

PRESIDENT'S CANCER PANEL

**Issues of Access in
Today's Health Care System**

**September 24, 1996
San Antonio, TX**

Overview

The President's Cancer Panel was chartered to monitor and evaluate the development and execution of activities of the National Cancer Program and to report to the President on barriers to implementation of the Program.

The second in a series of four meetings, the purpose of this meeting was to explore the extent to which access to cancer-related clinical trials and innovative patient care are being affected by managed care. Fifteen speakers shared their perspectives on a variety of issues such as the impact of managed care on the availability of clinical research funds; access to clinical trials; managed care from the user's perspective; and the influence of managed care on health care delivery, among other topics.

Opening Remarks

Dr. Harold Freeman
Chairman

In opening the meeting, Dr. Freeman indicated that:

- This meeting is the second in a series of four meetings to explore the impact of managed care on the National Cancer Program, including its effects on research, medical education, and access to care. The first meeting included representatives of academic health centers, the community, clinical oncology programs, and managed care organizations in California and the Northwest. The focus of the meeting was to examine the impact of managed care on the conduct of clinical research and bringing cancer advances to the public.
- Recurring themes at the first meeting of the President's Cancer Panel suggest that patient access to clinical trials or studies at their institution of choice is limited by economic considerations related to third-party payment. Community-based physicians are expected to do more with less time, support, and resources, adversely affecting their ability to support clinical research protocols.
- Research questions are being influenced by the likelihood of obtaining reimbursement from third-party payers. Researchers have expressed increased hesitation to undertake complex experimental therapies requiring longer inpatient stays and expensive testing due to the difficulties associated with obtaining full reimbursement. Treatment delays resulting from lengthy reimbursement preapproval processes have the potential to preclude study participation.
- Clinical trials may become disproportionately dominated by higher-income patients who can pay for their own treatment in the absence of reimbursement and/or are able to challenge adverse reimbursement decisions related to their participation in clinical research. The possible dominance of this population group may affect the generalizability of newly developed therapies to the entire American population.
- Among the other issues raised during the first meeting were: whether or not patient access to clinical trials should be mandated by a "standard of care"; the

- impact of the shift to outpatient care on care quality; and discussion of who should be responsible for financing the costs of clinical research.
- Issues affecting access to investigative clinical trials are important because they are fundamentally linked to advancing cancer care. Unless we are ready to accept current standards of care for cancer patients as the best we can achieve, the Panel believes we must find new ways to advance the quality of care and patient outcomes. New and better therapies cannot be developed without testing them in humans; the conduct of well-designed clinical trials presents the opportunity to advance knowledge and improve care.
 - The purpose of this meeting is to explore in greater depth how, and to what extent, access to clinical trials and innovative patient care have been affected by managed care, including managed care's effect on the quality, quantity, and timeliness of clinical trials and their reported outcomes.
 - The last two meetings of the President's Cancer Panel will focus on managed care-related changes in translational research, outreach, prevention, and the quality of care. Issues related to information dissemination, education, and training will also be addressed.

Director's Remarks

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

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

- Clinical trials have had an enormously significant impact on medical practice and the attainment of improved patient outcomes. The American public may need to be reminded of the progress that has been made through clinical research. For example, major advancements in the treatment of breast cancer were identified and tested through clinical trials, including replacement of the Halstead radical mastectomy with modified radical mastectomy, and subsequently, with lumpectomy followed by radiation.
- Currently, only 3 percent of adults participate in clinical trials; adequate payment mechanisms are critical if all individuals who are eligible and want to participate are to be included. At present, NCI is negotiating with the Department of Veterans' Affairs, the Health Care Financing Administration, and private-sector insurers to provide increased patient access to clinical trials for cancer treatment, control, and prevention.
- A major issue affecting access to clinical trials is how the trials will be financed. To obtain health insurer support for clinical trials, researchers must demonstrate that either in the long or short run, health insurers will realize treatment-related savings as a result of patient participation in clinical research.

Welcome

Dr. Charles Coltman
Southwest Oncology Group and
Director, San Antonio Cancer Institute

Dr. Coltman welcomed the Panel, speakers, and other attendees. He provided an overview of the San Antonio Cancer Institute and its research programs, including:

- The Breast Cancer Research Program led by Dr. C. Kent Osborne, noted for its breast cancer Specialized Program of Research Excellence (SPORE), and other cutting-edge breast cancer translational research.
- The Drug Development Program, perhaps the largest new drug development program in the world, directed by Dr. Daniel D. Von Hoff.
- The Southwest Oncology Group, the largest clinical trials organization in the country, has 3,500 registered physicians at 540 institutions spanning 45 States. These institutions follow nearly 28,000 cancer patients, including more than 11,000 breast cancer patients. Members of SWOG annually accrue 7,000 patients from all 50 States to clinical trials.

ISSUES OF ACCESS IN THE CLINICAL RESEARCH ARENA

Dr. Charles A. Coltman
University of Texas
Southwest Oncology Group

Key Points

- The incidence of cancer among men and women under the age of 65 is 2.2 per 1,000, while the incidence of cancer among those over the age of 65 is 22 per 1,000—a 10-fold greater incidence in the over-65 population. U.S. population statistics indicate that the population 65 years of age and older will double by the year 2030 and will carry with it an age-related increased incidence of cancer. By the year 2000, 4 of every 10 Americans will develop cancer in their lifetime. As a result, cancer-related care will become the Nation's leading contributor to health care costs, comprising 15 to 20 percent of total costs. In 1996, an estimated 1.3 million new cancer cases will be diagnosed.
- Questions forwarded to meeting participants by the Panel were posed as a survey to 27 physician members (clinical investigators) of the San Antonio Cancer Institute and the Southwest Oncology Group, located in 13 States. The respondents indicated that there are greater difficulties associated with patient access to Phase I clinical trials than to Phase II and III trials. Respondents noted that as managed care presence in the marketplace increases, researchers encounter greater difficulty in patient recruitment for clinical trials and a decrease in referrals to Phase III trials.
- The cost of clinical research is borne by a wide variety of entities, including research institutions, private foundations, insurers, and individuals. Research sites

- permit treatment-associated tests, (e.g. MRIs, CT scans, blood gases) to be performed at local hospitals to facilitate participation.
- Respondents cited a number of adverse effects of managed care on the conduct of clinical research. Due to increased pressures to contain health care costs, the lack of preapproval requirements, patient preferences, and other factors, outpatient trials are increasingly favored (e.g., smaller trial populations, shorter trials). Managed care may ultimately skew research efforts to those that can be most easily financed. As a result of managed care, medical practice revenue has decreased, resulting in decreased funding for research. In addition, providers have less time to participate in research efforts, community service, and patient education due to the volume and pace of activity that often accompanies managed care participation. Managed care has also resulted in increased competition for patients, increased time and expense devoted to obtaining reimbursement, and a shift to patients most able to afford the costs of care.
 - Survey respondents indicated that wellness and preventive services, including cancer screening and smoking cessation, are frequently offered but seldom reimbursed.
 - Positive effects of managed care identified by the survey participants include the potential for clinical pathways to result in more effective and perhaps cost-effective care; improved access to standard care for some patients; patient protection from ineffective and dangerous treatments; and incentives for cost awareness and efficiency. Respondents also suggested that managed care plans might provide the financial incentive for subscribers to enroll on cancer prevention and control studies.
 - Additional issues/questions related to the impact of managed care on clinical research were raised by those surveyed for consideration by the President's Cancer Panel. These included: How can clinical research be integrated into the standards of care for cancer patients? Should managed care fund a portion of clinical research costs and, if so, how much? What State or Federal legislation is necessary to ensure that managed care patients have access to clinical research? How can proper referrals from primary care physicians to oncologists be ensured? What would be the financial effect of increased member participation in clinical trials? Who will determine research priorities?
 - Private insurer contracts specifically exclude reimbursement for services provided as part of research initiatives, though they actually pay a high number of such claims. Similarly, Federal programs such as Medicare prohibit provider reimbursement for services provided in investigational studies, those involving preventive medicine, and services provided to asymptomatic patients. Medicare has denied claims for tests provided to participants in the Prostate Cancer Prevention Trial, even though the tests (e.g., prostate-specific antigen [PSA]) are considered standard and are reimbursed for other Medicare beneficiaries.
 - A number of Federal-level efforts are under way to provide increased support for clinical research. A major initiative between the Department of Defense and the NCI will significantly enhance participation in cancer clinical trials. A similar agreement between NCI and the Department of Veterans' Affairs is expected to be reached shortly. The Health Care Financing Administration is considering

- coverage of selected clinical trials—most likely, late-phase studies. Non-FDA-approved investigational new drugs (INDs) and biological agents will not be included.
- Federal legislation is currently under consideration (the Rockefeller-Mack bill) that contains a broad, inclusive policy covering individual investigator INDs, industry INDs, and other peer-reviewed trials.

Dr. Leonard Zwelling
University of Texas
M.D. Anderson Cancer Center

Key Points

- Clinical research is an investigation in which the care of the patient and the conduct of the research effort are inextricably intertwined. The best clinical research of today becomes the standard of care of tomorrow. This principle must be kept in mind as society weighs the relative values of increasing access and improving quality while containing health care costs.
- The University of Texas M. D. Anderson Cancer Center has not experienced a decline in the amount of clinical research conducted, despite the increase in managed care patients and the decline of indemnity-insured patients at the facility. In fact, managed care plan enrollees constitute a disproportionately higher proportion of the research population. Participation in clinical trials continues to increase overall, regardless of the research funding source (institution-supported, NCI-funded, or private industry). Participation in NCI-funded trials has decreased, while the number of patients on industry-sponsored trials has increased.
- Industry-sponsored research is increasing due to the growing number of pharmaceutical and biotechnology companies that have maturing products in the marketplace and the FDA's requirement for clinical data to support drug approvals. An increasing number of the study proposals submitted for scientific and patient protection review at the M. D. Anderson Cancer Center have been both designed and written by the private sector. While the increase in industry-sponsored research at the Center may limit innovation among faculty, the private sector is a worthy partner in the development and use of new cancer therapeutics.
- M. D. Anderson has made several recent infrastructure investments in response to the changing managed care environment. These are designed to maintain patient access to clinical studies, ensure the quality of studies, and increase awareness of research costs. To help ensure reimbursement for care provided, a case management system has been implemented to ensure that faculty and staff caring for managed care patients obtain all required clearances prior to initiating treatment. Case management activities are undertaken regardless of whether the treatment is experimental or conventional. Denials associated with the proposed use of experimental therapy occur approximately four to five times per week, with a success rate for obtaining approval of approximately 80 percent.
- M. D. Anderson has introduced a clinical research cost system to facilitate and strengthen its negotiations with sponsors. Availability of cost-related data will

enable researchers to engage in more judicious expenditure of scarce revenue on the most promising cutting-edge research. This system is currently in a testing phase to determine the degree to which projected costs compare with actual costs and to compare the costs of clinical trials with standard care. Clinical trial costs will also be compared with collections. Results of these analyses will be used to support improved strategic planning and funding for clinical research.

- The clinical trial scientific review process has intensified, including not only the traditional academic and biostatistical evaluations, but also the evaluation of laboratory utilization and use of radiological resources in the absence of an attendant income stream. This rigorous review process has earned the institution a special NCI designation enabling M. D. Anderson to receive patient referrals from the DoD CHAMPUS HMO program and to receive payment for care provided in clinical trials to these CHAMPUS enrollees.
- M. D. Anderson is pursuing efforts to enable clinical research to become revenue neutral, and perhaps even revenue generating. These efforts include seeking NCI grant funds, partnerships with other clinical research programs, pharmaceutical company funding, and philanthropic participation.
- In response to Federal agency shifts of responsibility for data quality and trials monitoring to individual facilities, M. D. Anderson has established an office of Clinical Research Quality Assurance to routinely measure and monitor clinical trial quality indicators through computerized registration of all clinical trial participants. Other responsibilities of this office include: research nurse orientation, internal auditing, and an ombudsman function.
- The type of research conducted at M. D. Anderson has been affected by managed care. Health services research such as cost-effectiveness analyses examining the use of antiemetics, antibiotics, growth factors, and blood products to support the patient through his or her cancer treatment, particularly in the outpatient setting, are critically important to the academic and financial health of the institution. Also of importance are quality-of-life studies and the development and use of treatment guidelines and clinical pathways to assist physician decision making.
- Managed care offers potentially important benefits and opportunities. The added emphasis on cost containment efforts will require institutions to adopt cost-effectiveness as a measure of success and reengineer key processes to enhance efficiency and improve outcomes. Such changes will also give rise to new kinds of research.
- Though it now appears that access, cost containment, and quality of care are mutually exclusive and competing priorities, it is possible to strike a balance between containing costs and underinvesting in the future. This balance is essential, since without high-quality clinical research, there will be no progress in the war on cancer. It is a false economy to squander this precious time when we have the opportunity to save many lives just to save a few dollars.

Dr. C. Philip Steuber
The Texas Children's Center
Baylor College of Medicine

Background

The Texas Children's Center is one of the largest comprehensive pediatric oncology centers in the country. It is affiliated with Baylor College of Medicine and the Texas Children's Hospital and is a member of the Pediatric Oncology Group. Approximately 200 new cancer cases are treated annually at the Center. Seventy-five percent of the cases are involved in clinical trials. Active follow-up is performed on 3,000 children, adolescents, and young adults with cancer or a history of cancer. The Center has a 40-bed inpatient area and a nine-bed bone marrow transplant unit. Approximately 11,000 encounters are performed annually.

At present, approximately one-third of the Texas Children's Center's patients are covered under managed care contracts involving 70 relatively unique managed care organizations. As the Texas Medicaid Program embraces managed care, over four-fifths of the Baylor Cancer Center patients will fall under managed care guidelines and restrictions.

Key Points

- Pediatric oncology offers perhaps the best example of the effectiveness of the clinical trials process. Nationwide, only 3 percent of adults with cancer are enrolled in clinical trials; in contrast, over 70 percent of children with cancer are treated in NCI-sponsored clinical trials. Thus, clinical trial enrollment defines the standard of care for children with cancer in the United States. Consequently, any impediment to clinical trial access for children with cancer or any compromise in the quality of clinical trials will have a profound negative effect on the level of care for cancer in the United States and also on our ability to develop improved and innovative therapies for these patients.
- Pediatric cooperative multidisciplinary cancer study groups provide cancer patients with access to state-of-the-art treatment. The two largest of these groups are the Children's Cancer Study Group and the Pediatric Oncology Group, which encompass 200 pediatric oncology programs. Over 90 percent of children with malignancies in the United States are referred to centers with either CCSG or POG affiliation. It is widely agreed that the pediatric cooperative multidisciplinary groups are one of the NCI's true success stories.
- Approximately 11,000 new cases of cancer in children and adolescents are diagnosed annually in the United States. Cancer is the leading disease-related cause of death in children. With early detection, accurate diagnosis, and proper treatment, approximately 70 percent of childhood cancers are now curable. Five-year survival trends for children with common solid tumors have shown marked improvement over the last 30 years. Dramatically improved outcomes have also been demonstrated for children with acute leukemias and lymphomas. Such

improvements can be attributed to the conduct of successful clinical trials. Pediatric oncologists have been using collaborative, protocol-driven therapies for decades; these protocols are truly clinical practice guidelines, detailing required diagnostic imaging and laboratory studies, the involvement of other subspecialties, the therapeutic regimen, and the assessment of outcome.

- By comparison, there are over 1 million cancer cases diagnosed in adults annually. It is not surprising that concerns about quality of care for children with cancer are sometimes buried in the avalanche of adult cases. Unfortunately, treatment guidelines developed by managed care organizations for adults with cancer are being applied inappropriately to children with cancer. Effective treatment for children with cancer requires that patients have access to pediatric subspecialty consultation and care at every level. Managed care is jeopardizing access to such care.
- Staff at the Texas Cancer Center are extremely frustrated by their interactions with managed care systems. Providers report that managed care distances caregivers from patients and their families, forcing them to spend more time on paperwork and less time on patient care. Care is fragmented by requiring that patients obtain services at multiple sites, thereby jeopardizing the continuity of care that is essential for patients to receive the maximum benefits of clinical trial participation. Managed care also fails to provide comprehensive services such as experienced pediatric home care or hospice programs.
- Managed care approval processes are excessively bureaucratic, causing nurses to spend an estimated 4 hours per day obtaining telephone approvals for services, including routine visits, scheduled and unscheduled admissions, and laboratory and imaging studies. Such approvals are required for each patient visit, even though most patients participate in approved clinical trials using detailed practice guidelines. The approval process is inconsistent, unreliable, and inflexible. Denials or delays occur when the managed care gatekeeper judges the therapy to be experimental because the patient is participating in a clinical trial. Approvals may require the involvement of multiple gatekeepers, and approvals are sometimes rescinded after the service has been provided, leaving the patient or institution responsible for the cost.
- In addition to the above, it has been necessary to add two additional full-time equivalents (FTEs) to accommodate added paperwork required by managed care plans. Further, reduced managed care reimbursements are endangering programs important to the optimal care of children, such as social work, child life, and family education programs.
- Managed care often requires patients to use selected laboratories for needed studies. Such laboratories are usually off-site and pose a number of important problems affecting patient care and the conduct of clinical research. These include: physical hardship associated with travel to laboratory sites; scheduling delays; delays in obtaining results due to poor communication between providers; lack of specific expertise, training, and technology to perform pediatric-specific testing and diagnostic imaging using state-of-the-art-techniques; lack of quality control resulting from use of multiple facilities; and difficulties in obtaining actual laboratory studies to enable comparison with those previously performed. When

tests performed under these circumstances have to be repeated because they are technically unsatisfactory, the child may be exposed to additional radiation or caused additional discomfort. In addition, cost for the evaluation of studies by, for example, a pediatric radiologist may not be covered by the managed care plan.

- Managed care can also cause significant problems for children with cancer who require bone marrow transplants. Managed care providers must first be convinced that it is necessary. Facilitating the transplantation within a managed care setting is often a nightmare, requiring 6 to 8 hours per patient (on average) to prepare and submit the paperwork for transplantation approval. The Texas Children's Center's Transplantation Coordinator spends approximately 31/2 months securing approvals per year. Despite this investment of time, approvals often exclude or limit coverage for evaluation of family members as potential donors; the cost of searching marrow registries to find an appropriate match; and the donor's hospital costs. Sixty percent of managed care-insured families at the Texas Children's Cancer Center have had to seek charity funds to cover these expenses.
- Managed care plans may also require that transplants be performed at designated facilities that are different from the patient's primary source of care. This disrupts care and the physician-patient relationship, poses hardships for families who must travel to remote sites, and complicates the essential follow-up process post-discharge.
- The unique health care needs of long-term pediatric cancer survivors are inadequately addressed under managed care. Coverage must be provided for follow-up to identify and monitor late effects of treatment therapies and to enable early detection of potential second malignancies. Under the present system, approximately half of the Texas Children's Center's long-term survivor patients have been denied coverage of these services. These problems are expected to intensify as the survivor population expands. By the year 2000, one in 900 young adults will be a survivor of childhood cancer. By the year 2010, this figure will be one in 250. The issue of coverage for ongoing follow-up care poses very significant ramifications for pediatric clinical trials, since evaluation of the patient over a lifetime is essential to truly assess the impact of a new therapy.
- Adolescents with cancer may be affected most negatively by managed care. Managed care programs tend to refer older adolescents with cancer to adult oncologists, when research has clearly demonstrated that treatment on a pediatric clinical trial protocol at an established pediatric cancer center significantly enhances their potential for cure. Conversely, poor outcomes have been obtained when adolescents are treated on adult clinical trials.
- Unless managed care providers recognize the importance of covering the costs of clinical trials, the overall quality of care will be significantly compromised. In the future, clinical trials will take longer to complete because of reduced entry of children with cancer into clinical trials. It has been estimated that over 2,000 lives, and over 150,000 person-years will be lost in the next 5 years if the current steady rate of improvement in outcome for childhood cancer is arrested at the present level.

Additional Research Needs and Other Recommendations

- NCI should consider assessing researchers' ability to accurately evaluate clinical trial results in light of the lack of quality control resulting from the use of multiple, nonpediatric-oriented laboratory or diagnostic imaging facilities.
- As has been done by the Blue Cross/Blue Shield Association, managed care programs should consider establishing pediatric cancer networks to ensure coverage for children with cancer and to facilitate referrals to established pediatric cancer centers where clinical trials are the standard of care.
- Unless the managed care industry takes the initiative to see that the needs of children with cancer are addressed, legislation may be necessary to guarantee that coverage for their treatment will be provided. As Medicaid programs move into managed care, States should require that the benefit package include comprehensive coverage for children with cancer.

Drs. Coltman, Zwelling, and Steuber **Discussion Period**

- Dr. Zwelling elaborated on the cost system under development at M. D. Anderson to predict and monitor the costs associated with the conduct of clinical trials. Such a cost system was necessary to improve negotiations with pharmaceutical contractors and to help guide program expenditures. The most significant challenge associated with cost prediction is trying to estimate complication rates prospectively. Treatment of complications is one of the highest cost factors in a clinical trial. Retrospective review of complication rates will be performed and results will be used to derive estimates for various populations. Using the cost model, cost estimates will be prepared for trials that have already been completed and the results will then be compared with actual costs to assess the validity of the costing model.
- M. D. Anderson's dramatic shift in clinical trial sponsorship from NCI toward the pharmaceutical industry has more to do with growing industry involvement in clinical research than Federal grant funding issues.
- Though the pharmaceutical industry tends to finance a greater portion of clinical trial costs than does the NCI, it typically does not pay for all of the costs. Participants expressed concern, however, that research efforts may be designed differently in order to obtain funding and that fundamental research questions may not be addressed in favor of those that serve the sponsor's interests.
- It was conjectured that if HCFA recommends coverage of clinical trials and managed care continues to play a dominant role in the U.S. health care system, managed care plans will compete to provide coverage of investigational treatment. The result may be the conduct of more cost-effective clinical trials and the entry of a significant population into trials that will facilitate obtaining answers to important research questions about adult tumors.
- It must be expected that research sponsors and payers will want considerable influence over the direction of research. This applies particularly to pharmaceutical and biotechnology companies. Likewise, as managed care programs become more active in clinical research, they are likely--as they have

- been in dictating the delivery of care--to be far more controlling and directing concerning the "delivery of research" than previous types of sponsors (e.g., government).
- Opinions vary regarding the quality guidelines to be imposed before managed care would cover a clinical trial or patient care costs attendant to clinical trials. Proposals range from an all-inclusive approach (as detailed in a current Senate bill) to one that is more tightly reasoned (as proposed by the NCI). The guidelines for peer-reviewed research currently serving as the foundation of the DoD/NCI agreement (and perhaps shortly, the Veteran's Affairs and HCFA agreements) are a useful benchmark against which it will be possible to measure future experience. It will be important to monitor the peer review process, the types and importance of research questions being pursued, the relationship of the research conducted to the FDA approval process, and the other types of data being collected and used (e.g., outcomes, quality of life).

Dr. Karen B. Heusinkveld
American Cancer Society

Background

The American Cancer Society (ACS) represents both the provider and user perspectives of cancer care. Issues of access are extremely important to the overall mission of the organization, which assumes an advocacy role by developing, reviewing, and promoting cancer prevention, screening, and treatment guidelines, and by serving as a comprehensive health care information resource to the public. Over 2 million ACS volunteers and staff direct its cancer advocacy and control efforts.

Key Points

- The ACS and the managed care industry share a common vision—stronger emphasis on primary and preventive care, and a greater coordination of services to improve outcomes and eliminate waste. Significant questions are being raised by the health care community, however, about the ability of managed care to handle complex health issues such as appropriate treatment for people with cancer.
- Health care plans must provide timely access to cancer screening, early detection tests, and comprehensive, preventive health education services.
- Health care plans increasingly use restrictive payment systems that discourage specialty referrals. Individuals with cancer must have direct access to interdisciplinary care and be able to obtain second opinions from cancer specialists, when desired. During active cancer treatment, cancer specialists must assume the role of principal caregiver for the cancer patient. In addition, point-of-service options should be available, with a reasonable copayment, to enable individuals to obtain care outside a managed care plan network. Plans should also provide coverage for rehabilitation services to ensure that patients return to their fullest potential and for follow-up care.

- Capitated or discount fee-for-service contract plans have an obligation to state clearly how cancer care will be managed, with detailed information concerning restrictions on provider choice, limitations of coverage, and access to clinical trials. This information should be available to potential contract holders, health care providers, and consumers.
- Plans should provide access to specialized supportive care, including aggressive symptom control, optimum pain relief, psychosocial care services (available throughout all cancer phases) and end-of-life care. Patients should have access to cancer prevention, detection, and treatment trials. Children with cancer must have access to pediatric oncology specialists.
- The ACS is seeking ways to work with health care purchasers, managed care plans, and Federal and State legislatures to ensure continued patient access to clinical trials. Managed care plans should support member participation in cancer prevention, screening, and diagnostic trials that have been subjected to high-quality peer review, and cover patient care costs associated with participation in a peer-reviewed clinical treatment trial when:
 - Treatment is provided with therapeutic intent
 - Treatment is provided pursuant to a NIH-approved clinical trial, in cooperation with the NCI or an NCI affiliate; the FDA, as an IND; the VA; DoD; the ACS; or other private-sector research organizations meeting NIH cancer support grant guidelines
 - The protocol has been reviewed and approved by a qualified institutional review board
 - The facility and personnel providing treatment are qualified to do so by virtue of their experience and training
 - No clearly superior noninvestigational therapy exists
 - The available clinical and preclinical data provide a reasonable expectation that the protocol treatment will be at least as effective as noninvestigational therapy.
- Plans should collect outcome data related to key organizational functions, clinical services, and program management activities. Outcome data include: utilization, incidence and survival data, stage of disease at diagnosis, recurrence rates, smoking and lifestyle factors, quality of life and provider and consumer satisfaction data.
- The ACS supports the use of clinical guidelines or pathways for cancer treatment.
- As part of their proposed action plan on managed care, the ACS will develop a consumer education manual containing a checklist for health plan evaluation.
- Health plans should be prohibited from interfering with communications between health care providers and patients concerning full disclosure of cancer diagnostic and treatment options.

Dr. Lloyd Kitchens
American College of Physicians

Background

The American College of Physicians (ACP) consists of nearly 90,000 physicians specializing in internal medicine or its subspecialties, such as cardiology, gastroenterology, pulmonary medicine, and oncology, among others. It is the Nation's largest specialty medical society, second only to the multispecialty American Medical Association in total membership. Founded in 1915, the ACP strives to promote the highest standards of ethical patient care, medical education, and research.

Key Points

- With the advent of managed care, physicians are increasingly challenged to remain the patient's advocate while working as cooperatively as possible with business executives whose motivation is the health of the corporate bottom line.
- There is growing concern about the impact of managed care on clinical research conducted at academic medical centers. Closed provider networks may reduce access of AMC-based investigators to research subjects. Managed care plan scrutiny of service utilization may result in payment denials for research-related services. In addition, price-competitive managed care markets may adversely affect use of cross-subsidies to support education and research.
- AMCs may increasingly attract and serve uninsured or underinsured patients from lower socioeconomic levels. If these patients comprise the majority of research populations, research results could be skewed.
- The willingness of managed care plans to underwrite large-scale clinical research into common and widespread problems (e.g., chronic obstructive pulmonary disease) may limit the amount of research into other less common but still clinically important problems or diseases (e.g., macular degeneration) that have traditionally been investigated at AMCs.
- Meaningful clinical research conducted in the setting of the solo or small group practitioner's office is becoming a thing of the past. Prior to the heavy penetration of managed care, a significant incentive for participation in clinical research was obtaining the study drug or standard therapy at no cost. Now, managed care plans pay for necessary tests and medications with the exception of relatively low copayments or at a discount from standard charges. Removal of the patient's perceived financial incentive, coupled with voluminous and often frightening advised consent documentation and requirements associated with study participation, have dimmed the interest of potential study participants.
- Managed care's reliance on generalists in lieu of specialists also adversely affects clinical research. Whereas prior to managed care, patients would have ongoing access to specialty care, they now see a specialist for extremely brief episodes, making it virtually impossible to generate significant, reproducible data regarding an IND. In addition, the trend toward allowing generalists to administer

chemotherapy under the loose guidance of an oncologist raises serious quality-of-care and liability issues.

Dr. Richard F. Corlin
American Medical Association

Key Points

- Historically, change in medical care has been concerned first with quality of care, then with access, and lastly with cost. With the advent of managed care, however, the cost issue is often disguised as an access issue. Participation in clinical research involves providing financial support for results that may not be realized for a long period of time; this reality runs counter to the managed care organizations' objectives.
- The HMO Act of 1973 was based on the not-for-profit Kaiser Permanente model. With the shift to for-profit MCOs, however, the question must be revisited concerning who deserves to make either a living or a profit from delivering health care. Those who add measurable value to the system (e.g., nurses, doctors, hospitals, pharmaceutical companies) are so deserving. The insurance company, by absorbing the economic consequences of illness among those covered in exchange for premiums paid, acted as a buffer of risk. Under capitated reimbursement, however, the risk buffer role is passed directly through to the physician group and the hospital, leaving the insurer/MCO as simply a claims processor and premium collector. It is reasonable for the MCO to have its costs covered for these services, but it no longer adds significant value to the system and should not earn a profit on the services it provides.
- Managed care is not inherently bad; but significant differences exist between the for-profit and not-for-profit MCOs with respect to their participation in clinical research. Not-for-profit MCOs have pledged \$100 million in research funding, yet for-profit MCOs have contributed virtually nothing.
- Charitable care has traditionally been covered by institutional profit centers; with the growth of managed care, the only remaining profit center is the money taken out of the system by the MCOs.
- Government regulation requiring MCO support of clinical research would result in increased funding; however, such regulations may have an additional, and perhaps unintended, impact on clinical research. Failing to limit severely the ability of the courts to interpret such regulations could lead to requirements to expand the definition of clinical research to include alternative and other folk medicines traditionally outside the scope of clinical research efforts.

Additional Research Needs And Other Recommendations

- The National Committee for Quality Assurance (NCQA) and the Joint Commission on Accreditation of Health Care Organizations (JCAHO) evaluation criteria should include measures of the extent to which MCOs will pay for care provided by non-network providers to provide clinical trial access for members. MCOs should also be evaluated regarding the administrative mechanisms that are required to obtain approval for this type

of care. NCQA and JCAHO measures should also be developed to evaluate MCO commitment to research funding.

- The Federal Government should reexamine its position with respect to how MCO payment rates are structured. The for-profit hospital industry provides a relevant example. Payment to for-profit hospitals eliminated reimbursement for their return on equity because they did not provide a reasonable level of charity care. Similarly, perhaps MCO payments should be exclusively cost based, and profit-related payment removed from the capitation rate because of their lack of clinical research financial support.

Pamela Haylock, R.N.
Oncology Nursing Society

Background

The Oncology Nursing Society (ONS) represents almost 25,000 registered nurses who work with cancer patients and their families. The ONS strives to promote excellence in oncology nursing and quality cancer care, assure the RN's role in cancer care, and promote research-based oncology nursing practice. Its membership includes over 200 doctorally-prepared nurse-scientists who are primary investigators.

Key Points

- Oncology nurses are highly affected by the current health industry turmoil and the shift toward managed care. Oncology units are either being disbanded or merged with medical-surgical units. This has resulted in job loss among nurses at all educational and skill levels. These organizational changes also require nurses to provide care for a wide variety of medical ailments, and thereby threatens their ability to focus on the complexities of evolving cancer care.
- Managed care organizations' reliance on formularies limit ready access to the best treatment or medicines used in symptom control. Nondrug approaches to symptom management and multidisciplinary conferences are not always covered. Insistence on a hierarchy of consultive care slows the process of patient care.
- Use of gatekeepers limits timely access to specialty providers. According to the August 1996 issue of Consumer Reports, 18 percent of its readers go outside their managed care plans to obtain the care they believe they need.
- Oncology nurses need to be a key element in the care of patients with cancer throughout the continuum of care. They bring to the patient specialized expertise in oncology care that cannot safely be replaced by other types of providers such as case managers and discharge planners typically employed by MCOs.
- The ONS membership is skeptical of the willingness of managed care providers to commit to the cost of cancer prevention and early detection measures since the benefits are only realized in the long term.
- The effect of managed care on the availability of cancer care services available to the indigent, the uninsured, the underinsured, and the underserved is of great concern. Cost shifting from the insured to uninsured groups has declined and

perhaps even disappeared, as providers and institutions rely more heavily on capitation financing. This issue will be compounded as employers offer less generous health benefit packages, Federal funding declines, and not-for-profit facilities are taken over by for-profit entities. These trends increase the risk that a two-level system of health care (i.e., those who can pay and those who cannot) will develop in this country.

- Funding for clinical trials should include costs associated with supportive care needed to manage treatment sequelae that frequently are unknown or of unknown extent.
- Cuts or changes in funding as a result of the shift to managed care are likely to jeopardize funding for research that ensures effective, safe nursing practices. Such research addresses issues generated by the shift in delivery systems; complexities of modern cancer treatment; advances in genetic technology associated with cancer risk and early detection; increasing survival rates and concomitant survivorship issues; the shift to community and ambulatory care; and the increasing reliance on self-care and family caregivers. This type of research, historically generated by nurse researchers, may be viewed as less critical in an agenda that is directed by economic concerns.
- Administrative burdens placed on providers involved in managed care are excessive. For example, radiation oncologists, and often their nurse managers, need to continually obtain authorization for care provided throughout the course of conventional treatment for breast cancer. According to the Association of Community Cancer Centers, on average, medical oncologists spend 3 hours per week on appeals, and other staff spend an additional 20 hours.
- Coverage of pain medications varies widely among health care plans and providers lack sufficient knowledge in managing cancer pain. The prevalence of unrelieved cancer pain is evidence of the need for specialty cancer care services. Cancer pain can be managed effectively and relatively simply using available methods and techniques in up to 90 percent of people with cancer. Yet 30 to 40 percent of people with pain at diagnosis and at intermediate stages, and nearly 75 percent of people with advanced cancer have pain. Of those, 30 percent describe the pain as very severe. Nurses at City of Hope have documented a potential cost savings for one institution of over \$5 million annually, if unscheduled admissions for pain could be eliminated. These savings could be realized through development of simple and cost-neutral pain management strategies.
- Tremendous opportunities for improved patient and family outcomes under managed care are possible, if managed care encompasses the entire cancer trajectory, and if it offers a coordinated network of patient and family care.
- The Oncology Nursing Society supports a health care system that contains costs; ensures universal access; promotes health networks; supports health education; enhances preventive and primary care; and ensures the monitoring, coordination, and evaluation of health care services and policies. Managed care fills many of these criteria. Of great concern, however, is the "de-skilling" of cancer care. In its position paper, "Assistive Personnel: Their Use in Cancer Care," the Oncology Nursing Society asserts that overall accountability in nursing care coordination, particularly related to cancer care, is best accomplished by registered nurses. ONS

supports the use of assistive personnel under the direction and supervision of RNs.

- The Oncology Nursing Society acknowledges the importance of bench and clinical research and the impact of reimbursement on patient care associated with clinical research. ONS supports reimbursement for off-label use of oncology drugs and access to the most effective therapies and to nursing experts during clinical trials. Its priorities for nursing research reflect current issues in clinical practice, individual and family needs, and factors influenced by health care delivery. Managed care plans need to focus on effective cancer prevention and health promotion, especially in underserved and underrepresented populations.
- Research has demonstrated costs savings associated with advanced practice nurses in clinical specialist and nurse practitioner roles. These professionals enable physicians to focus on care that only they are qualified and licensed to provide. This is especially important in cancer care settings. Oncology nurses are uniquely prepared to serve as case managers and can play a central role in prevention and early detection for people affected by cancer. Managed care plans need to recognize the valuable role that nurse practitioners and clinical nurse specialists can play in this respect.

Drs. Heusinkveld, Kitchens, Corlin and Ms. Haylock
Discussion Period

Key Points

- A question was raised as to whether the absence of "preventive intent" among the American Cancer Society's peer-reviewed clinical trial criteria was intentional or merely an oversight. Dr. Heusinkveld suggested that it was most likely an oversight, since the ACS is currently funding some prevention trials.
- Potential payers for Phase I trials are the NIH, through increased funding of the general clinical research centers (GCRCs); the NCI, because of its interest in the development of cancer drugs; pharmaceutical companies, because of their interest in bringing drugs to market; managed care, because it stands to benefit from improved methods of patient care; and a collective or conjoint mechanism of some design. Participants supported the notion that all of these entities should participate in paying for Phase I trials, since all will benefit in some fashion.
- MCOs resist supporting Phase I studies, which they perceive as being solely toxicology studies, compared with Phase II and III trials which have clear therapeutic intent. It was suggested that drug response in Phase I studies is important and, in fact, is predictive of success in the marketplace.
- Ms. Haylock clarified that the ONS supports off-label use of drugs that is supported by the peer-reviewed literature or the three accepted compendia, even if the drug is not FDA-approved for that specific use, and believes costs associated with such use should be reimbursed. Other discussants indicated that the FDA does not use NDA (New Drug Application) as a criterion for using compounds in patient care and, in fact, the FDA has indicated that evidence in the peer-reviewed literature on the off-label use of compounds is often superior to that available for NDA and marketing of that compound.

- At this time, much of the Society's data on problems associated with lack of access to appropriate specialty care and the de-skilling of oncology nurses is anecdotal; the organization is exploring ways of documenting these problems more fully.
- Although accumulated on patients in fee-for-service settings, documentation of the access-related issues of the uninsured, the underserved, and other populations is found in emergency room data, data related to cancer stage at diagnosis, and in lower survival rates for the poor and uneducated.
- Dr. Corlin indicated that he would forward for the Panel's information examples of cases in which the courts interpreted regulations (as opposed to specific insurance contracts) resulting in expansion of coverage in ways not intended by the statute to which the regulations pertain.
- In discussion concerning physicians' response to managed care in the early years of its development in the United States, there was general acknowledgment that the medical community was not sufficiently organized, timely, or vocal in its objections and concerns about managed care. The medical community did not anticipate the magnitude of managed care expansion, or the impact on the existing system that the for-profit MCOs would have. While managed care has clear cost advantages, it has seriously jeopardized the provision of care to the uninsured and pushed out of the system a greater number of those who previously had at least marginal access.
- Managed care is in a continuing state of evolution; it is likely that in the next 10 to 15 years the number of managed care companies will shrink dramatically, and current problems related to service access and delivery will be addressed.

ISSUES OF ACCESS: THE USER'S POINT OF VIEW

Ms. Emily Untermeyer
Texas Cancer Council

Background

More than half of the 254 counties in Texas are Federally designated as health professional shortage areas. Approximately 30 counties lack primary care physicians. Since most of the cancer treatment centers are located in the cities, many Texans lack access to nearby cancer diagnostic and treatment services and clinical trials. Texas has the highest rate of uninsured residents in the Nation (24 percent), which is significantly higher than the national rate of 15 percent. Of the Texans living below the Federal poverty level, 44 percent are uninsured (compared with 29 percent nationwide). In 1994, 50 percent of all unemployed Texans were uninsured, far exceeding the national rate of 35 percent. More than 20 percent of all employed Texans have no health insurance and more than 40 percent of Hispanics in Texas are uninsured. Approximately 5 million Texans lack health insurance coverage.

The Texas Cancer Council was created in 1985 by the Texas legislature after an extensive 3-year study revealed a fragmented system of cancer prevention and

control in the State. The Council is responsible for promoting the development and coordination of effective statewide policies, programs, and services related to cancer and for encouraging collaborative and comprehensive planning among the public, private, and volunteer sectors related to cancer prevention, detection, treatment, and research.

In 1996, the Texas Cancer Council was cited by the NCI as one of 10 awardees of the Partners in Coalition Building from the Cancer Information Service. Examples of current initiatives are: a mobile mammography clinic to serve rural west Texas; smoking cessation initiatives; a variety of community-based, culturally relevant cancer prevention projects; and the Texas Cancer Data Center. The Texas Cancer Council routinely provides technical assistance to community groups seeking to raise revenue for cancer services. It has also funded the development of oncology education programs through the State medical, nursing, and dental associations and developed a model for assessment of medical students' knowledge of cancer-related issues. The Texas Cancer Council recently established a 20-member multidisciplinary managed care steering committee to study the impact of managed care on cancer services in the State.

Key Points

- The Texas Cancer Council plans to work with managed care organizations to determine the state-of-the-art training needed by MCO physicians and nurses. Of special interest are the needs of primary care physicians serving as gatekeepers, who require ongoing education regarding cancer clinical pathways, including indicators for specialty referrals.
- Whether the clinical practice guidelines and outcome parameters used in managed care are being applied appropriately to individual patient scenarios and conditions is another current concern. The Council supports a role for the NCI in promoting the use of consistent guidelines that can be actively supported by cancer specialists, health care providers, managed care companies, and corporate service purchasers. Similarly, the Council encourages the NCI to provide leadership to ensure the quality and consistency of prevention and early detection services within managed care systems.
- There is a need for patient education and self-advocacy programs and materials geared to diverse language, literacy, and cultural groups to help consumers navigate managed care systems. In addition, physicians' offices and clinics may benefit from computerized tools to trigger routine cancer risk assessment and screening services and track related outcomes.
- Charity care has been the backbone of the indigent care system in Texas. As physicians, hospitals, and cancer care providers face decreased revenue under managed care reimbursement systems, they are becoming increasingly reluctant or contractually unable to provide charity care. Coupled with Federal welfare reform, there is growing concern about how affected populations will be able to access needed health care.

- The Texas Statewide Health Coordinating Council has prepared a report on managed care produced through the conduct of 13 public hearings across the State. A Senate committee in Texas conducted public hearings and is making recommendations focusing on managed care and consumer protection issues.

Ms. Judy Gerner
M.D. Anderson Cancer Center

Key Points

- Of 23,000 calls to the M. D. Anderson information line in the first fiscal year, over 7,600 calls concerned information requests about appointments or consultations for non-M. D. Anderson patients. An additional 3,000 calls related to the availability of treatment options and appropriate clinical trials. Approximately 38 percent of the calls were the result of word-of-mouth recommendations regarding M. D. Anderson. Fifteen to twenty percent of calls related to research or medical breakthroughs cited in the media. Both the number and nature of the calls to the information line reflect consumers' growing interest and involvement in their care.
- The responses of cancer patients to a survey about managed care indicate that many are confused about what managed care is and what it should provide, and that the overwhelming majority are both frustrated and angered by their interactions with managed care plans and the restrictions imposed by the plans.
- Control of cancer pain, psychiatric care, and physical rehabilitation for the cancer patient are unique specialties, and should be provided by professionals with expertise in cancer management and in tandem with other aspects of cancer treatment. Under managed care, these and other psychosocial and rehabilitative services are sometimes provided on a limited basis as "carve-outs," but frequently at a facility different from the one at which the patient is receiving his or her principal therapies. This approach disrupts continuity of care.
- M. D. Anderson estimates that as many as 16 percent of patients previously diagnosed and currently admitted to M. D. Anderson were misdiagnosed prior to admission. This underscores the importance of case review and consultation at a comprehensive cancer center or academic or research center prior to consideration of treatment options or participation in clinical trials. For this consultation to occur, however, most patients must have the approval and coverage of their health plan.
- Specialty providers like M. D. Anderson are concerned about the moral dilemma posed by their increasingly popular and visible role in the cancer treatment arena. As consumers learn of the advances in cancer treatment achieved in centers of this type, demand for such care will surely increase, but access may well be denied by the consumer's insurer, which is increasingly likely to be a managed care program.
- Managed care and other health insurance policies that are relatively inexpensive can turn out to be extremely costly when one becomes ill and needed care is excluded from coverage. In some cases this occurs because subscribers choose low-cost plans when they believe they are invincible; in other cases, employees

- have been provided only summary descriptions of their health plan and may not know that certain care is not covered.
- Benefit denials tend to be based on the following arguments: treatment is considered experimental or investigational; it is determined to be medically unnecessary; and the cost exceeds the expense limitation of the policy. Patients argue that cancer centers whose operating budgets include and require funding for prevention, teaching, and research cannot be expected to have costs that are comparable or compatible with the general hospital.

Ms. Sydney T. Hickey
National Military Family Association

Key Points

- The opportunity for military health care beneficiary participation in Phase II and III clinical trials has been greatly expanded under a 3-year demonstration agreement reached by DoD and the NCI. Access is currently limited for the active-duty population and is essentially nonexistent for the fastest-growing DoD beneficiary population—Medicare-eligible individuals over age 64. Active-duty members constitute approximately 20 percent of DoD's 8.3 million beneficiaries. An additional 15 to 20 percent are dual Medicare/military eligibles. The DoD-NCI agreement is limited to military beneficiaries who are eligible under the Civilian Health and Medical Program of the Uniformed Services. Active-duty members and over age 64 dual military/Medicare beneficiaries are not CHAMPUS-eligible.
- Thus far, the demonstration agreement has not been publicized sufficiently to achieve beneficiary and provider awareness. DoD is taking steps to expand public awareness through the Physician Data Query (PDQ) database; dialogue with military oncologists to identify military hospitals currently participating in clinical trials; and the DoD Web site. Information flow to beneficiaries stationed overseas is currently unclear; the National Military Family Association (NMFA) is concerned about reaching this population, since many active-duty family members and retirees must access their health care through host nation providers and facilities. The NMFA has been asked by the NCI to review informational materials being prepared and to identify distribution channels for this information.
- Active-duty members can access clinical trials in military hospitals or in the civilian sector through the supplemental care program in which DoD pays directly for all health care costs. Active-duty members must be referred to private physicians by military physicians to access clinical trials.
- Access to military hospitals for clinical trials is becoming increasingly difficult. Approximately 65 to 70 percent of dual Medicare/military beneficiaries do not live near a military hospital and they are totally Medicare reliant. Base closures and realignment have removed their source of health care. Moreover, because they are not CHAMPUS-eligible, these beneficiaries are not eligible for trials outside the direct military system. NMFA is particularly concerned about the exclusion of this population under the NCI-DoD agreement, since they are more likely than CHAMPUS-eligible beneficiaries to have cancer or be cancer patients.

- The tradition in the military of using exclusively military health care facilities is strong. Beneficiaries have routinely accepted extremely long waiting times for initial appointments at military hospitals. The resulting limitations on access to screening and timely evaluation have been consistent barriers to early detection and treatment. Waits for specialty care may be from months to years. This population is accustomed to accepting the information it is given and assumes the physician will tell them all they need to know. If military physicians are not adequately informed of clinical trial options, it is unlikely that beneficiaries will find out about them.
- Difficulties related to clinical trial participation by the military population include: failure to routinely provide beneficiaries information regarding their eligibility for participation in NCI-sponsored Phase III breast cancer trials; and difficulty in arranging for procedures and obtaining timely results from the military facility.
- Unlike provisions for the Phase III breast cancer trials, DoD will not cover transportation and lodging costs under the NCI-DoD agreement. Enrollees in TRICARE (the DoD's new managed care program for CHAMPUS-eligible personnel) who can access clinical trials close to home may find clinical trial costs affordable. Cost factors could pose a significant deterrent to clinical trial participation, particularly for junior personnel. Similarly, TRICARE risk contractors must be convinced that clinical trial participation will not result in increased costs. Given the potential disincentive to participate in clinical trials, DoD must monitor TRICARE contractors to ensure clinical trial access is not denied based on their fear of incurring cost increases.

Ms. Untermeyer, Ms. Gerner, and Ms. Hickey
Discussion Period

Key Points

- DoD has planned to market the NCI-DoD agreement extensively; its first priority was to support TRICARE enrollment and, secondly, to promote coverage of cancer clinical trials as an incentive for military service retention. Despite DoD's expressed commitment, implementation has been slow. Since the demonstration is limited to 3 years; there is concern that time is running out for many beneficiaries.
- It was suggested that consumers need to be better informed about health plan limitations before they subscribe, but it was acknowledged that better information may not counter the tendency to buy low-cost policies when one is well. Improved patient self-advocacy skills might help consumers better navigate within their health plans, but it was also pointed out that patients are ill-equipped to fight the system when they are ill and are expending all of their energies just to get well. Nonetheless, it is likely to take consumer demand to effect substantive changes in the existing health care environment.
- Trends in San Diego, where managed care is pervasive, were noted. Because providers will not lower their costs further, health plans are now competing on the basis of provider choice. For a slightly increased premium, members can have point-of-service options. This pattern is echoed by Kaiser Permanente in

California and elsewhere, due to consumer opposition to lack of provider choice. In Minnesota, some employers are so dissatisfied with managed care that they offer vouchers to employees to enable them to seek their own care.

ISSUES OF ACCESS: THE PROVIDER'S POINT OF VIEW

Col. Doris Browne, M.D.
Department of Defense
TRICARE/CHAMPUS Program

Key Points

- TRICARE is the military managed care program. Its goals include: medical readiness, increased access to health care, and improvement in health care quality. Cost containment, though not a priority, is an issue. The basic program involves establishment of 12 TRICARE regions (plus Europe and the Pacific). TRICARE support contractors must develop a network of civilian providers to complement providers at military treatment facilities. Uniform benefits are provided and enrollees are assigned to a primary care manager. Health care finders assist enrollees in gaining access to necessary services or providers.
- TRICARE Prime is the HMO option which offers minimal cost sharing and the broadest set of benefits, with a significant emphasis on preventive care benefits. TRICARE Extra is the Preferred Provider Organization option, which involves somewhat greater cost sharing but has a point-of-service option. TRICARE Standard is the standard CHAMPUS program. Active-duty personnel are automatically enrolled in TRICARE, but family members must be enrolled separately and can choose among the coverage options.
- TRICARE/CHAMPUS emphasizes prevention and encourages a variety of routine screenings coupled with counseling and education. Targeted health promotion and disease prevention examinations are performed as part of cancer surveillance activities. Baseline mammography is required for females over the age of 40 and annual mammography is required annually beginning at age 50. Pap smears for sexually active women, testicular exams for young men over the age of 18, colorectal exams, and skin examinations are also performed. Dental exams and thyroid screenings and examinations are also performed.
- DoD participation in the breast cancer demonstration project was spurred by the provision of bone marrow transplantation/stem cell rescue by Federal employee health benefits programs. DoD was interested in contributing data to determine whether marrow transplantation would become the standard of care for treatment of breast cancer. This project provided the foundation for DoD participation in all Phase II and III clinical trials under the 1996 NCI-DoD agreement.

Discussion Period

- TRICARE is not currently available to the over age 64 DoD Medicare-eligible population. DoD is seeking to provide TRICARE for Medicare-eligibles in three

- of the TRICARE regions and has been negotiating with HCFA to cover these beneficiaries in a demonstration project.
- DoD is using performance measurements under the TRICARE program that compare DoD experience in selected areas to the national average using established care criteria. It is not currently used for clinical trials programs; however, DoD is evaluating the cost-effectiveness of its participation in clinical trials; the resulting data may provide evidence that will help persuade insurers that clinical trials participation is a cost-effective modality.

Dr. Joseph Bailes
Physician Reliance Network

Background

Physician Reliance Network is the country's largest oncology practice management network, providing physicians with the services necessary to maintain fully integrated outpatient oncology care, e.g., financial services, management expertise, facilities, administration, technical support, and ancillary services. The Network supports care for cancers of all types and oncology-related multidisciplinary care. The Network is strongly committed to clinical trials, and is involved in cooperative group and FDA licensing trials.

Key Points

- The latest version of the Health Plan Employer Data Information Set (HEDIS), the voluntary managed care performance measures developed by the National Committee for Quality Assurance includes only a few cancer-specific measures focused on breast cancer and cancer screening. A new set of cancer care quality measures were developed by the American Society of Clinical Oncology for inclusion in HEDIS. These measures have been endorsed by a wide range of stakeholders and have been submitted to NCQA for review. Adoption of these measures into the NCQA accreditation process would help ensure that managed care organizations approach the care and treatment of people with cancer in a more comprehensive and higher-quality fashion and enable employers and consumers to better compare plans.
- The recommended cancer care quality measures include: access to a multidisciplinary provider team throughout the continuum of cancer care (prevention, early detection, initial treatment, palliative care, supportive therapies, long-term follow-up, psychosocial services, and hospice care); access to specialty care; timely referral; cancer specialist integration in the gatekeeping process during active treatment; and timely access to specialty care in specialty centers that are outside the plan network. Other recommended measures include: screening and preventive services (e.g., smoking cessation); coverage for appropriate use of off-label indications of FDA-approved drugs; formulary-related information; identification of radiation therapy as an accepted treatment modality under managed care; and access to clinical trials (all phases) meeting NIH guidelines.

- Positive influences of managed care on medical practice include: increased, though inconsistent emphasis on preventive care; improved record keeping; improved coordination of credentialing processes; and increased emphasis on utilization review (including underutilization of services) and quality assurance.
- Managed care has affected clinical trials negatively. Physicians have less time for research or for placing patients on trials, general patient care revenues previously used to support research efforts are no longer available, and contract-directed patient flow limits physicians' ability to refer patients to trials. In addition, approval and payment processes have become more burdensome.

Additional Research Needs and Other Recommendations

- Health plans need to be educated that they are not being asked to pay for research, but for routine patient care when patients participate in trials.
- It will be up to providers and researchers to develop cost data related to cancer care under clinical trials. Insurers' databases currently do not readily permit extraction of data on specific components of care.
- To increase patient accrual to clinical trials, trial design and informed consent procedures should be simplified and coverage opportunities should be improved.
- Managed care support of clinical research should be actively encouraged in combination with voluntary accreditation and regulatory approaches.

Dr. David C. Hohn
The University of Texas
M.D. Anderson Cancer Center

Key Points

- A majority of physician referrals to the M. D. Anderson Cancer Center come from primary care physicians rather than other oncologists. Therefore, the relationship with the primary care physician is critical in planning a diagnostic workup, patient routing, and long-term oncology follow-up. By virtue of the managed care contract, primary care physicians must also be integrated into the non-oncology care (e.g., hypertension, diabetes) of cancer patients. When such care is provided at M. D. Anderson during the course of cancer treatment, however, it is frequently not covered by the patient's health plan and the associated costs must be absorbed by the cancer center.
- Managed care is evolving such that in some areas of the country the primary care physician increasingly is acting as the oncologist, and the oncologist is consulted only for a second opinion and to provide a "cookbook" treatment plan for execution by the primary care physician. This trend raises serious issues as to patients' access to trials, quality of care, and licensure/certification of providers performing specific types of treatment. Policy may be needed to clarify and address these issues.
- Evolving health care funding models do not currently support the development of well-integrated provider networks for cancer prevention. Establishing such networks requires the involvement of rural and urban primary care physicians,

community oncologists, cancer centers, academic medical centers, and public policy leaders. To fulfill their roles in providing cancer preventive services, primary care physicians and their patients will require educational resources, stable funding, access to telemedicine conferences, and a variety of other resources. Currently, there is inadequate follow-up of mass screening and detection efforts, and managed care systems may discourage alignment of these critical resources.

- M. D. Anderson was faced with an economic crisis arising from its traditional open-door policy and provision of indigent cancer care. Over time, the Center had come to be the cancer care provider for half of the medically indigent population in the county, for whom there was no source of reimbursement. In response, the Center developed a network approach to providing prevention, screening, and primary- and secondary-level oncology to this population; the program has resulted in significantly reduced costs and improved geographic access to services for these patients.
- Red tape associated with payer authorization consumes as much as 20 to 30 percent of Dr. Hohn's time. Patients who successfully negotiate the managed care system do so because they are willing and able to fight for coverage. Other factors discouraging referrals to M. D. Anderson include physicians' fear of economic reprisal or deselection, fear of losing increasingly rare indemnity-covered patients, provider cost competition, and disincentives to increase the cost of care for patients insured under capitated arrangements.
- Statistics on new cancer cases by payer demonstrate that managed care has reduced access to cancer care at M. D. Anderson. HMOs provide less access to M. D. Anderson than either PPO or indemnity plans. The data also indicate that PPO enrollees are willing to make higher copayments for expanded choice of provider. Managed care preference for geographic convenience poses referral and access problems for tertiary centers in urban environments; as a result, most centers in this situation are currently considering networking options.
- The conversion of Medicare and Medicaid to managed care will likely result in a provider panel that includes only full-service entities and excludes specialty centers like M. D. Anderson. The implication of this is that children, the poor, and minorities may be "locked-out" of access to specialty-oriented cancer care because they are disproportionately represented in the Medicaid population. Similarly, Medicare managed care may restrict seniors' access to cancer centers.
- One advantage of capitated managed care is that risk transfer to the provider may result in clinical trial participation because, in fact, it may be less expensive than standard care. At this time, however, little usable disease- and stage-specific annualized or per-cycle treatment cost data for cancer patients exist to help at-risk providers make such determinations. Until these data are developed, providers may lose money on their capitated patients, and may be tempted to undertreat to avoid fiscal loss.
- Managed care programs are exceedingly hesitant to pay for investigational care, yet routinely pay for cancer care that is ineffective, inappropriate, or obsolete. M. D. Anderson believes that the key to progress lies in investigational care and

- creative partnerships with other health industry experts, providers, and other system participants to identify and achieve common or complementary goals.
- Initial managed care authorization of Phase I investigational care at M. D. Anderson is rare; Phase II authorization occurs occasionally, and Phase III trials are frequently approved. Overall, the approval rate is 70 to 80 percent, but would be much lower without the dedicated staff who negotiate with and provide literature and other documentation to the payer to achieve approvals.
 - Approximately half of the cost of research and education in academic medicine has been funded with earned income from university hospitals and clinics and practice plans. At present, there is no replacement for this dwindling source of support. The many beneficiaries of research and education should participate in its support. We are willing to pay the embedded costs of R&D when purchasing other products (e.g., automobiles) and services, but this tends not to be true in health care.
 - M. D. Anderson no longer views itself purely as a specialty center to which patients are referred. Given the complexities of its relationships with other facets of the health care industry and the diversity of its patient population, the Center now views itself as a cancer or disease manager. Some of this management is done at a distance through linkages with other community providers, and part of this role is accomplished through efforts to shape local, State, and national health policy.

Additional Research Needs and Other Recommendations

- There is a serious cost/value dilemma unique to cancer care that requires further study. Cancer does not fit the episodic cost accounting model, yet this model is used for cost comparison purposes. Though a cursory analysis might indicate higher costs for selected services and perhaps higher per diem rates at M. D. Anderson, a comprehensive analysis may reveal that substantial savings result from proper diagnosis and effective treatment over the life of the patient. More sophisticated cost measurement systems are needed to enable more accurate cost comparisons, but doing so is complicated by the frequent movement of individuals from one health plan or provider to another. Nonetheless, such analyses are urgently needed if we are to understand the true costs of care and design our systems to accommodate the most effective care.
- Clinical cancer researchers must play a continual and pivotal role to define the dynamic boundary between standard and investigational care. Efforts must be made to educate policy makers, industrial partners, payers, and the public about the importance of supporting clinical and translational research and the long-term consequences about not doing so.

Dr. Jose Lopez
San Antonio Tumor and Blood Clinic

Key Points

- The private practice paradigm involves maintenance of a physician-patient covenant based on trust rather than contractual arrangements; a commitment to continued medical education and clinical research; the responsibility of a leadership role in the community; and reasonable financial reward. This paradigm is threatened by changes in the health care system.
- Managed care seriously threatens physicians' ability to provide high-quality cancer care, as defined by the Institute of Medicine and criteria sponsored by the National Coalition for Cancer Survivorship. These criteria include: recognizing the primacy of the doctor-patient relationship; acknowledging that a diagnosis of cancer implies a specialist referral and the importance of a multidisciplinary approach; permitting oncologists to function as gatekeepers for cancer patients; supporting participation in peer-reviewed trials; and ensuring that post-treatment monitoring is performed by a specialist and that there is access to hospice and psychosocial services.
- Among the problems related to providing cancer care to patients enrolled in managed care are inappropriate and inhumanely early hospital discharge after surgery, inappropriate use of hospice, failure to cover the use of approved drugs, and disruption of established doctor-patient relationships.
- Over a 5-year period, Dr. Lopez has seen 922 patients with cancer, the majority of whom are Hispanic (730); the average age of these patients is 65 years. Fifty-one percent of these patients have less than an eighth-grade education, many have household incomes of less than \$10,000 per year (53 percent), and many speak only Spanish (50 percent). They also have a high level of comorbidity, such as diabetes, hypertension, and renal disease. Half of these patients have been diagnosed with stage IV disease. These patient profiles are characteristic of a substantial portion of cancer patients in this community, but these are not the type of patients typically enrolled in managed care. It is also unlikely that they would be candidates for clinical trial participation.
- The San Antonio Tumor and Blood Clinic has also been involved in prevention trials, such as a prostate cancer prevention trial. Of 59 participants, four were covered by HMOs, none of which would pay for PSA screening. To enable this population to participate in clinical trials, it was necessary to establish weekend clinic hours.
- The bureaucracy associated with clinical research can be overwhelming. Dr. Lopez cited multiple notification requirements, consent form revisions, and protocol changes for participants taking tamoxifen in conjunction with NSABP trials.
- A tremendous number of organizations throughout San Antonio are devoted to breast cancer education, yet there is no evidence of coordination among them. One reflection of this lack of coordination may be that of 143 consecutive women with breast cancer seen by Dr. Lopez over a 5-year period, approximately half already had stage III or IV disease at diagnosis.

- In an attempt to adapt to the managed care environment, Dr. Lopez and his practice partners have affiliated with a cancer-specific management organization. It is their hope that this affiliation will enable them to limit their direct negotiation with managed care plans; improve access to research protocols, practice guidelines, educational materials, and pharmaceuticals; and assist with geographic expansion and recruitment of additional oncologists to help care for a growing patient population. At the same time, Dr. Lopez indicated that his practice must increasingly consider research less for its inherent merits than for its potential to help support other practice activities.
- It should be recognized that practicing oncologists are under continual emotional stress related to providing care to extremely ill and often terminal patients. Dr. Lopez expressed concern that these pressures, coupled with managed care-related issues, are limiting the interest of young oncologists in clinical research and may lead to a shortage of clinical researchers when many of those currently conducting research reach retirement.

Drs. Bailes, Hohn, and Lopez
Discussion Period

Key Points

- Dr. Coltman expressed concern about the displacement of oncologists in the care of patients with cancer, their replacement with primary care physicians, and the possibility that oncology as a multidisciplinary specialty will eventually vanish. He suggested that M. D. Anderson's practice of discharging patients to their primary care physicians, despite the fact that they were referred to M. D. Anderson by their oncologist, mirrors the national trend and may reflect concerns that the oncologist might disrupt the clinical trial process. In response, Dr. Hohn underscored his concerns about the future of oncology under managed care scenarios. He emphasized that M. D. Anderson's patterns of discharge do not stem from concerns about the "purity" of the clinical trials but, rather, a reflection of the pressure managed care places on the institution. Further, many of M. D. Anderson's patients come from rural communities where there are no oncologists, and in many cases it is the patient who insists on a particular referral at discharge. Dr. Hohn does not advocate shifting oncology care to primary care physicians but recognizes their value in performing screening and detection. Specialists can provide assistance in ensuring accurate diagnosis and appropriate referrals.
- Public policy will be necessary to delineate responsibility for clinical research funding; such policy describing the roles of all stakeholders is needed now. With the economic realities of managed care, historical sources of funds for clinical research are dwindling. Consequently, identifying alternative funding sources needs to become a national priority. This is particularly an issue for Phase II and III trials in which there is clear therapeutic intent and in which investigational care may also cost less than conventional therapy. Speakers differed, however, in their views concerning the appropriateness of the provisions of the proposed Rockefeller-Mack legislation.

Closing Remarks

Dr. Harold Freeman

Key Points

- The Panel's current inquiry into the effect of managed care on the war on cancer was sparked by testimony provided at a previous meeting focusing on leukemia and diseases related to childhood cancer. At that meeting, pediatric oncologists brought to light the difficulties they were experiencing in conducting research and their inability to obtain reimbursement from managed care companies for any type of treatment that had not been proven effective. These reimbursement policies posed serious threats to the viability of research efforts and the quality of teaching in the future. Moreover, these threats were of special concern given that the model of childhood cancer care (e.g., reliance on clinical trials) has resulted in the most striking improvements in survival of these malignancies. Therefore, the Panel's current investigation is intended to examine these issues as they relate to the entire National Cancer Program and all types of research.
- The testimony provided at this meeting has been instructive in expanding on issues raised at the first in this series of meetings (in Seattle) and has raised additional issues and questions. These and other related issues will be pursued further in the two remaining meetings on this topic—in Providence, Rhode Island, where discussion will focus on Phase I activity; and at Duke University, where translational research considerations will be discussed.