzi Krockover, Vice President for Women's Health, Humana, Inc. Ms. Susan Leigh, National Coalition for Cancer Survivorship

Dr. Mark S. Litwin, Assistant Professor, Urology and Health Services, Jonsson Comprehensive Cancer Center, University of California, Los Angeles

Dr. Diana Petitti, Director, Research and Evaluation, Kaiser Permanente

Dr. Ronald Ross, Professor of Preventive Medicine and Associate Director, University of Southern California Norris Cancer Center

Dr. Mark Schuster, Senior Natural Scientist, The RAND Corporation; Assistant Professor of Pediatrics, University of California, Los Angeles

Dr. Faina Shtern, Office of the Secretary for Women's Health, U.S. Department of Health and Human Services

Dr. Antronette Yancey, Adjunct Assistant Professor, Division of Cancer Prevention and Control Research, University of California, Los Angeles, Jonsson Comprehensive Cancer Center

Opening Remarks

Dr. Harold Freedman, Chairman

In opening the meeting, Dr. Freeman stated that:

- This is the first of three meetings to consider the meaning of quality of care and quality of life, from preventive care through palliation. This meeting is intended to explore how the Nation defines good medical care for cancer. Future meetings will examine how quality of care is intertwined with quality of life and survivorship considerations and how guidelines impact quality of care definitions.
- The President's Cancer Panel is a three-member, Presidentially appointed advisory committee charged with examining barriers and making recommendations to the President on issues affecting the National Cancer Program. Since 1991, the Panel has championed access to appropriate delivery of quality cancer care, recognizing that access to services is as critical as the caliber of services offered.
- In 1994, the Panel called for the identification of obstacles preventing access to existing cancer prevention, diagnosis, treatment, and supportive care. A cooperative effort was mounted to educate the American public regarding its options in cancer prevention and health care access.
- In 1995, recommendations to the President included strengthening the collection and sharing of data to assure that the public has complete, truthful, and understandable information about health risks; developing and implementing a national curriculum beginning in primary schools to foster health-promoting behaviors and lifestyles; and enhancing support for and participation in clinical research.
- The Panel's 1996 annual report included recommendations for developing measures to ensure that minorities, the poor, the elderly, the uninsured, and the underinsured are not excluded from access to appropriate cancer care as the health care system evolves. The Panel also recommended that participation in all phases of clinical trials be formally incorporated into the standards of care for cancer and

that appropriate clinical trials participation be an integral component of care guidelines for specific malignancies.

- The American consumer expects to receive high-quality care, but quality cancer care has not been well defined. At a minimum, every person waging a personal war against cancer needs timely access to diagnosis and treatment, as well as assurance that medical knowledge and care will be applied appropriately. The difficulty lies in determining the basis upon which guidelines are established that will assure that appropriate care is delivered under appropriate circumstances and in a cost-effective manner. The American consumer desires the most economical health plans when well, but the most advanced care when ill.
- The war against cancer involves not only the quality and effectiveness of treatment, but also the quality of prevention and detection efforts. How health-related messages are delivered and how services are provided can significantly impact individual perceptions of quality. For example, it may be that delivering standard information on cancer screening and prevention is not sufficient; to achieve quality, information may need to be delivered in a culturally tailored manner.
- How we define success in preserving quality of life during and following treatment, and at the end of life when cure is not possible, must be examined. An overarching issue is how to respond to individual perceptions of quality in light of geographic, cultural, ethnic, and socioeconomic concerns. Rapid evolution of the Nation's health care delivery system to for-profit managed care also raises issues in defining quality of care, and cost may be used as a measure of quality.
- Whether access to clinical trials should be included in the definition of quality cancer care is a critical question. From a research perspective, clinical trials must be supported and conducted for new therapies to be tested and for the overall quality of cancer care to continue to improve. Access to state-of-the-art or optimal cancer care has been equated with access to clinical trials. Therefore, any discussion of quality of care must recognize that care options encompass both investigational clinical trials as well as noninvestigational standard care.
- Cancer encompasses a continuum of care that must include screening and disease detection, treatment, symptom and side effect management, surveillance of recurrent disease, psychosocial and behavioral support, palliation, and end-of-life care, including bereavement counseling. The issue of access to care is central to any discussion of quality. Depending upon economic status, considerations range from access to any type of care, ability to obtain standard care, and ability to access clinical trials or state-of-the-art care. These fundamental needs, as well as the appropriateness of medical interventions, timeliness of delivery, consistency of medical decision making, and the ability to communicate to the consumer the basis on which medical decisions are made, must be considered in developing quality measures for cancer care.

Welcome

Dr. Judith Gasson, Director, Jonsson Comprehensive Cancer Center

Background

The University of California, Los Angeles (UCLA), and the Jonsson Comprehensive Cancer Center have developed partnerships with a number of oncology practices extending north into the Bakersfield area, to the east in Las Vegas, and to the south into Orange County. These partnerships provide state-of-the-art care in the communities they serve and provide access to available clinical trials for individuals for whom there is no standard therapy.

Key Points

- For the 50 percent of cancers that are not curable, research is focused on finding new technologies for treatment, better methods of detection, and, ultimately, strategies to prevent them. Cancer care must be available to all members of our society regardless of their socioeconomic status, geographic location, or educational level.
- As technology improves, treatment efficacy must be judged both in terms of extended survival and quality of life.

NCI Report

Dr. Otis Brawley, Assistant Director, Office of Special Populations Research, NCI

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

- This year's NCI budget has increased and will likely continue to rise along with the overall budget at the National Institutes of Health (NIH). Declining cancer mortality and the aging of the American population are contributing to a dramatic increase in the number of cancer survivors for whom quality-of-life issues are essential. Interest in cancer screening and prevention, and the recent findings related specifically to breast cancer prevention are bringing quality-of-life issues to the forefront for the entire population.
- NCI will establish an Office for Diffusion Research in the Division of Cancer Control and Population Science (DCCPS) to examine methods related to the diffusion of treatment-related findings and issues to the public.
- Recent declines in cancer mortality rates were not experienced uniformly across ethnic groups. Though African-American, Hispanic, and Native American populations experienced mortality rate declines, they were not as steep as those experienced by whites. Recent NCI research revealed different patterns of care related to socioeconomic status and perceived race. Further understanding of these disparities will be necessary if society is to progress.

PRESENTATION HIGHLIGHTS

Defining Quality in Cancer Care

Issues in Defining Quality in Relation to Cancer Care

Dr. Mark Schuster

Key Points

The Institute of Medicine defined quality in 1990 as: "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Close examination of this definition reveals a number of significant implications. First, the term "degree" shows that quality of care is a continuum (i.e., better versus worse) rather than a dichotomy (i.e., good versus bad). The term "health services" emphasizes that quality refers to those elements of care that the health care system can affect, including the extended care system (e.g., rehabilitative care, hospice care). It does not include genetics or educational level. Reference to "individuals and populations" recognizes that quality care can involve delivering care to both. "Increase the likelihood of desired health outcomes" takes into account the concept of chance, i.e., evaluating the probability that a particular intervention will have a positive impact. The term "outcomes" is of paramount importance as it emphasizes achievement of the ultimate goal. The statement also makes the connection between "health services," or processes of care, and "outcomes."

- There are two basic approaches to quality assessment: implicit review and explicit review. Implicit review involves rendering professional judgment about the quality of care through review of pertinent information. It is not systematic or necessarily data driven. It is based largely on impression or "gut feeling." Current trends have moved toward explicit review, which involves the use of care standards to assess quality.
- The three basic dimensions in quality assessment include: structure, process, and outcome. Structure refers to characteristics of the health system or individuals that affect the system's ability to meet the health care needs of individuals or communities. These include health care organizational characteristics (e.g., staffing patterns, number of beds) and provider attributes (e.g., specialty mix, provider qualifications and experience). Structure also takes into account community characteristics that impact the health system (e.g., number and types of other facilities, transportation patterns). Also influencing care quality from a structural point of view are population characteristics, such as economic status or ethnicity.
- Service volume is the most significant structural characteristic associated with quality care. The presence of critical thresholds of patients with a specific condition being treated by the same (institutional or individual) provider is directly related to the quality of care. Service accessibility is another key element in assessing structure.

- The process of care includes both the technical expertise of the provider and his or her interpersonal skills. Process assessment considers not only whether the provider makes the right choices regarding diagnosis and treatment and is sufficiently aware of alternatives, but also whether care is provided skillfully and effectively. Interpersonal measures of quality assess whether care is provided in a patient-focused, humane manner; whether patient preferences are incorporated; and whether sufficient information is provided to support informed decision making. Process measures also take into account the appropriateness of referrals.
- Outcomes represent the results of the health care delivery process, the classic outcomes being biological status including 5-year survival rates and many aspects of morbidity. In recent years, functional status (i.e., ability to participate in physical, cognitive, and social activities; sense of well-being; and ability to fulfill one's role in the world) has also been taken into account. Patient satisfaction (perceptions about the quality of care received) is also an essential element of quality of life.
- In measuring and assessing patient outcomes, risk adjustment is important to ensure that differences are attributable to quality rather than characteristics not under the control of the health care system. Depending on the situation, adjustment factors may include co-morbidity, patient age, and a host of other patient attributes that affect outcome.
- Process measurement includes determining whether an intervention or service is appropriate (i.e., expected benefits outweigh the risks); necessary (there is a reasonable chance of benefit to the patient and withholding care would be harmful or unethical); and whether care adheres to professional care standards.
- Process indicators can be derived through review of the research literature and professional consensus and should be associated with outcomes. Such indicators generally target a few key markers of clinical care for a condition rather than all aspects of care, the assumption being that if one performs well on the markers, it is likely that the other aspects of care are also of high caliber.
- The low incidence of particular types of cancer in a particular hospital or health plan makes quality assessment more challenging. In many types of quality-related assessments, a certain minimum volume of patients may be necessary to observe a particular effect.
- The classic paradigm of 5-year survival rates has been very useful for research, but it is not always useful for quality assessment because of the long delay associated with obtaining meaningful results. By the time results are available, the environment or facility may have undergone substantial change.
- Another challenging issue associated with quality assessment is poor documentation in the medical record, particularly related to counseling and discussion of treatment options. This problem is compounded by increasing fragmentation of care across delivery sites and providers.
- Quality assessment information is used by an extremely diverse community that includes consumers, private employers, insurers, policy makers, and researchers. It is incumbent upon clinicians to use this information to improve the quality of care they provide.

Discussion

Dr. Schuster

Key Points

- Most of what is done in the health care system has not been and will not be studied because, ultimately, practices become so routine that they evolve into the standard of care. This does not mean that current approaches are the best. However, resources are limited and research is constrained by various ethical issues (e.g., withholding standard care would not be permitted by human subjects committees, even if that care was not firmly based on quality research).
- Panels established to develop quality indicators should be sufficiently diverse to incorporate multiple perspectives and ensure that the views of any single organization do not unduly dominate the discussion.
- Though much of standard cancer care has not been adopted as the result of research, the cancer field has, unlike many other areas of medicine, established a research system to attempt to prove the efficacy of care.
- A continuing dilemma exists in that expert panels are asked to assess quality, yet their experience may not be based on scientific evidence, and little additional evidence from controlled studies may exist to support or refute the efficacy of standard practice.

Issues in Assuring Quality in Relation to Cancer Care

Dr. Laura Esserman

Key Points

- Much of the information related to what consumers consider quality of care may not be available to assist in decision making. Further, what is considered an important factor in care decisions varies significantly depending upon who is making the decision. For example, many choices women make regarding their care may have less to do with mortality concerns than with other factors. Therefore, mortality rates may be either irrelevant or of marginal importance in choosing between surgical options. Small differences in survival rates may be highly significant to some patients, but not to others. Physicians may equate quality with ensuring that patients take into account the latest results from clinical trials and making sure that every possible alternative is explored for their patients.
- Finding ways to provide complex information from clinical trials at the bedside in an environment where providers are pressured to decrease time spent with patients is extremely challenging. There is a lack of good tools to assist in explaining treatment options in the office. Results of clinical trials are presented at national meetings in the most positive light possible (relative reduction) which leads to confusion about absolute benefits to patients and an overestimate of the value of intervention.
- Quality of care is interpreted from a variety of perspectives. The purchaser/employer may care about the cost of care, the associated mortality

rates, and policy implications, rather than what the patient is most concerned about. The health care plan may be more focused on low variation in patterns of care, adherence to standards, and few requests for second opinions. Plans also want ways to contain costs, and therefore develop standard, predictable ways to measure the cost impact of decision making by patients or physicians—none of which measure the true quality from the patient's perspective.

- Certain process elements may be highly correlated with high-quality care but, in fact, may be difficult or perhaps impossible to measure. Many process-related events, however, may be easy to measure but are less relevant to the quality of care.
- The range of outcomes is broad, and may include morbidity, complication rates, unnecessary procedures, mortality, and patient satisfaction. Outcomes are often related to process, the quality of the procedures performed (surgery, cytology), and the skill of the operator. For example, the use of good-quality fine needle aspiration (FNA) can eliminate surgical biopsy. It has been shown that the higher the volume of FNAs performed, the better the quality of the FNA itself. If an FNA is not done well, however, the patient is better served by an open biopsy.
- A new framework is needed to enable us to capture and systematically use data routinely collected in medical charts to document patterns of care. In the absence of such meaningful data, quality of care cannot be measured or improved. Significant issues exist as to who should finance the data collection infrastructure. Among the possibilities are the health plans, purchasers, physicians, consumers, or some combination of these.
- Currently, proposed quality measures are related primarily to what data are available, such as breast-conserving surgery rates. These rates, which vary widely from 20 to 80 percent nationwide, are highly influenced by both physicians and consumers; therefore, measuring the rates themselves may paint an incomplete picture of quality when patients were offered a choice, and capture of the reasons for that choice are critical to understanding variation.
- NCI has an initiative to try to create uniform data standards; these standards will provide the foundation for better data collection, comparisons, and analyses.
- Only about 3 percent of adult patients with cancer are on clinical trials. Among the many reasons for this is that the system is cumbersome. For example, there is a great deal of additional paperwork and forms to fill out and there are hundreds of different data standards for clinical trial eligibility; such variation and extra work is unnecessary.
- In addition to adjusting provider outcomes based on severity of illness, risk adjustment should also take patient preferences into account. Some patients do not want standard therapies, while others may find the benefits of chemotherapy insufficient to endure its toxicities, and still others may prefer alternative care. These patterns of preference may tell the physician a great deal about the quality of care he or she is providing.
- Effective methods for presenting clinical information to patients are currently under study at UCSF. Videodisc programs have been created to support shared decision making for many different diseases. A good example is one regarding surgical intervention for prostatic hypertrophy. In examining factors that

influenced patients' decision making, five significant questions were found to define patients' perspectives regarding their willingness to live with the side effects of surgery (e.g., sexual dysfunction, sleep interruptions due to more frequent urination). Responses to these questions were key determinants of the choices patients made among treatment options.

- Physicians must be provided with the tools to access data, identify different ways to present it to patients, and help understand the patient's hierarchy of values.
- We cannot pretend that the cost of care is unimportant; it is what currently drives the system. Health plans may care whether patients are satisfied with the plan if they can align wellness with benefits.
- Physicians are data driven, and providing data on quality, costs, and patient satisfaction is likely to influence them. Physicians would like to know and understand their morbidity rates. Having systems that help improve patient satisfaction or give physicians more time with their patients would make a difference.
- Empowering consumers by giving them information would result in changing the system and influencing the quality of care. People care about the details and how they will affect their daily lives. They also care about how information is presented. In addition, advisory groups, regulatory bodies, and advocates can have enormous influence on how care is delivered.
- Patient-centered care is essential. The goal is not to treat the disease but the patients who have it and to make their lives better, not worse.

Additional Research Needs and Other Recommendations

- To make a significant impact on quality, the stakes and major issues of concern to health care payers must be taken into account. The best system can be developed in a vacuum, but it will not necessarily influence medical practice. Market power and strategic analysis must be taken into account in implementing change. However, the most important element in the system is the patient and his or her perception of quality. Purchasers would be most interested in how quality affects people's wellness, their productivity, their disability, and the costs of their care. We need to better understand the quality measures used by purchasers to determine how to influence their decisions in favor of quality care. Thinking about who in the market has the power to affect change is critical. The food chain is not fixed. Hopefully, those now at the bottom-the patients-can become much stronger and have greater influence over the health care system.
- NCI's current efforts to re-engineer the clinical trials process should be supported. This effort may result in an increase in public-private partnerships and the development of systems for point-of-service data capture and tracking. Creating systems that decrease daily provider tasks will provide incentives for data reporting that in turn will facilitate efforts to monitor quality. Systems must be implemented to enable data tracking as part of the routine care process.
- Facilitating data capture from mission-critical processes and outcomes is very important.

- The hard questions are: Who will pay? Who will care? How much can we afford to pay? What fraction of the health care dollar can go to measurement and to extra services that contribute to better outcomes? Who are we going to allow to decide?

Quality Cancer Care - Kaiser Permanente Perspective

Dr. Diana Petitti

Background

Kaiser Permanente is a group-model HMO located in California. It consists of two major entities—the Kaiser Foundation Health Plan and Hospitals, and the Permanente Medical Groups. The Kaiser Foundation Health Plan and Hospitals are a not-for-profit HMO that sells insurance products. The Permanente Medical Groups contract exclusively with the Health Plan and hospitals to provide physician services to Kaiser Foundation Health Plan members. Kaiser has 9.1 million members, of whom 5.5 million are located in California. According to 1997 figures, 6.6 million (or 73 percent) were located either in California or in the Northwest Divisions. Kaiser's mission and purpose is ". . . to provide affordable, high-quality health care services and to improve the health of our members and the communities we serve."

Key Points

- Quality exists only in the context of a system designed to ensure the delivery of quality care. A quality health care system has structures and processes that ensure access to and receipt of quality health care. Kaiser views itself as a system of care and not simply as a deliverer of services.
- Kaiser uses a population-based approach to health care delivery. Kaiser's members experience between 22,000 and 25,000 cancers per year. Of these, 4,000 to 5,000 are breast cancers; 2,000 to 3,000 are lung cancers; 2,500 to 3,000 are colorectal cancers; and 3,000 to 4,000 are prostate cancer. There are 150 to 200 new cases of pediatric cancers annually.
- To provide a context in which to view the cancer problem as experienced by plan members, Kaiser estimates that its membership experiences approximately 10,000 acute stroke cases per year, about 8,000 new acute myocardial infarctions (MIs), and 8,000 new diagnoses of other coronary artery disease. An estimated 250,000 members have diabetes, 800,000 members smoke, and about 6,000 members have Parkinson's disease.
- Kaiser's operational definition of quality health care is "delivering the right care for the right people at the right time, in the right place, and having the best outcomes."
- Knowing the type of care to deliver stems from the use of evidence-based guidelines. In some cases, Kaiser has developed the guidelines it employs; in other cases, guidelines developed by others have been adopted. To ensure that Kaiser knows what "the right care" is, a research component is maintained to evaluate the impact of the care provided.

- The ability to identify the needs of the target population is an essential element of quality. Kaiser has invested heavily in information systems to help determine the prevalence of various diseases and behaviors (e.g., diabetes, smoking) and support efforts to target outreach, screening, and necessary followup.
- Kaiser's Breast Buddies Program provides social support by pairing women with newly diagnosed breast cancer with a breast cancer survivor to assist in decision making regarding care options. An extensive evaluation of this program was performed to assess its impact.
- In southern California, Kaiser uses a defined process for selecting areas for specifically targeted programs to improve quality of care. The clinical strategic goals list includes the following priorities: cardiovascular disease, cancer, immunizations, pregnancy outcome, and asthma. These priorities were selected because of their associated high morbidity and mortality among Kaiser's membership.
- The following elements are used to define quality of care for clinical strategic goals: use of evidence-based guidelines; attempts to implement guidelines through communication, system changes, and processes; specific performance and outcome measures related to guidelines; performance target setting; action planning to improve process and outcome; implementation of action plans; and attempts to align performance targets with incentives.
- Clinical strategic goals have been developed for breast and cervical cancer. Goals related to smoking are included in the cardiovascular area. Process and outcome measures for breast cancer include the percent of women 50 through 75 years of age having a mammogram within 2 years. A yearly satisfaction survey of members newly diagnosed with breast cancer is also conducted. Five-year survival rates are monitored, though this is a poor measure of the current quality of care. Including the time required to do the evaluation, it is not expected that outcomes will be known for women now being treated for breast cancer until 2006.
- Quality-of-care measures for cervical cancer include the percentage of women having pap smears within 3 years, and the rate of followup within 1 month of abnormal pap smears.
- Experimental treatments differ in terms of type and level. For example, old drugs may be used in new ways (e.g., Taxol for lung cancer); new treatment devices may be developed (e.g., proton-beam therapy for prostate cancer); established procedures may find new applications (e.g., high-dose chemotherapy and bone marrow transplant for ovarian cancer); and diverse new treatments may be proposed (e.g., gene therapy, crystals). If everything new were better, research would not be necessary. People are quick to see the new as better, without waiting for adequate proof.
- Access to experimental treatments should be provided in the context of efforts to determine whether the treatment works. Unless this is the case, experimental treatment should not be provided.
- Purchasers have influence on how their premium dollars are spent. Many contracts specifically exclude experimental therapies in response to market pressure to limit premiums or out-of-pocket expenses. Kaiser would like to

- provide access to experimental treatments when they are provided within the context of attempts to find out what works.
- Payment for experimental treatments under Phase III randomized clinical trials is facilitated because they represent either new uses of old drugs or cases in which the drug is provided free of charge either by the NCI or by the pharmaceutical company. Participation in Phase I and II studies poses greater difficulties since there are no comparison groups, and because the treatment may not be funded by any entity other than Kaiser.
 - The hierarchy of clinical trials includes primary prevention, screening, initial therapy, monitoring, symptom management, and, finally, trials of last-chance experimental therapies, which receive the greatest media attention.
 - Kaiser often competes with university centers to participate in primary prevention and screening trials; these trials are often relatively simple and generally do not place heavy burdens on the health care system. Kaiser's Southern California, Northern California, and Northwest Regions, as well as Group Health Cooperative, are all affiliated with specific adult and pediatric cooperative trials groups. However, Kaiser experiences many of the same difficulties in recruitment as do other institutions; further, all patients do not want to be in a study, and for some, no appropriate study is available.
 - Until recently, the NCI has been relatively impervious to complaints about some of the unnecessary cost elements of clinical trials, including tests and procedures that are done as part of the trial but are not part of routine care and may not be necessary to address the main issues of the trial.
 - Until recently, little attention has been given to assessing the marginal costs of clinical trials versus conventional therapies (i.e., the issue has been largely ignored). This may account for higher enrollment of Kaiser patients in trials and/or sending patients elsewhere for trial participation.
 - In Dr. Petitti's opinion, clinical trials in cardiovascular disease have provided the best model for making contributions to the knowledge base of evidence-based medicine. Clinical trials for selected aspects of cardiovascular disease have resulted in about a 10 to 15 percent difference in overall survival between patients treated with and without the new drug. One of the reasons for the success seen in cardiovascular disease trials is the simplicity of most of these trials.
 - Closer partnerships could be forged with academic medical centers if a number of significant issues are addressed. One particularly troublesome example is the "bait-and-switch" phenomenon in which a patient is sent to an academic medical center to participate in a well-designed, randomized, controlled study of an apparently promising therapy and, instead, the patient is recruited for alternative regimens that may not have a strong scientific basis, may not be a randomized study, or for which there is no good plan for scientific data gathering.

Additional Research Needs and Other Recommendations

- The clinical trials enterprise within cooperative groups and in health care centers should be scrutinized more carefully. The NCI has not taken a strong lead in providing direction to the national cancer research agenda in clinical trials. Some

of the questions asked are not the most important clinical questions. There are concerns about the degree to which studies compete for the same patients or that there is duplication among different trials groups. This slows the process of accrual which in turn extends the research timeframe.

Discussion

Dr. Petitti

Key Points

- Kaiser's decision to participate in clinical trials is based upon a number of factors that include but are not limited to: whether it will answer important scientific questions; whether the cost is reasonable; whether the protocol is well defined; and whether Kaiser has sufficient capacity to participate.
- Kaiser is proceeding from the research phase to the implementation phase of its colon cancer screening effort. Screening for colorectal cancer is now recommended for Kaiser members, and the plan is attempting to develop strategies for increasing compliance. It is recognized that the cost savings associated with colorectal screening will not be realized for 10 years or more. Although there is concern that the savings are not immediate, the plan feels it should offer a service proven to be of benefit.
- The rise of for-profit HMOs has increased competition in the health care marketplace, resulting in cost accountability and downward premium price shifts. Though limiting cost to the consumer has always been a concern, Kaiser questions whether the level of care can be maintained if there is continued downward cost pressure. Dr. Petitti maintained that quality of care is not threatened at this point, but that Kaiser and other plans struggle to both maintain quality and ensure maximum efficiency. A central strategy for doing so involves removing from the system things that cannot be justified based on quality.
- Kaiser's southern California cancer clinical trials unit is located in San Diego. Efforts are under way to make clinical trials more accessible elsewhere. In northern California, trials are available throughout the system. Patient participation in clinical trials is less the result of a selection process than an attempt to identify potential participants and inquire about their desire to participate. Kaiser relies heavily on physicians to identify people who might be eligible for clinical trials.
- Many Phase III trials are open to Kaiser members, as are some Phase II trials. A number of Phase I and II trials for novel therapeutic agents are also anticipated in the near future. Kaiser's decision to participate in these trials will be based on the scientific value of the study and the likelihood that the novel therapy will offer benefit. It is Kaiser's strong preference to offer clinical trials within its system rather than referring patients to other facilities.
- Comprehensive cancer centers have a major role in developing clinical trials and establishing the research infrastructure to evaluate them; however, increased competition in the health care marketplace is likely to limit the number of patients available to the centers. To address this issue, the UCLA Jonsson Cancer Center

- has formed partnerships with high-quality community-based oncology practices. Research nurses and data managers are hired from the communities and are supervised by the Jonsson Cancer Center Clinical Research Unit. The Center subsequently works with the hospitals and practices to establish research pharmacies and to obtain Institutional Review Board (IRB) approvals.
- At present, UCLA funds the research nurses and data managers, which is very expensive. Funds obtained through philanthropic activities, such as the Revlon Run-Walk, are used to offset some costs. UCLA forwards any reimbursement associated with the trials to the physician practice. In the future, UCLA hopes that sufficient resources will accompany the trials to fund the support costs. Dr. Gasson underscored that a critical mass of resources is needed for infrastructure development. Once the infrastructure is in place, patients can accrue to clinical trials more rapidly. Thus, the first patient is the most expensive and the cost per patient decreases with subsequent accruals.
 - UCLA has reached out to Kaiser and to community physicians to elicit participation in its trials of novel therapeutic agents. Kaiser participates in one UCLA trial, but accrual has not been strong. The trial is located in Woodland Hills and in Riverside, California. These sites were selected due to the interest of the specific oncologists working in those settings in participating in the trial, and the fact that Kaiser was not offering other trials in that setting. At present, UCLA accrues one or more patients per day from approximately 20 practices and 50 physicians. UCLA expects to accrue more than 1,000 patients per year through such network sites as more community practices achieve full participation.
 - Dr. Calabresi questioned the disparity between the limited percent of revenues the managed care industry devotes to research compared with industries such as the pharmaceutical industry, the automobile industry, General Electric, and others that invest approximately 15 percent of revenues into research and development. Dr. Petitti suggested that an accounting of investment by managed care varies depending on how research is counted and tracked. Kaiser invests substantially in operations research, program evaluation, and information systems. Consumer pressure to contain premium costs acts as a negative incentive to invest in medical research.
 - Dr. Schuster indicated that his work has shown that a black woman in the United States with a T1 or T2 breast cancer is only half as likely as a white woman with the same type of tumor to receive treatment with curative intent. This disparity accounts for 40 to 50 percent of the mortality difference between black and white women with breast cancer. Asked if Kaiser has studied this phenomenon, Dr. Petitti indicated that data from an unpublished study of women diagnosed with breast cancer in the Kaiser system in the 1980s demonstrated no difference in 10-year survival rates according to ethnicity once adjustment for stage at diagnosis was made. Dr. Petitti acknowledged, however, that ethnic differences in survival rates by stage do persist in the Kaiser population.
 - Although people tend to believe that new and expensive treatments are better, research may actually demonstrate that the less expensive approaches may be more effective.

- In response to an audience question concerning what is being done to study breast cancer among black women, Dr. Brawley indicated that a great deal of data exist. NCI studies, for example, show that equal treatment yields equal outcome, regardless of race. There is no biological difference in breast cancer in white versus black women; however, race may be a factor in whether or not one enters the system and receives equivalent treatment.

Quality Cancer Care – Humana Policy and Research Perspective

Dr. Mitzi Krockover

Background

Humana is now a managed care/health services organization that no longer owns hospitals and currently covers approximately 6.4 million lives in commercial accounts, Medicaid, Medicare, and the military health system (CHAMPUS). Humana's approach to health care and to quality is population based.

Key Points

- Women in HMOs are more likely to obtain mammograms, pap smears, and clinical breast exams (CBE) than women under fee-for-service (FFS) plans. Compared with FFS, HMOs improve access to preventive services for women with low levels of education. Cancer screening is more readily available to HMO enrollees and vulnerable groups are more likely to receive screening.
- Data from a variety of studies indicate that Medicare HMO patients are diagnosed at earlier stages than FFS patients with melanoma, breast, cervical, and colon cancers. Treatment and outcomes related to colorectal cancer are similar between HMOs and FFS plans. No significant differences between Medicare HMO and FFS patients were demonstrated in symptoms duration prior to diagnosis, training of physicians rendering diagnoses, type of primary tumor, anatomic location of the tumor, disease stage, or survival rate. Another study demonstrated that low-income prostate cancer patients in HMOs live longer than FFS patients.
- Humana's highest utilizers of health care are its sickest members. The top 10 percent of Humana's highest utilizers have two or more chronic diseases and approximately one-third have one chronic disease or one primary chronic disease. In the aggregate, most of these individuals suffer from approximately 30 conditions; identifying this cluster of conditions in this population has helped Humana to focus efforts related to quality measurement.
- A number of interventions affect the quality of care: the use of care guidelines; case management to provide continuity of care; member education to ensure understanding; provider education; provider profiling to compare individual practice patterns with peers; patient profiling; and risk-sharing initiatives aimed at provider behavior change, among others.
- In 1994, Humana developed a breast cancer-related program in the Chicago area that was designed to standardize and coordinate services; improve consistency in imaging report terminology and recommendations; improve consistency in

mammography image quality; and reduce the time from identification of an abnormality to problem resolution. A multidisciplinary breast care committee was convened, including internists, oncologists, radiologists, surgeons, nurses, and administrative staff. Program goals included: developing a system to improve care coordination and evaluation for women undergoing mammography; standardizing coding and mammography reporting; developing a database management system; developing a quality control system based on data from the breast care management system; and achieving American College of Radiology (ACR) accreditation.

- The breast care coordinator and the breast care team used a computerized database to track the data needed to provide outcome reports and support the delivery of quality care. The system recorded standardized mammography results and the patient and physician were notified immediately regarding a questionable finding. Patients with positive findings were tracked to ensure followup testing and treatment. Primary care physicians were notified as to patient adherence with recommended followup or treatment. Radiologic and surgical performance outcomes were monitored, and the system also generated screening reminders to primary care physicians and patients.
- Timeliness of care was measured by the mean or median time between abnormal mammogram detection and biopsy and from biopsy to surgery, if necessary. Clinical outcome measures included the percent of newly diagnosed Stage I breast cancers and results from a patient satisfaction survey.
- Radiologic quality control measures included film and equipment quality, level of mammographer certification, and ACR accreditation.
- Quality is a feedback loop between research, data, and the patient care that generates the data that educates the plan and providers. Optimal appropriation of care is achieved through the most appropriate use of both resources (cost) and quality measures.

Discussion

Dr. Dr. Krockover

Key Points

- Actual cost savings associated with the Humana breast care management program have not been assessed. Since Humana is moving away from a staff-model approach to care, the program itself may not be replicated in other settings; however, certain of its components may be implemented (e.g., community partnerships) in other areas.
- Case managers at Humana are individuals assigned to a member who has been identified as needing either support, services, facilitation, or education.
- Humana uses care guidelines developed by a variety of organizations; it is recognized that these may not all be evidence based, but the plan is trying to move in that direction.
- Regarding the Humana study that concluded that low-income prostate cancer patients in HMOs live longer, Dr. Krockover indicated that the study showed that

for all prostate cancer patients, over a 6-1/2 year period, lifespan was increased for patients enrolled in an HMO versus FFS plan. Such differences were observed to be greater for low-income individuals. Dr. Freeman suggested that the study period was extremely short given that prostate cancer progresses very slowly, and that these results might not apply to the low-income uninsured.

Healthy and At-Risk Populations

Dr. Roshan Bastani

Key Points

- Recruitment and retention of minorities is an essential element of research planning. Similarly, incorporating all segments of the population into quality assurance planning is vital.
- Minorities must be actively recruited from the communities in which they live, work, and receive health care to ensure their participation in cancer research. This principle also applies to the provision of quality health care to minority populations.
- Research results derived from studies of the general population are not necessarily applicable to minority populations. For example, mammography rates in Los Angeles County were found to be drastically different from the statewide average for all ethnic groups; it was also discovered that physician referral for screening mammography had a major influence on target women. An intervention was planned to ensure that every eligible woman received such a referral. It is essential to conduct interventions that are theoretically driven and to tailor the interventions for target audiences. UCLA has adopted a theoretical model and related interventions to measure outcomes related to adherence and psychological distress related to abnormal mammography results.
- Local studies of knowledge levels about breast cancer risk factors and other information revealed that there were more similarities among ethnic groups than there were differences. It is incorrect, however, to assume that similarities in selected areas, such as specific knowledge and attitudes, will translate into similarities in other areas, such as receptivity to programs and educational materials. To ensure broad appeal, program elements must be tailored with respect to ethnicity, gender, income, and education. In addition, it must not be assumed that people who are not white are poor and uneducated. These concepts apply equally to research and to the delivery of quality care.

Molecular Epidemiology

Dr. Ronald Ross

Key Points

- The medical community's acceptance of treatment side effects depends on the indication for treatment. Short- and long-term side effects of treatment for life-threatening conditions are obviously much more acceptable than when treatment

is for less severe conditions. For example, for patients treated with chemotherapy for testicular cancer there is a very wide tolerance for side effects. Due to medical advances, the survival rate for germ cell testicular cancers has risen from nearly zero percent to more than 80 percent. Since testicular cancer patients are living longer, and some have survived 15 to 20 years following their treatment, some of the long-term toxic effects of their chemotherapy are now emerging. Cisplatin, one of the key drugs in the therapeutic regimen, is toxic to the kidneys, cardiovascular system, and neurologic system. The full impact of this drug is unknown. Also unknown is information about the quality of life for testicular cancer survivors (e.g., ability to secure and maintain employment, quality of reproductive experiences). But whatever the long-term effects, they are accepted because they occur in the context of treating life-threatening conditions.

- The medical community must have a much lower acceptance for medication side effects when medications are provided as elective therapies, such as estrogen replacement therapy for menopausal symptoms or analgesics for mild headaches or muscular aches and pains.
- Tolerance for major medication side effects must be absolutely minimal when used for prevention-related therapy in otherwise healthy populations.
- Tamoxifen is an excellent adjuvant therapy for breast cancer treatment and for breast cancer prevention in healthy populations. Recent clinical trials reveal that tamoxifen also substantially reduces the risk of sustaining a major osteoporotic fracture; however, there are associated small but real increases in endometrial cancer risk. This increased risk for endometrial cancer may result in caution among the scientific and lay communities in recommending tamoxifen as a breast cancer preventative for the healthy population as a whole.
- Experience to date with tamoxifen has led to increased interest in other antiestrogen drugs, referred to as Selective Estrogen Receptor Modulators (SERMs), such as raloxifene. SERMs are designed to maintain the preventive effect of tamoxifen for breast cancer, without some of the purported risks, but have not yet been tested adequately.
- Finasteride, an example of a preventive therapy for prostate cancer, selectively blocks the enzyme that activates testosterone to dihydrotestosterone, which causes prostate cells to grow and divide. A national clinical trial is under way to evaluate the impact of finasteride on prostate cancer prevention in healthy men, including identification of potential side effects. Controversy remains concerning the drug's impact; in fact, some believe that finasteride may selectively stimulate certain precancerous lesions in the prostate. The medical community must have a lower tolerance for any serious side effects when prescribing drugs to otherwise healthy populations.
- Other types of iatrogenic therapies, such as low-dose radiation, have associated risks and benefits. Though radiation is a known carcinogen, as a specific therapy, tolerance for its associated acute or chronic side effect risks is higher than if it were given for diagnostic purposes.
- Aspirin is an effective, wide-spectrum, anti-inflammatory agent. It is also a wide-spectrum analgesic, useful in treating headaches and all types of muscle aches and pains. Aspirin has been recognized as effective for preventing second heart

attacks in men and women, and is a primary preventive agent for heart attacks in healthy men and, logically, in healthy women. Aspirin is now being promoted as an agent that may prevent colon cancer because it reduces the rate of division of cells in the colon lining.

- The principal outgrowth of Harvard's Physician's Health Study was the recommendation that low-dose aspirin should be used to prevent myocardial infarction. A lesser finding was that aspirin use was associated with a small increase in the risk of both fatal and nonfatal strokes. Notably, however, there was no decline in overall cardiovascular-related and noncardiovascular-related mortality. Questions remain whether aspirin is a good drug for reducing overall mortality through cardiovascular disease prevention when balanced against its risks, such as ulcers, gastrointestinal bleeding, and stroke.
- There has been less study of the possible cancer-causing properties of analgesics. Phenacetin, an active ingredient in analgesics popular in Europe and the United States in the late 1950s, '60s, and '70s, is a known Class I carcinogen that causes renal pelvis cancer. Evidence that analgesics cause cancer of the renal pelvis is not limited to phenacetin, but also includes acetaminophen (the major active ingredient of phenacetin) as well as aspirin, which is known to be toxic to the kidneys.
- Approximately 10 years ago, investigators at UCLA began a major study to determine whether or not analgesics could cause cancer in the body of the kidney, i.e., renal-cell carcinoma or renal parenchymal cancer, as it was well established that these could cause renal pelvis cancer. Study results revealed that regular users of acetaminophen or phenacetin had twice the level of kidney cancer risk compared with nonusers; risk also increased with increased cumulative dose. Aspirin and other nonsteroidal anti-inflammatories carried slightly lower but statistically significant increases in risks. Lower doses associated with cardiovascular disease prevention (e.g., one aspirin a day or less, even for long periods) did not demonstrate increased risk, but aspirin at higher doses for 10 or more years was associated with an almost fivefold greater risk compared with nonusers. Thus, physicians should carefully instruct patients about the regular use of these drugs.
- Early studies conducted in the 1970s revealed that estrogen therapy caused endometrial cancer. This observation led to a marked drop in the use of estrogen replacement therapy among American women and to a marked reduction in the usual dose prescribed. These studies also resulted in increased use of progestin to protect the endometrium. Estrogen replacement therapy substantially reduces risks associated with hot flashes, osteoporosis and associated fractures, and heart disease. The impact of estrogen replacement therapy on breast cancer risk is unknown. Such therapy may result in a modest increase in breast cancer risk of approximately 2 percent per year. Thus, after 10 years of therapy, breast cancer risk would be increased approximately 20 percent relative to nonusers. Recent evidence also indicates that estrogen increases the risk of thrombotic events.
- There is current interest in whether or not estrogens reduce the risk of presenile dementia such as Alzheimer's disease as well as the risk of colon cancer; minimal clinical evidence currently exists.

- Risk-benefit modeling was used to calculate the impact of long-term (10 years) low-dose estrogen replacement therapy on mortality rates. The benefits of such therapy (e.g., fewer deaths from heart disease and hip fractures) appear to exceed the risks (e.g., breast and endometrial cancers). These findings do not necessarily indicate that estrogen therapy is recommended for all women. For every breast cancer death, approximately six heart disease deaths would be prevented. Despite this significant benefit, any increase in breast cancer risk might be unacceptable to some patients. Providers must be aware of the risks and benefits of alternative treatment approaches, and patients must be educated about them and play an active role in determining their course of therapy.

Cancer Prevention in Women of Color

Dr. Antronette Yancey

Key Points

- UCLA has conducted recent research in the primary prevention of cancer and other chronic diseases through community-based, lifestyle change intervention. Early evidence suggests that voluntary changes in diet and exercise decrease circulating estrogen levels and that weight loss is associated with reduced breast cancer incidence.
- One of the largest gaps in the cancer prevention literature is how to produce and sustain lifestyle change, especially in high-risk populations such as African-American women. African-American cancer incidence and mortality rates are higher than those of other major racial and ethnic groups. African-American women are the major ethnic and gender group in the United States at highest risk for obesity, excess dietary fat, and low activity levels.
- Literature reviews conducted in the last several years revealed a lack of cancer prevention research involving interventions in physical activity and diet for populations of color.
- UCLA conducted a pilot study to assess its ability to recruit middle-income, relatively well-educated (e.g., about 15 years of formal education), African-American women into a lifestyle change study and to identify appropriate incentives. Study goals included identifying correlates of leanness and obesity in African-American women and evaluating the success of various recruitment strategies. Recruitment strategies for African-American women varied by education and level of obesity. Women with higher education levels were more likely to be recruited through print and electronic media than women with less formal education. Personal recruitment strategies (personal contacts with friends, relatives, and coworkers) were more successful in recruiting obese women. Study findings will be published in the May issue of the *American Journal of Health Promotion*.
- A second study involving conduct of onsite physical activity programs demonstrated that key organization-specific factors contributing to success in developing and sustaining such fitness promotion activities were pre-existing group cohesion, social support, and site leadership commitment.

- "ROCK Richmond!" a community fitness promotion effort currently under way in Richmond, Virginia, is focused on increasing community involvement in healthy eating and exercise practices. Through this project, more than 800 people receive direct service (free fitness instruction) weekly and 2,500 to 3,000 people have been involved in special events. Most project participants are overweight, female, African-American, and at high risk for chronic diseases.

Discussion

Drs. Bastani, Ross, and Yancey

- What we perceive as good-quality care may not be what is valued by various populations. For example, telephone counseling is a way of providing care or information, but limited research has found that various populations tend to be more (e.g., Hispanics) or less (e.g., Asians) comfortable with this method of intervention.
- Combined efforts to improve diet and promote healthier living through exercise will be successful. Previously, most of the focus in cancer prevention, especially weight loss, has related to nutrition. Other prevention efforts have concentrated almost exclusively on increased levels of exercise. The synergy between these two approaches must be harnessed if people are going to achieve and sustain substantial weight loss. Methods to institutionalize social support have not been well established.
- It is incumbent upon public health professionals, especially cancer prevention specialists, to find ways to enable people to be more active as part of their regular routines.
- Recommendations concerning various interventions, whether preventive or related to elective therapies, should be based on the results of population studies identifying the entire gamut of associated risks and benefits of such interventions. Study results can then be applied at the individual level by taking into account specific patient characteristics.

Cancer Control

Quality of Life in Breast Cancer Survivors

Dr. Patricia Ganz

Key Points

- An implied goal of all therapies for patients with cancer is quality of life. However, quality-of-life measurement has been difficult until the last 10 to 15 years when health services researchers and social scientists have begun to systematically collect information from patients regarding their quality of life.
- Recent research at the Jonsson Comprehensive Cancer Center has focused on the impact of adjuvant therapy on the quality of life for breast cancer survivors 1 to 5 years following diagnosis. Except for differences in body image, quality of life during recovery is similar for women having either mastectomy or breast-

conserving surgery. Less is known about the impact of adjuvant therapies on patients' daily lives, level of functioning (physical, emotional, and sexual), and other measures of quality of life. The study included an ethnically diverse population of women with early breast cancer (noninvasive, Stage 1 or Stage 2). Study participants completed a comprehensive survey instrument that collected detailed medical and demographic information. Use of this questionnaire enabled comparisons to be performed with women who did not have major health problems. The Centers for Epidemiologic Studies-Depression (CES-D), a standardized measure of depression, was used to compare depression levels between healthy women and breast cancer survivors. Other measures were used to assess levels of sexual functioning and body image.

- Nearly 1,100 women aged 25 to 90 years completed the survey instrument. On average, participants were nearly 3 years postdiagnosis and had recovered from treatment. At least 69 percent were either married or involved in a committed relationship. Approximately 62 percent of the women had breast-conserving surgery, approximately 22 percent had mastectomy without reconstruction, and a sizeable portion had mastectomy with reconstruction.
- Approximately 24 percent had no therapy beyond surgery or surgery with radiation as their primary treatment. These were mostly women with early-stage disease, such as Stage 0 or 1. Approximately 16 percent had chemotherapy alone and 32 percent received tamoxifen alone.
- Treatment differed somewhat by age. Women who had no adjuvant therapy were on average approximately 55 years old. Those taking tamoxifen were somewhat older (about age 63) because tamoxifen alone is a more common treatment for older postmenopausal women. Those receiving chemotherapy alone were the youngest (average 47 years), and those receiving chemotherapy and tamoxifen averaged about 53 years of age.
- Type of surgery received also differed among the study group. Those who had favorable prognoses and needed no adjuvant therapy had somewhat higher rates of breast-conserving surgery compared with others, with the lowest rates of conservative surgery occurring in women who needed chemotherapy and tamoxifen (50 percent).
- Although unexpected, differences in the time since diagnosis were observed. Women receiving chemotherapy and tamoxifen were somewhat further out from their diagnosis.
- Breast cancer survivors are virtually precluded from receiving hormone replacement therapy (HRT) because of the association of breast cancer and exogenous hormones. Of the women who did not receive any adjuvant therapy and were not receiving HRT, approximately 40 percent reported having hot flashes. Sixty percent of women receiving tamoxifen alone reported hot flashes. Of those receiving chemotherapy alone, 50 percent reported hot flashes, and women receiving chemotherapy and tamoxifen reported the highest rate of hot flashes. Thus, the likelihood of hot flashes varied significantly by treatment group; more intensive therapy was associated with a greater chance of hot flashes, although the symptom was fairly frequent even among women receiving only surgery or surgery and radiation.

- Vaginal dryness, also related to hormone deficiency, was common even in study participants who had not received adjuvant therapy. There was a significant relationship between vaginal dryness and pain during intercourse in women who received chemotherapy; thus, chemotherapy leads to late toxicity contributing to sexual dysfunction in breast cancer survivors.
- Women have a tendency to gain weight after a diagnosis of breast cancer. Previously, this was attributed to chemotherapy, and possibly to the use of steroids as an antiemetic. Self-reported weight gain in the study population, however, was not significantly different among study participants. Body image concerns were a significant issue in the study population, but were not strongly related to type of adjuvant therapy.
- Generic measures of health-related quality of life (e.g., aspects of physical functioning, social and emotional functioning, pain, energy, fatigue, and general health perceptions) did not reveal significant differences by treatment type, except that women receiving some form of adjuvant therapy had more difficulty in physical functioning than those who did not.

Additional Research Needs and Other Recommendations

- Cancer survivors must be active participants in quality-of-life research.
- Additional study is warranted to examine the impact of adjuvant therapy on physical and sexual functioning for breast cancer survivors.

Quality of Life in Prostate Cancer Survivors

Dr. Mark Litwin

Key Points

- According to the Donabedian model of quality-of-care assessment, quality of care can be best assessed by looking at its three major components: the structure of care, process, and outcome. The structure of care refers, for example, to provider mix in a managed care organization, access to specialists in one health care system or another, or demographic differences in one population versus another. Process refers to what actually occurs between the clinician and patient (e.g., what tests or referrals are made or ordered, what the interaction includes, and treatments recommended). Outcome refers to what happens to the patient as a result of the care process. Common disease-oriented outcome measures include morbidity, mortality, and clinical variables such as prostate specific antigen (PSA) levels related to prostate treatment and disease recurrence. Patient-centered outcomes include satisfaction with care and health-related quality of life.
- Quality of life consists of a number of general domains including, for example, physical function, social interactions, and mental health. Cancer-specific domains include anxiety about recurrence, difficulty concentrating, weight loss, fatigue, and loss of appetite. Other quality-of-life issues related to cancer type may also emerge; with prostate cancer, these may include issues related to sexual, urinary, and bowel dysfunctions.

- In certain respects, quality-of-life research in prostate cancer is in its adolescence. One of the early lessons to emerge is that the degree of dysfunction and the degree of "bother" from that dysfunction are discrete phenomena.
- The UCLA/RAND Quality of Life Project examined quality of life in 1,000 men with early-stage, clinically localized prostate cancer from a large managed care population in southern California. Study data suggested that there were no discernable differences between the study and control populations regarding physical function, social interactions, mental health, and pain, among other measures, regardless of whether they underwent surgery, radiation, or received no treatment at all.
- In a similar study, approximately one-third of men undergoing radical prostatectomy needed to use devices to control incontinence; approximately one-half of these men felt this posed a significant problem. Only one-third of men who were potent prior to surgery and lost potency after surgery felt that this was a major problem. Almost 40 percent indicated that they were unable to have erections, but also indicated that it was not a problem. These findings further emphasized the dissonance between function and bother in these domains—although some men experience significant urinary and sexual dysfunction after prostate cancer treatment, in general, they tend to have reasonably good overall physical and mental functioning. Despite the potential dysfunctions that can occur following prostate surgery, 64 percent indicated that they would still select surgery as their treatment of choice.
- A University of Miami study of prostate cancer patients receiving surgery versus radiotherapy produced similar results; there were no significant differences between these patient groups with respect to emotional and some physical measures.
- According to research conducted at the University of Connecticut, patients' quality of life decreased as the degree of disease advanced. Though this finding may be somewhat intuitive, it is one of the earliest studies to demonstrate the ability to predict degree of disease purely by quality-of-life measures. Dr. Ganz' work likewise indicates that patients' cancers can be staged relatively accurately without direct contact based on their performance on some quality-of-life measures.
- Significant variation exists in quality-of-life-related data, depending upon the data collection methodology used. Written, self-reported data are generally the most reliable. For example, only 4 percent of urologists performing a routine postsurgical assessment of prostate cancer patients reported that the patient was experiencing significant impairment; in contrast, 35 percent of the patients reported significant impairment.

Additional Research Needs and Other Recommendations

- Quality-of-life instruments should be cancer-specific, as certain cancers and their treatment approaches have varying impact on patients' quality of life. Self-administration of quality-of-life instruments is highly important.

- Findings from quality-of-life studies need to be presented before any prostate cancer-related treatment is undertaken and prior to making treatment decisions. There is no room for paternalism in the decision-making process. Patients must make informed decisions, taking into account their expectations concerning recovery and anticipated quality-of-life levels after treatment for prostate cancer.

Discussion

Drs. Ganz and Litwin

Key Points

- Among men undergoing radical prostatectomy, younger patients tend to have better baseline quality of life and function and are more likely to return to that baseline following surgery. Younger patients, therefore, have a better chance of maintaining both general quality of life and sexual, urinary, and bowel functions. Findings from an American Cancer Society-funded study indicate that younger patients are less willing to tolerate any risk for impotence and incontinence. However, these patients, assessed immediately after treatment and 6 months after therapy, tended to adjust to potency- and continence-related dysfunction quite well.
- According to Dr. Litwin, the available evidence does not support the contention that PSA screening decreases mortality in the general population; therefore, routine PSA screening cannot be recommended from an epidemiologic perspective. Since the advent of PSA screening, there has been a substantial stage migration to earlier stages of prostate cancer that presumably are more curable. As a result, more men are undergoing radical prostatectomy. It is unclear to what extent men, particularly in poor communities, are being counseled about the possible major side effects of prostate cancer treatment. Of interest, in a randomized, controlled trial of men who were offered PSA screening with varying levels of discussion devoted to the risks and benefits of screening, patients were three to four times less interested in obtaining PSA screening as their knowledge of the associated benefits and risks increased. This tendency (intervention effect) was eliminated if the patient had personal family experience with prostate cancer.
- Since there is no evidence that population-based PSA screening in healthy men decreases population mortality from prostate cancer (though such evidence may surface in five to ten years), Dr. Litwin disagrees with the American Cancer Society and the American Urological Society's recommendation that men over age 50 should have PSA screening performed routinely. The exceptions are the particularly young patient with first-degree relatives with prostate cancer or the African-American patient, who is likely to have a higher genetic risk for prostate cancer. In the general population, however, if all cases of prostate cancer were detected through 100 percent screening, the United States would not have sufficient resources to treat them.
- Urologists' data regarding treatment outcomes is based on patient reporting, but patients often minimize their symptoms and tend to want to please their physicians. It may also be true that the survey instrument does not ask the right

- questions (or ask them the right way) or the physician may not be listening for the information. Regardless of the reason, the importance of conducting quality-of-life research by surveying patients directly is clear.
- It is too early to identify the impact of seed-implant radiation therapy on symptom improvement in prostate cancer patients. Only 6 or 7 years of data related to the use of modern techniques are available.
 - It has been assumed that tamoxifen universally reduces the risk of osteoporosis. A recent article in the *Journal of Clinical Oncology*, however, indicated that osteoporosis actually increased in premenopausal women taking tamoxifen on a prevention trial. Studies of postmenopausal women showed that bone density was preserved with tamoxifen in postmenopausal women receiving adjuvant therapy. These studies have only recently been replicated in premenopausal women, where an attempt was made to preserve bone with the new bisphosphonates on a prevention trial. In a British prevention trial, premenopausal patients given tamoxifen for prevention experienced bone loss within the first 2 years of starting the drug. There is a bone substudy currently under way in the Breast Cancer Prevention Trial; however, data are not yet available. It is possible that premenopausal women taking tamoxifen experience an initial loss of bone that subsequently stabilizes.
 - In Dr. Litwin's research, patients whose prostate cancer was being managed with watchful waiting alone had significantly higher levels of anxiety about recurrence and mental health disturbances. In every other quality-of-life domain, they were indistinguishable from patients who were never diagnosed with prostate cancer. Watchful-waiting patients and control patients were similar with respect to sexual, urinary, and bowel functions. Those who had radical prostatectomy or radiation therapy had significant problems in those areas.
 - Dr. Litwin indicated that though Gleason scores were assessed, they were not used as control factors in his study. He concurred with Dr. Calabresi's statement that Gleason scores typically make a difference in determining whether patients receive treatment or watchful waiting. According to Dr. Litwin, the biggest difference between the patient populations is with respect to mortality; those with higher Gleason scores are more likely to drop out of the sample because they die from Gleason-8 prostate cancer.

Additional Research Needs and Other Recommendations

- Many women who receive adjuvant therapy for breast cancer are never told that the therapy will cause them to become prematurely menopausal, or even that premature menopause is a risk associated with the therapy. As a quality-of-care issue, it is important to communicate what life will be like after breast cancer treatment. Women will tolerate an outcome if they have been prepared for its possibility. Many physicians do not have the relevant information readily available.
- It is the responsibility of the health care system to develop alternative strategies to address these issues. Many of the women treated for breast cancer can expect to live a very long time as a result of that treatment, but they should be aware of the

- possible negative outcomes that may accompany it. For some women, small differences in survival benefit associated with certain treatment regimens may not be worth the everyday experience of related treatment side effects.
- To get information on treatment outcomes to patients, physicians, and policy makers, the relevant data must be systematically collected, along with descriptions of what people actually experience. This information must be translated into educational tools, and patients and providers must be instructed in their use. As new treatments and technologies are developed, it will be very important to collect these outcome data so that patients can make informed decisions about their use; the experience with autologous bone marrow transplant for breast cancer underscores this need.

Imperatives for Cancer Care

Ms. Susan Leigh

Key Points

- Well-trained oncology nurses and social workers are essential to the delivery of high-quality care for cancer patients. There is a need to protect the integrity of oncology nursing and social work, because many oncology units nationwide are closing due to the rise of managed care. Oncology patients increasingly are assimilated into the general services in hospitals, and nurses who are not trained in oncology are delivering chemotherapy.
- Once patients have been treated for one cancer, they are at risk for recurrence of their primary cancer, developing other cancers, experiencing late effects of therapy, and organ system failures. Therefore, quality-of-life issues and quality cancer care must be examined as a continuum of cancer survivorship beginning at the point of diagnosis and extending for the duration of the patient's life.
- There is no guarantee that an initial cancer will not reappear, even if the patient is cancer free for 5 years following diagnosis. Recurrence is still possible, as are second primary cancers and organ system problems resulting from cancer treatment. Rather than focusing on the 5-year mark, many survivors focus on living life as effectively and as fully as possible as soon as possible after diagnosis.
- The NCCS surveyed 300 oncology professionals, including cancer center administrators, cancer and health services researchers, health economists, patient survivor support and advocacy organization leaders, the pharmaceutical industry, and payers. The survey addressed three domains. First, it focused on defining quality cancer care by comparing and contrasting fee-for-service and managed care. Second, it attempted to define psychosocial issues and their implications for total quality care. Lastly, it sought to define long-term followup care and its implications for total quality care.
- Survey results were published by the NCCS in *Imperatives for Quality Cancer Care* in May 1996; this publication is available at no cost. It is also available on the NCI's web site. The chapters dealing with psychosocial and physiologic long-term and late effects served as the inspiration for the creation of the NCI's Office

of Cancer Survivorship. The original imperatives identified by NCCS have been adapted and used by scores of cancer organizations including the American Cancer Society (ACS), the American Society of Clinical Oncology (ASCO), the Oncology Nursing Society (ONS), and the American Federation of Clinical Oncology Services (AFCOS).

- Presently, the Cancer Leadership Council, a patient-led and patient-focused forum for issues related to quality of care for people with cancer, is working to modify the imperatives. Organizations involved in the revision of the imperatives include: NCCS, Cancer Care, the Susan G. Komen Breast Cancer Foundation, the National Alliance of Breast Cancer Organizations, Y-Me National Breast Cancer Organization, Candlelighters Childhood Cancer Foundation, the North American Brain Tumor Coalition, and the US-TOO International Prostate Support Organization. Also contributing to the writing of the revised imperatives were ACS, ASCO, ONS, AFCOS, the Leukemia Society of America, and the National Breast Cancer Coalition.
- In a rapidly changing health care environment where patients are managed, costs are controlled, and relationships between patients and physicians are monitored, maintaining the quality of health care can be difficult. The Cancer Leadership Council has developed 10 principles that will help achieve its goal of ensuring that all Americans have access to quality cancer care:

1. All obstacles to access and coverage based on pre-existing conditions, genetics, or other risk factors must be eliminated.

2. All persons with cancer and their families must have access to complete and accurate information related to their diagnosis, treatment options, and the anticipated benefits and risks of treatment to allow them to be full partners in decision making.

3. All people should have timely access to screening; preventive services; early detection; initial treatment; supportive therapies to manage pain, nausea, fatigue, and infection; long-term followup; psychosocial services; palliative care; hospice care; and bereavement counseling.

4. In the presence of any indications of cancer, the patient must be referred to a cancer specialist for timely confirmation of diagnosis.

5. All people with cancer should have access to care that is planned, coordinated, and delivered by a multidisciplinary team of oncology professionals across the full continuum of care.

6. Payers must provide ready and continuing access to pediatric specialists, recognizing that childhood cancers are biologically distinct. Though pediatricians are doing an excellent job in following young patients into adulthood, there are no transition clinics to support the patient when he or she leaves the pediatric specialist and obtains other sources of

care. The adult survivor of pediatric cancer is different from the adult survivor of adult cancers. Pediatric specialists are seeking to define transitional care to ensure that survivors entering adulthood understand the care they need and that the adult medical community understands how to care for them. The absence of transition support is evident in the number of pediatric oncologists who continue to follow their adult cancer survivors into their thirties and forties.

7. Standards of cancer care should be driven by the quality of care, not only by the cost of care, and should include participation in clinical trials with quality-of-life considerations. We must look at the best of the business world and medical world and develop a focus on health promotion, disease prevention, a full range of rehabilitative services, and identification and treatment of the physiologic and psychosocial effects of care. There are virtually no standards of care for long-term cancer survivors. If the health care system limits access to oncologists to a restricted period of time, who will develop the cancer care-related standards for primary care physicians? Patients will need to assume responsibility for understanding and communicating care plans to their primary care physicians.

8. People living with cancer and long-term survivors should have access to specialized followup care that focuses on health promotion, disease prevention, a full range of rehabilitative services, and identification and treatment of physiologic and psychosocial effects. So far, there are few, if any, standards of care for long-term survivors.

9. People with cancer must have access to end-of-life services, including symptom management, psychosocial services, hospice care, and bereavement counseling. Cost-effectiveness must also be examined in light of the cost of suffering and its contribution in the overall health care equation.

10. Patients with cancer, and their families, must have access to culturally sensitive cancer information, counseling, and care.

- The majority of Americans, not just historically disadvantaged populations, are now at risk of not having access to appropriate cancer care.
- Weighing the qualitative experience of people with cancer with the critical, quantifiable evidence of what works best in cancer care is critically important. The value of patients' perceptions of their experiences must be recognized as an integral measure of the quality of their care. In the coming months, NCCS will work closely with others who share this agenda, including the Institute of Medicine's National Cancer Policy Board, the President's Commission on Quality Health Care, the Health Care Quality Alliance, the Measurement Advisory Panel of the National Committee on Quality Assurance, the Robert Wood Johnson

- Foundation's National Advisory Commission of Care at the End of Life, the Foundation for Accountability, and the Progressive Foundation.
- NCCS efforts to develop standardized care guidelines and quality measures will focus on the following domains: provider accreditation, health plan initiatives, use of practice guidelines, outcome measures, and accountability.

Additional Research Needs and Other Recommendations

- Continued care for adult cancer survivors could be modeled after the long-term followup available in pediatric oncology.
- The movement toward accountability in health care is very important. Quality report cards should be developed that can be easily understood by consumers and should contain useful outcome information. Community-based support and advocacy groups need to interpret the information and tailor it to their populations.
- The human experience must be incorporated into the quality-of-care assessment process. There is no such thing as a generic cancer patient, and we currently lack adequate ways of measuring terror, fear, anxiety, social stigma, sadness, loss, emotional distress, financial burden, and suffering. Progress will come from understanding and valuing personal experience rather than only identifying and applying systemic solutions.

Discussion

Ms. Leigh

Key Points

- Establishment of the NCI Director's 15-member Consumer Liaison Group was a major step toward collaboration between the advocacy community and the research and medical communities regarding evidence-based medicine and evidence-based decision making. The National Breast Cancer Coalition's Project Lead has been highly successful in teaching advocates and activists about relevant scientific issues so that they can participate effectively in such discussions.
- Ms. Visco suggested that the advocacy community might be particularly effective in shaping public policy as it relates to managed care and third-party payer systems. She noted that observations related to quality of care (particularly criticism) are perhaps more an outgrowth of health care system changes, such as limited access, and may have nothing to do with evidenced-based medicine. Advocates and their constituencies must become more educated about the importance of evidence-based care.
- In June 1998, the President's Cancer Panel will hold a special meeting at Yale University focusing on cancer survivorship.
- Effective methods do not exist for following cancer survivors for second tumors. More studies should be performed to determine the cancer prevention needs of survivors compared with those of the general population. Further, rehabilitation for cancer has lagged far behind rehabilitation for other types of disease. For

example, patients who have heart attacks are immediately enrolled in some type of rehabilitation program, yet these patients frequently do not live as long as cancer survivors.

- It has been observed that the best model for rehabilitation in oncology has been hospice. However, there are now more than 4 million cancer survivors who have survived for more than 5 years. Survivors want to know how to be healthy after their disease. Researchers need to be encouraged to develop research protocols to examine survivorship issues, including issues of long-term survivorship.
- Research is needed to identify protective agents that in combination with chemotherapy may reduce the long-range risk of heart disease, pulmonary disease, or neurological disease. The NIH and the Food and Drug Administration should more vigorously pursue research in these areas.
- Ms. Leigh observed that standards are often developed based on cost rather than quality. This is distressing to many who believe that quality of care must be part of the equation. It is disturbing to see business people making decisions that should be made by patients and their physicians or by the medical community in conjunction with advocates. This situation is unlikely to change until the country is united in expressing concern about who is making health care decisions.

Diagnostic and Treatment

Pathology

Dr. David Kleiner

Key Points

- The goal of pathology is to provide an accurate and complete professional assessment of the patient's specimen so that appropriate care can be given. The challenge inherent in pathology, particularly anatomic pathology, is that patient samples are unique and irreplaceable. Therefore, pathologists are under a very serious obligation to do the best they can, even in the absence of adequate or complete information.
- Pathology includes surgical pathology, cytopathology, cytogenetics, flow cytometry, and autopsy pathology services. Pathologists must also depend upon the excellence of work performed by technicians in the histology and immunohistology laboratories, and those who perform electron microscopy, cell culturing, *in situ* hybridization, and other molecular techniques.
- Quality assurance for pathology is divided into two broad categories: technical quality and professional quality. Technical quality is formally regulated under the Clinical Laboratory Improvements Amendments Act of 1988 (CLIA) and compliance with the Act is monitored by independent inspection of the laboratory by either agents of the Federal Government, usually acting for the Health Care Financing Administration (HCFA), or by other CLIA-approved agencies. These agencies may include State inspectors for States with approved inspection programs, and an array of professional organizations such as the Joint Commission on the Accreditation of Health Care Organizations (JCAHCO); the

College of American Pathologists (CAP); the Commission on Office Laboratory Accreditation (COLA), which inspects laboratories; the American Association of Blood Banks (AABB), which inspects blood banks; and others. Technical quality inspections are performed to document technical competence, which includes assessing staff capabilities, validating methodologies employed, assuring reliability of results, determining the availability of written procedures for all techniques; and ensuring the presence of safe work practices.

- Professional quality assessment is performed through peer review to determine how well the pathologist performs his/her activities, particularly with respect to diagnoses. Accuracy of diagnoses, completeness, and timeliness of results are all evaluated. Quality assurance is performed as part of the routine process of care. For example, prior and current specimen materials are compared and diagnoses are routinely reviewed by two pathologists either internally or externally.
- Systematic internal quality assurance review might, for example, involve examining all of the breast cancer diagnoses in the most recent year; with intraoperative evaluation (i.e., the frozen section diagnosis is compared with final diagnosis).
- Secondary review by referral centers is also common. Patients receive their treatment elsewhere, but then come to the NCI or other referral center for experimental therapy. Work performed by the outside pathologist is reviewed as part of this process.
- Another part of the pathology-related quality assurance process is the correlation of pathology with clinical diagnoses, which includes open communication with the referring physician. Pathologists present pathology information to tumor boards, where patient care is planned, and also participate in tissue committee reviews, where specimens are reviewed for adequacy.
- Professional quality assurance poses several challenges. Legitimate differences in professional interpretation can occur; not everyone views the same lesion in the same way. In some cases of borderline malignancy, diagnosis can be very difficult to ascertain. In addition, universal reporting standards are lacking; issues in this regard include the data that should be included routinely and questions about the reporting of new tumor markers and other measures such as vessel or mitotic counts. Currently, the Association of Directors of Anatomic and Surgical Pathology are developing standards for the different cancer types; these standards will specify the information to be reported and how it should be presented.
- Pathology diagnoses are often used as the gold standard for assessing diagnostic accuracy and for determining patients' eligibility for entering clinical research protocols. Autopsy is used as a final assessment of patient care; in fact, about 10 to 15 percent of autopsy cases show major, unexpected findings at autopsy that reveal the inadequacy of diagnosis prior to death.
- The NCI's patient population is very mobile, and these patients are generally searching for new therapies. All of the institutions involved in the care process must have complete and timely access to pathology reports to determine the accuracy of diagnosis and to compare the diagnosis with any subsequent tissue biopsies that may be taken.

Additional Research Needs and Other Recommendations

- Ongoing dialogue between oncologists and pathologists is essential to develop cancer-specific reporting standards, including identification of the data to be collected and how the information should be presented.

Discussion

Dr. Kleiner

Key Points

- Managed care is affecting pathology in important ways. Questions have been raised regarding the essential elements of specimen evaluation and how evaluations can be performed most cost-effectively. Reduced staffing may reduce the time the pathologist has to assess any particular specimen, which may adversely affect the quality of the diagnosis. The potential for tremendous personal costs to the patient and greater health care costs is significant.
- Dr. Calabresi noted that pathologists have developed and use extensively a consult network to ensure diagnostic accuracy (i.e., difficult specimens are sent to another pathologist for a second opinion). Under a fee-for-service system, the insurance plan or laboratory is billed for the consultation. Under managed care, however, laboratories may receive capitated payments and may be responsible for paying all consultants from the capitated amount. This situation poses potentially very serious problems for the patient, since the financial incentives may be in direct conflict with a preferred standard of care.

New Technologies

Dr. Faina Shtern

Key Points

- Radiologic imaging will never prevent breast cancer. Until there are fundamental breakthroughs in breast cancer prevention and treatment, however, radiologic imaging remains at the center of breast cancer care, particularly early detection and accurate staging for treatment planning.
- Conventional mammography has been shown to reduce breast cancer mortality, particularly for women older than 50 years of age. Decreased mortality for younger women has also been demonstrated, although to a somewhat lesser degree. The presence of dense tissue renders diagnosis of breast cancer with conventional mammography problematic. This is especially significant for women in their thirties and forties, since recent data indicate that up to 60 to 70 percent of women in these age groups have dense breast tissue compared with approximately 30 percent of women over age 50 years. These findings present a powerful incentive to support novel breast-imaging technologies.
- Novel breast-imaging technologies will improve early detection, which in turn will contribute significantly to decreasing mortality rates and increasing

probability of effective treatment. Better imaging will improve the accuracy of cancer staging essential for treatment planning and local disease control. The development of novel technologies will also contribute to cost-effective care for breast cancer patients by eliminating unnecessary diagnostic and therapeutic procedures. Further, digital technologies such as telemammography will bring world-class radiologic expertise to community hospitals and rural, remote, and underserved areas.

- Over the last 7-1/2 years, the Department of Health and Human Services has established numerous programs in novel breast-imaging technologies, including digital mammography, breast magnetic resonance imaging (MRI), ultrasound, nuclear medicine, and positron emission tomography for anatomic, molecular biologic, physiologic, and metabolic tissue characterization.
- The goal of the novel breast-imaging program is to facilitate the transfer of promising technologies from laboratories to routine clinical settings. To achieve these goals, collaborations have been established with multiple Government agencies, industry, and academia to facilitate all stages of technology transfer, including development, evaluation, and implementation.
- At present, digital mammography is viewed as the key research area for improved control of breast cancer in large-scale screening programs. Compared with conventional film-based studies, digital mammography is expected to improve image quality (and therefore cancer detection) at reduced radiation doses. Digital technologies can lead to image processing for improved visualization, computer-aided diagnosis for automated lesion identification, and telemammography for facilitated expert consultation.
- In 1993, the NCI established an international multidisciplinary digital mammography development group that brought together industrial and academic partners. In the absence of Government leadership, industry and academia would not have invested efforts and resources in the development of full-field digital mammography, which was considered high risk from a marketing perspective. Without both industry and academia, full-field digital mammography instrumentation would not be available today.
- Multiple-agency collaborations were also established, including the Central Intelligence Agency (CIA), National Aeronautics and Space Administration (NASA), Department of Energy (DOE), Department of Defense (DoD), and other agencies that have considerable experience in digital-imaging development, processing, display, and transmission. Cooperative efforts were also developed with the Food and Drug Administration, the Agency for Health Care Policy and Research (AHCPR), and the Health Care Financing Administration to address regulatory and reimbursement issues and facilitate the transition of technologies to the market. As a result of these extensive collaborations, development of full-field digital mammography was facilitated by at least 5 years, conservatively estimated.
- The U.S. Public Health Service's Office on Women's Health (PHA OWH) currently supports eight major academic institutions evaluating the diagnostic value of digital mammography compared with that of conventional

- mammography in women who have radiodense breast tissue and are at high risk for breast cancer. The study will be completed in about 6 to 9 months.
- Other work by the digital mammography development group has shown that sophisticated computer-aided diagnosis has resulted in detection of about 50 percent of lesions missed through routine mammography screening. The telemammography research component of this group has to date transmitted more than 60,000 images without any loss of data or compromise in image quality.
 - Approximately 1 year ago, the PHS OWH in the Office of the Secretary identified extensive capabilities in the Department of Energy related to high-performance computing and communications for image storage, processing, and transmission. The PHS OWH, Office of the Secretary, currently supports utilization of these capabilities to develop centralized national archives of digital-imaging libraries to assist in clinical diagnosis, research, and education.
 - Traditionally, imaging technology development is viewed as industry's responsibility. Breast imaging, however, is limited by low revenues. The world market is estimated at about \$250 million per year for all companies involved in breast imaging, and only 5 to 7 percent of these revenues are devoted to research and development; therefore, there are virtually no incentives for industry to support technologic innovation in breast imaging. DHHS programs demonstrate how joint efforts and risk- and cost-sharing of Government agencies, industry, and academia can stimulate development of technology that is judged by industry as high risk from a short-term marketing perspective and by the medical community as having high potential for long-term impact on health care.
 - DHHS has been traditionally supporting research programs in technology evaluation. Currently, NCI is conducting a multi-center evaluation of image-guided needle biopsy as a minimally invasive and cost-effective alternative to open breast surgery. Clinical trial results will be completed within the next several months.
 - In September 1997, the NCI and the Office on Women's Health jointly funded the Multicenter Clinical Evaluation of Breast MRI to facilitate validation of this promising technology. Breast MRI is most promising for detection of early breast cancer in women with radiodense breast tissue and has been shown to detect lesions as small as 1 to 2 millimeters. The multicenter study of breast MRI is expected to answer a number of critical questions: What is the accuracy of breast MRI compared with other imaging technologies for breast cancer detection? By improving local staging accuracy, can high-resolution MRI assist in the selection of optimal treatment? And, finally, can MRI improve the cost-effectiveness of breast cancer care by eliminating unnecessary diagnostic and therapeutic procedures?
 - The PHS OWH, Office of the Secretary, is also supporting a study in the development and testing of MRI-guided administration of a focused ultrasound beam, a noninvasive approach that may potentially replace breast conservation surgery.
 - The traditional view has been that high technologies inflate health care costs. Clinical trials conducted with breast MRI and image-guided biopsy may demonstrate that high technologies can actually decrease health care costs.

- In summary, DHHS programs demonstrate that partnerships within and among Government agencies, industry, the academic community, and consumer organizations can bridge the gap between research and marketing of innovative technologies to improve quality, access, and cost-effectiveness in breast cancer care nationwide.

Discussion

Dr. Shtern

Key Points

- Dr. Shtern clarified that MRI's diagnostic utility and effectiveness appear highly promising, but study results are not yet definitive. Clinical trial results will be available in approximately 2-1/2 years. Digital mammography is also still in the testing stage and until clinical results are available, these technologies, while highly promising, must still be considered experimental.
- Though MRI technology is currently very expensive, if clinical trials prove that MRI is superior to conventional mammography, industry will be more likely to develop breast-dedicated MRI units that will substantially reduce the cost of MRI breast imaging.

Closing Remarks

Dr. Freeman

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

- Therapies developed for breast cancer treatment must be available to all people—rich, poor, educated, and uneducated.
- Quality can be defined and evaluated from a variety of different perspectives, including those of the patient, physician, purchaser, and health plan. These perspectives must be blended in a way that will make sense to the American public. Significant issues remain regarding who will pay for the quality care we want the American public to have.
- The speakers have provided valuable input to the Panel's report to the President on these complex topics.

I certify that this summary of the President's Cancer Panel meeting on Defining the Quality of Cancer Care, held on April 23, 1998, is accurate and complete.

Certified by:

Harold P. Freeman, M.D.
Chairperson
President's Cancer Panel
Date: August 6, 1998