

PRESIDENT'S CANCER PANEL

**Coping Strategies for Maintaining Outreach,
Information Dissemination, Teaching, Recruitment,
and Care in Today's Health Care Environment**

**November 22, 1996
Durham, North Carolina**

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 purpose of this meeting, the last in a series of four, was to exchange strategies for maintaining programs targeted at outreach, information dissemination, teaching, recruitment, and cancer care in today's changing health care environment.

Seventeen speakers described the important role that such initiatives play in advancing the goals of the Program and outlined the challenges of continuing these activities in light of adverse economic trends, including the impact of managed care. Participants also addressed the special needs of medically underserved populations, including minority and poor individuals. Recommendations regarding the funding and development of culturally appropriate and effective interventions were offered, including suggestions for increased collaborative efforts between providers, community organizations, and government agencies.

OPENING REMARKS

Dr. Harold Freeman
Chairman

In opening the meeting, Dr. Freeman stated that:

- The Panel believes that the growth of managed care could lead to a deterioration in the health care delivery system's ability to disseminate vital information, to train and recruit promising young health care professionals, and to implement successful outreach programs to the underserved. While managed care officials often cite their organizations' commitment to prevention, exemplified by their practice of covering routine physical examinations and screening for certain conditions, the Panel believes that more can and should be done to ensure that these other important programs continue under managed care.
- One example of this troubling trend, related at the Panel's meeting in Providence, Rhode Island, involved the State ASSIST program's issuance of two Requests for Applications from managed care organizations to include physician counseling as the first step in smoking cessation programs for pregnant and postnatal women. Despite the demonstrated effectiveness of such interventions, the managed care organizations failed to respond to either request, reflecting their focus on short-term rather than long-term cost savings.
- Managed care's corporate preoccupation with the bottom line has serious ramifications for training and educational opportunities in cancer research. The refusal of managed care companies to pay the frequently higher costs of care at academic medical centers is particularly disturbing. These specialized institutions traditionally have relied on patient care revenues to support teaching, research, and care for the poor. Decreased practice revenues have led to fewer funds to sustain training programs and to provide other support to young physicians and

scientists pursuing a career in cancer research. Cancer centers also are facing this dilemma as they struggle to maintain their commitment to state-of-the-art treatment in an era of tight cost controls.

- The Panel is concerned especially about the impact of managed care's cost containment mechanisms on underserved populations who must overcome additional barriers in this environment to access even basic health care.
- Cancer research holds the key to improving patient treatment and care, but only if new health care advances are brought from the laboratory to the public. Thus, the Panel is troubled by the reluctance of managed care organizations to reimburse the patient care costs of enrollees participating in clinical trials. This stance could lead to a decrease in clinical trial accruals and seriously impair our ability to continue to make advances against cancer. In the Panel's opinion, all phases of peer-reviewed clinical trials have therapeutic value, and so should be incorporated into standards of care for cancer patients in a cost-sharing health care system.
- Representatives from the pharmaceutical industry, research institutions, and government agencies have stated their willingness to share in the costs of clinical research, as long as their differing responsibilities are taken into account in allocating those costs. Panel members look forward to suggestions by today's speakers about appropriate cost-sharing arrangements to further support cancer research.

DIRECTOR'S REMARKS

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

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

- For the first time since records have been kept, Americans experienced a decrease in cancer mortality rates during the years 1991 to 1995. This positive trend reflects effective cancer prevention and control efforts as well as advances in treatment. Many diverse organizations helped to achieve this success, including the National Cancer Institute, the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the American Cancer Society, and many grassroots community groups.
- From 1991 to 1995, cancer mortality rates declined 1.7 percent for white males and females and 5.6 percent for black males and females. Interestingly, the overall declines were much more noticeable in people under age 65 than in people aged 65 years and older. For males, a significant portion of the overall reduction in cancer mortality is attributable to a decline in lung cancer deaths, along with declines in deaths due to prostate cancer, colorectal cancer, bladder cancer, and oral cancer. Unfortunately, most groups of women did not exhibit a similar decline in lung cancer deaths, so it will be important to increase smoking cessation efforts among women.
- Declines in cancer mortality rates depend in large part on efforts to inform the public about cancer treatment, prevention, and control, so that individuals know

what to do to lower their personal risks of developing various cancers. It is always better to prevent a cancer than to cure one; prevention is more cost-effective than treatment over extended periods of time. Managed care officials who are focused on this year's bottom line may not fully appreciate these kinds of long-term savings.

- With their sharp focus on immediate cost savings, managed care programs may eliminate effective cancer prevention and control programs and associated research programs that are necessary to disseminate health-promoting messages to the public. This trend could be exacerbated because cancer prevention and control programs and research often do not have vocal, dedicated constituencies who argue forcefully for their continued existence.
- If cancer mortality rates are to continue to fall, it is absolutely essential that the public be educated through effective cancer prevention and control programs.

WELCOME

**Dr. Ralph Snyderman
Chancellor for Health Affairs and
Dean of the School of Medicine
Duke University Medical Center**

Dr. Snyderman welcomed the Panel, speakers, and other attendees, adding that:

- The data assessing managed care's effect on the health care delivery system are not yet complete; however, as a medical administrator at an institution serving over 1 million people, he is very concerned that the managed care industry is driven solely by a desire to contain costs. The emphasis on lowering costs eliminates incentives for providers to initiate programs that bestow only future benefits on patients. This leads to distortions in the health care system, as when a hospital opts to give a patient therapy that is cost-effective only if the brief hospital stay rather than the long-term overall health status of the patient is considered.
- Clearly, numerous distortions are present in the current health care delivery system, not the least of which is the fact that the consumers of care (i.e., patients) often have little or no choice in the health plan under which they are covered. Most individuals are insured through plans offered by either their own or a spouse's employer; in large part, managed care evolved in response to these employers' demands for less expensive health coverage.
- In cancer, the most recent treatment often represents the best therapeutic option available to a patient. Historically, academic medical centers have played a primary role in cancer research and development by offering cutting-edge treatment to their patients. This type of care can be costly, however, and is becoming more difficult to offer when managed care plans refuse to reimburse experimental therapies or the patient care costs attendant to participating in a clinical trial. This, in turn, leads to a deterioration in the research and development infrastructure, as providers no longer have any incentive to offer these innovative therapies.

- The viability of the biomedical research infrastructure must be ensured in light of managed care's growing strength, as it is an absolutely essential component of this country's efforts to prevent and treat cancer.

WELCOME

Dr. O. Michael Colvin
Director
Duke Comprehensive Cancer Center
Duke University Medical Center

In welcoming the Panel, speakers, and other attendees, Dr. Colvin stated that:

- Much progress has been made since the war on cancer was declared 25 years ago; for the first time, the cancer mortality rates declined in the years 1991 through 1995. Advances in chemotherapy, radiation, and surgery; better diagnostic tools; and reduced exposure to carcinogens have contributed to this trend.
- At the same time, changes in the delivery and financing of health care threaten our ability to continue these impressive gains, and may deny patients the benefit of the extensive current knowledge regarding cancer prevention and treatment.

OUTREACH EFFORTS AND CONCERNS

Dr. Paul K. Halverson
Center for Public Health Practice
School of Public Health
University of North Carolina

Background

Although managed care is making inroads into the North Carolina market, particularly in urban areas, it is not yet the majority payer in the State. The University of North Carolina (UNC) has not experienced a significant impact on either cancer treatment or prevention activities as a result of managed care's entry into the marketplace, although there is a generalized focus on cost containment at all levels. In addition, UNC has started to network with rural facilities and outlying physician practices, a trend that is positive for cancer prevention and outreach. UNC officials also are considering developing managed care products for the medical school and integrating the services offered by its various facilities.

Key Points

- Research conducted by the University of North Carolina School of Public Health suggests that managed care markets, and their potential effect on the health care delivery system, vary dramatically depending on their stage of development. While there are some short-term dangers presented by the move towards managed care, patients in more mature markets could experience better-quality care.

- Growing, less mature markets are characterized by the influx of a large number of managed care plans, each intent on growing market share; this leads to intense price competition among the various plans. They achieve these cost efficiencies by reducing payments to both physician and hospital provider panels; at the same time, there is an emphasis on building the number of providers participating in each particular plan.
- This concentrated focus on short-term market share gains can lead to deficiencies in overall patient care as a result of several negative developments. Coverage for cancer prevention and control activities can evaporate as a result of the drive to limit costs. Frequent changes in provider panels can frustrate patients with illnesses like cancer, who need the continuity of care provided in a long-term physician/patient relationship. Negotiated payments to providers often are insufficient to support care provided at academic medical centers. Finally, providers struggle to learn how to practice in a capitated environment, while patients are lured away from established networks that are more likely to offer comprehensive outreach, assessment, and treatment.
- Even the highly touted benefits of managed care can prove illusory in the immature, growing market. For example, managed care officials frequently highlight their emphasis on prevention; when pressed, however, they acknowledge that preventive services are woefully underutilized by enrollees. Thus, expenditures on preventive services have not yet proven to be a significant expenditure for managed care plans.
- As the market matures with time, a shift in outlook and philosophy often occurs as plans consolidate and more people are covered by some type of managed care. With this shift, the risk of the surviving managed care organizations is related directly to the health of the community's population. As a result, the managed care plans may begin to pay more attention to ensuring that their enrollees receive quality care, including preventive services.
- Other positive changes could occur in a mature managed care market. For example, it should be possible to improve clinical practice through such techniques as profiling, clinical practice guidelines, and protocol dissemination. This is especially true in group and staff model health maintenance organizations that often begin to appear in the later stages of a managed care market's development.
- Perhaps the most promising opportunities for improving patient care will occur as managed care organizations, public health departments, community health centers, university and teaching hospitals, and other providers realize they must collaborate in order to maintain a healthy population. These alliances could improve the delivery of cancer treatment, prevention, and control services, and also increase and improve cancer research.

Dr. M. Robert Cooper
Comprehensive Cancer Center
Wake Forest University
Bowman Gray School of Medicine

Background

The rising influence of managed care in North Carolina is illustrated by the following statewide market penetration figures: 1994, 12.1 percent; 1995, 14.4 percent; and 1996, 24.9 percent. In urban areas, penetration rates are much larger: Raleigh, 38 percent; Durham, 40 percent; Winston-Salem and Charlotte, 36 percent. The next two to five years should bring an exponential increase in managed care's penetration of the North Carolina market as more providers enter the market.

The Comprehensive Cancer Center of Wake Forest University, Duke Comprehensive Cancer Center, East Carolina University, and UNC participate in the Cancer and Leukemia Group B (CALGB), a national cooperative group clinical trials program. The CALGB, like most other clinical trials programs, accrues approximately 60 to 80 percent of its patients through community physicians. Historically, the CALGB has experienced high patient accrual rates, but the most recent data from CALGB participants, including the Bowman Gray Academic Medical Center and the Piedmont Oncology Association, show precipitous declines in accrual rates.

To continue a vigorous cancer program, State officials developed the Cancer Control Program for North Carolina. Among the Program's key components are an education and prevention arm, a diagnosis and treatment arm, and the Central Cancer Registry. This registry is one of the most advanced in the country, allowing officials to track cancer incidence by zip code; the resulting data can be used to develop a detailed picture of statewide cancer incidence and its socioeconomic implications.

The outreach portion of the Cancer Control Program, known as the Southeast Cancer Control Consortium (SCCC), has been successful in enlisting 15 communities in North and South Carolina, Georgia, Tennessee, and Virginia to accrue patients to clinical trials. As part of a regional initiative, officials from Duke, UNC, and Wake Forest are planning a regional conference to discuss the underrepresentation of minority populations in clinical trials.

Key Points

- The Community Clinical Oncology Programs have been responsible for many of the advances made in cancer treatment over the years, particularly in the area of pediatric oncology. Because of the limited resources available to NCI, however, the program is unable to fund a large portion of the meritorious grant proposals

- that are reviewed each year. Therefore, conducting clinical research through the CCOPs can be frustrating for participating institutions and physicians.
- At the same time, the pharmaceutical industry's support for clinical research is approaching \$2.4 billion per year, a sum larger than NCI's entire budget. This disparity means that a pharmaceutical company can offer investigators from \$1,500 to \$5,000 for each patient enrolled in a clinical trial, while NCI can offer only \$500 per case. When deciding which clinical trials to support, physicians must consider these economic realities since other traditional areas of support are eroding, especially in the wake of managed care.
 - The administrative costs of conducting clinical research have increased, placing a tremendous burden on physicians and other staff members who must fill out reports, patient charts, and other information required to withstand a stricter auditing process. These administrative requirements greatly expand the amount of physician time that is necessary to participate in clinical trials, yet physician investigative support has not kept pace with these administrative demands.
 - Another factor challenging investigators is the dynamic evolution of health care markets in response to managed care. Long periods of time can elapse between the submission of a protocol, its review and approval, receipt of funds, and actual implementation of the study. During this extended period, proposed study sites or investigators can merge, be acquired by third parties, or otherwise form alliances that obviate their participation in the research protocol. These market changes can be highly discouraging for researchers who have successfully navigated the hurdles of obtaining monetary support and the necessary approvals for conducting the proposed study.
 - Managed care plans also are detrimentally affecting clinical research by decreasing referrals to cancer centers or forcing patients to transfer from one institution to another after treatment has begun.

Dr. Gilbert H. Friedell
Kentucky Cancer Program
University of Kentucky

Background

The Kentucky Cancer Program is an umbrella organization made up of the cancer centers at the University of Louisville and the University of Kentucky. In addition to operating the Kentucky Cancer Registry, the Cancer Program also operates the NCI Cancer Information Service for Kentucky, Tennessee, and Arkansas. The Kentucky Cancer Registry allows officials to pinpoint cancer incidence throughout the State so that effective interventions, including education, outreach, and screening programs, can be designed to address the needs of each locality.

The Kentucky Cancer Program directs a number of interventions and participates in the management of a community health advisor program, known as Kentucky Homeplace, that targets low-income women and those with lower educational levels in an effort to improve screening mammography and Pap smear testing rates. The Kentucky Homeplace program also deals with other health issues that

affect low-income families. Women from the target communities are educated over a 4-week period about the need for screening, and also learn ways to encourage other women to use a variety of medical services, which are offered at low or no cost. The local community health advisors help program officials tailor health messages to fit the needs of women in their communities. They also facilitate entry into the health care system by accompanying their neighbors to examinations or working with staff at the health care facilities to ensure that the women feel comfortable; it has been found that the prevailing attitude at each local health department and at private providers is a major factor in achieving significant increases in screening rates. Since the pilot project was successful, the Kentucky legislature appropriated almost \$2 million to expand the program to almost all of eastern Kentucky, rural parts of central and western Kentucky, and the African American population of Louisville. This program has yielded substantial cost savings (e.g., reduced emergency room visits, reduced hospital and nursing home admissions) while giving underserved women access to previously underutilized services.

Key Points

- Many barriers to care prevent the application of gains in cancer prevention and treatment. Especially in eastern Kentucky, poverty poses several overwhelming challenges to people needing to access medical care: a lack of available health care providers and user-friendly services, the economic burdens associated with obtaining health care; a general outlook and culture that focus on securing the necessities of life--food, shelter, and clothing--rather than routine medical care, including screening and preventive services; low literacy rates that contribute to communication problems between providers and patients; and a lack of available transportation, either private or public, to allow people to reach health care providers. From a public policy standpoint, it is important to understand that availability does not necessarily result in utilization unless some of these informational and cultural needs are met.
- To address some of these barriers, NCI is funding the Appalachian Leadership Initiative to increase access to health care in a region of the country in which services are poorly available. The obstacles that inhibit access cut across race or ethnicity and are present in all underserved populations, including rural, poor Caucasians. It will be impossible to meet the Year 2000 goals unless appropriate, effective interventions are developed to reach these underserved populations.
- Managed care organizations must realize that tertiary prevention produces a return on the dollar in the immediate present. Primary and secondary prevention activities also generate cost savings, especially in cases of chronic diseases like diabetes and hypertension, but they are realized over a longer period of time. Incentives must be built into the evolving health care delivery system so that prevention and control activities can continue to exist and flourish.
- What has been lacking thus far in the public policy discourse on health care is a discussion of values. In 1992, researchers concluded that professional autonomy was the most important value supporting the system at that time; the currently

prevailing value may be third-party payer autonomy. The question that policy makers may wish to consider is what values should form the framework of the health care system; some might argue that fair access should be the most important essential value.

Additional Research Needs and Recommendations

- NCI should increase its support for the Cancer Literacy Working Group. Too few resources are being spent on efforts to improve literacy in a country where a large portion of the population has limited literacy skills. In particular, research assessing effective communication techniques for low-literacy individuals is needed desperately.
- To intervene effectively in underserved populations, one must develop a health message that is understandable and meaningful for people in the target group. Often, members of the target communities can provide invaluable insights about creating an appropriate message and assist in spreading it to their neighbors. In addition, it is advantageous to fold cancer care issues, such as the need for screening, into a broader discussion of general health care. These principles apply whether one is attempting to implement a cancer control program or increase clinical trial accrual among underserved individuals.
- Public policy debate about the future of the health care delivery system would be advanced if additional research was conducted to assess what values currently underlie the system and what values should provide its foundation.

Dr. Edward Partridge
Comprehensive Cancer Center
University of Alabama
at Birmingham

Background

Managed care's penetration into the Alabama market has been minimal to date. Blue Cross/Blue Shield of Alabama covers three out of four individuals with insurance, or 79 percent of covered lives in the State.

Alabama is undertaking several initiatives to improve the health care of its citizens, including poor, rural African Americans. The Alabama Partnership for Cancer Control in Underserved Populations is charged with bringing together public and private cancer, health, and community organizations to enhance participation of the medically underserved in cancer control activities. Its membership is broad based, and includes such organizations as the Alabama Department of Public Health, the medical center at the University of Alabama at Birmingham, minority health care providers, African American churches, community-based organizations, and others. Its initial goal is to increase participation in the public health department's screening mammography program; this year for the first time, Alabama is offering free screening to women without insurance or the ability to pay. The coalition has formed four action groups—

professional education, community education, treatment and follow-up, and policy maker education—to help achieve its goals. Rather than duplicating other more generalized educational efforts of groups like the ACS or the Centers for Disease Control and Prevention (CDC), the action groups will focus their efforts on designing programs to reach the target subject--a 55-year old woman with a sixth-grade education and an annual income of \$6,000. This pilot program is being tested in the seven poor, rural counties in the western part of the State, and will build upon the infrastructure put into place by an earlier program called the Alabama Black Belt Cancer Linkage Initiative.

A second important partnership that was created recently is the Coordinated Health Care Delivery System for Jefferson County. The goal of this coalition is to develop a coordinated health care delivery system for the medically uninsured residents of the county that will not overburden any single provider. Its members include the county commission, which traditionally has paid for indigent care in the county, the Alabama Hospital Association, the Jefferson County Medical Society, health care providers, and the Jefferson County Department of Public Health. The impetus for this group's efforts was the realization that the county's traditional way of financing and delivering indigent care will no longer work once managed care, with its bottom-line orientation, becomes a player in the community. The coalition is considering how to take the \$35 million that the county traditionally paid to support acute, tertiary care in the county's hospitals and allocate it to developing a community-based system in which indigent people can receive ongoing routine medical care.

Key Points

- Alabama and other States in the Deep South have a unique underserved population that faces special difficulties in accessing the health care delivery system—rural, poor African Americans, who number over 4 million, making them the fourth largest minority in the United States. In Alabama alone, six of the seven western counties in the State consistently are among the country's poorest 100 counties. This population cannot be ignored by officials charged with improving the public's health.

Additional Research Needs and Other Recommendations

- Broad-based community coalitions and partnerships can be an effective tool in cancer treatment, prevention, and control activities as long as each member is prepared to compromise and contribute something toward achieving the greater public good. In addition, it is imperative that all members of the affected community be involved in creating a successful community partnership--including representatives from the insurance and managed care industries, who must see that they have an ethical and moral obligation to take responsibility for improving health care in the communities they serve.

Drs. Halverson, Cooper, Friedell and Partridge
Discussion Period

Discussion following the presentations by Drs. Halverson, Cooper, Friedell, and Partridge included additional key points:

Key Points

- Numerous opinions were expressed regarding the social responsibility that managed care organizations likely will exhibit once their industry has matured; most participants agreed, however, that the overall picture likely will become worse before it improves. Most participants also believed that for-profit managed care companies will not ever provide the financial support necessary to fully operate cancer centers at today's levels or to support research and educational activities at their current levels.
- It may be that the application of managed care principles, when combined with the realization that it is in the best interest of managed care companies to improve the health status of the populations in their communities, will result in a system combining the best features of fee-for-service and managed care. It is also possible that as managed care systems evolve from channelization and point of service to capitation and risk pooling, physicians may once again have more autonomy in deciding how health care dollars are allocated to patient care.
- Several steps could be taken to ensure that managed care evolves into integrated care in which the health of the surrounding community is a priority for plan officials. First, efforts should be undertaken to increase community collaborations and partnerships, and to ensure that vulnerable populations are served, perhaps by including public departments of health in managed care plans. Natural partnerships between managed care plans and community members with the capacity to provide indigent care should be encouraged. Secondly, more attention should be focused on measuring participation in screening and prevention activities so that the public becomes aware of the importance of these initiatives and holds managed care companies accountable for their actions—or inaction—in these areas. Most participants agreed that the managed care industry will not embrace a socially responsible outlook unless the public demands that some of the values underlying the traditional health care delivery system are preserved in the emerging order.
- If public demands are not sufficient to drive socially responsible behavior, then it may be necessary to pass legislation requiring that all parties equitably share the burden of maintaining the necessary infrastructure to support a vigorous research program. Participants suggested several issues that may benefit from legislation, including oversight of the conversion of not-for-profit institutions to for-profit status and the development of effective information management systems that will facilitate continuity of care as patients change health plans and providers. A third suggestion for regulatory intervention concerned the development of potent oversight mechanisms that would police management's decisions and allow consumers access to solid data about quality care.

- Most participants agreed that managed care plans should cover the routine patient care costs associated with participating in clinical trials, since they already are obligated to provide such care to their enrollees. It is less clear that other costs directly attributable to research--such as those supporting administration, data management, and auditing--should be considered the sole responsibility of managed care companies or other insurers. Instead, some type of cost-sharing arrangement may be appropriate; most participants suggested that managed care companies have an ethical obligation to support indigent care and clinical research in the communities in which they are located.
- Another barrier to clinical research is the review and funding of grant proposals by NCI, which spends only \$66 million each year on clinical trials. This amount simply is insufficient to support all of the proposals receiving high scores in the rigorous peer-review process. The agency's low pay line forces it to allocate funds in a manner that arguably does not reflect the scientific merit of many of the projects. This process can be very discouraging to clinical researchers, although an NCI official pointed out that the agency funds as many meritorious proposals as possible in the amounts it perceives as being needed. (NCI FY95 expenditures are provided on page D-47.)
- Very small decreases in funding can have a major impact on the ability of CCOPs to accrue patients from community physicians' offices and hospitals. For example, Dr. Cooper noted that the 1994-1995 data showed a dramatic decrease in patient accrual rates when the CCOP was forced to lower its payments from \$500 to \$250 per patient; this meager amount barely covered administrative costs for participating physicians, and left no money for patient care costs. The Community Clinical Oncology Program is already over-burdened and inadequately funded, so that the increasing influence of managed care is very troubling. This is particularly true since managed care companies, at least to date, have not contributed to the infrastructure needed to support a vigorous clinical research program. Indeed, Dr. Cooper believes that the emerging health care system is reallocating money from indigent care and clinical research to the benefit of the insurance and managed care industries and their stockholders.
- Increasingly sophisticated population-based cancer registries should support prevention and control activities, as they will better enable officials to keep abreast of changes in cancer morbidity and mortality.
- To ensure that outreach efforts truly are targeting all potentially needy populations, future RFAs and RFPs should be broadened to include references to the underserved in addition to specific minority groups.

CLINICAL RESEARCH AND PATIENT CARE IN UNDERSERVED POPULATIONS

Dr. Edward Trapido
Sylvester Comprehensive Cancer Center
University of Miami

Background

Florida is unique in that its population is significantly older than that found in the other 49 States; because of this elderly population, many of whom are retirees, Florida has the highest crude incidence rate of cancer in the nation. In addition, undocumented aliens account for approximately 10 percent of the State's population. Florida has a fairly high penetration of managed care; for example, in Miami almost 50 percent of the population is enrolled in some type of managed care organization. Approximately 40 percent of Miami's 370,000 Medicaid enrollees and 257,000 Medicare enrollees participate in a managed care plan, and capitation has begun to appear in the State, particularly in south Florida.

At the University of Miami, the Medical Center derives 60 percent of its funds from clinical revenues, a figure significantly higher than the national average of 47 percent. The Center's clinical revenues are projected to decrease by about 5 percent each year, posing a serious threat to the Center's continued ability to operate. Reacting to these changes, in 1993 the Center's physicians reorganized into a network medical group providing inpatient and outpatient care, and also added primary care physicians to control referrals; as a result, the Medical Center now contracts with at least 50 different health plans. In addition, the Medical Center has attempted to maintain its research programs by partnering with outlying hospitals, foundations, and community-based organizations.

The Center has several thriving cancer prevention and control programs underway, including an early breast cancer detection initiative that has already shown tremendous progress as demonstrated by changes in the distribution of detected disease by stage. This program involves two mobile mammography vans that visit the primary health care centers in the community and provide low- or no-cost screening to underserved women, including Hispanic, African American, Caribbean-born black, and white, non-Hispanic women. The Center's department of radiology reads the reports, and any necessary follow-up care is provided at the county hospital or the University's Breast Health Center, a multidisciplinary facility. This highly coordinated approach, which minimizes treatment delay and prevents loss to follow-up, could serve as a model for managed care organizations.

The Center also operates a Cancer Information Service (CIS) that serves Florida and Puerto Rico. Concerns being expressed by callers include their ability under managed care to obtain second opinions or receive treatment at major medical

centers, delays in treatment resulting from lengthy preauthorization processes, and whether they will be referred to specialists in appropriate circumstances.

Key Points

- Principles of care and a commitment to teaching and research place university-based medical centers and cancer centers at odds with managed care's emphasis on low costs. In addition, the patients at academic medical centers and cancer centers often are suffering from diseases more advanced and more difficult to treat than those seen at other hospitals. Specialty care is a hallmark of academic medical centers and cancer centers, as is a commitment to using the latest technological advances. All of these factors mean that care at academic medical centers and cancer centers can be more expensive than at other treatment facilities.
- Managed care has negatively impacted patient care in Florida in a number of notable ways. First, accrual to clinical trials has dropped because physicians must spend less time per patient in managed care plans. Also, experimental treatments are not reimbursed, as Florida does not require coverage of Phase II or Phase III investigations. Follow-up care is strictly limited, even for non-protocol patients. The managed care plans require repeated authorizations to seek specialty care, another burden for overextended health care providers. In practice, these conditions mean that it is now easier to recruit clinical trial enrollees from the indigent patients at the county hospital rather than those at the University's Medical Center.
- Another important barrier to clinical trial participation is a general lack of trust of health care professionals due to the commercialization of medicine and the recent Medicare fraud cases.
- Through the Center's participation in the National Hispanic Leadership Initiative on Cancer, it has demonstrated that members of ethnically and culturally diverse populations are less aware of the need for, and benefit of, cancer prevention efforts and routine screening. They often are not knowledgeable about the meaning of their symptoms and diagnoses, and are less likely to comply with treatment and follow-up recommendations. Women especially depend on shared decision making with their friends and families, who provide critical avenues of support among the disadvantaged. Focus groups involving the Center's patients have documented a number of other troubling beliefs, including the conviction that cancer is incurable and that physicians have a financial interest in encouraging surgical options. Patients are interested in learning about alternative therapies, and they do not believe that physicians adequately inform them about their health status.
- Important questions that will need to be addressed as managed care continues to change the health care delivery system include:
 - To what extent will the underserved be empowered under managed care? What will convince managed care organizations to provide social or cultural support? Will those who are currently underserved simply remain underserved in managed care plans?

- Does society value the results that occur when a private university works with a public health facility to advance community health through outreach and clinical research? If yes, to what extent is society prepared to support these efforts?
- The impact of managed care on cancer control and prevention initiatives could be particularly devastating if managed care plans continue to cut staff and faculty time, reduce the availability of follow-up options, provide no educational outreach, and increase out-of-pocket costs for patients, many of whom will be unable to pay these additional expenses.

Additional Research Needs and Other Recommendations

- Managed care organizations must understand and adapt to the cultural expectations of the populations they are trying to serve if they are to offer their members quality care. Their services must be affordable and accessible to all, including the underserved.
- The CIS could be expanded to provide information to assist in monitoring managed care's performance and improving quality of care; it also could serve as an educational and outreach mechanism for managed care plans. Cancer registries now exist in over 40 States, and they should be more fully utilized, perhaps in conjunction with insurance databases, to design cost-effective approaches for cancer screening, prevention, outreach, and intervention programs.
- The patient care costs associated with participating in clinical trials must be covered completely. In addition, the eligibility criteria in protocols should be broadened to the extent possible, and clinical trials should be made as simple and cost-efficient as possible, including shifting to outpatient management systems, where possible. Outcome data should be generated to assess survival rates, quality of life, and cost-effectiveness.
- National organizations must assume a leadership role in promoting recommended options and guidelines for early detection and treatment of cancer.
- There must be greater cost-sharing among all parties--government agencies, drug companies, health care providers, philanthropic organizations, and third-party insurers, including managed care--in order to continue funding clinical trials and to provide patients with quality cancer care. In addition, academic medical centers probably will require increased public support in the future if they are to continue to teach and advance cancer treatment through research.

Dr. Margaret H. Hargreaves

**Drew-Meharry-Morehouse Consortium Center
Meharry Medical College**

Background

Meharry Medical College provides health care to the underserved by overcoming the barriers that traditionally operate to keep them out of the system. In keeping with its mission of "service to the under-served," Meharry has implemented a number of regional initiatives such as the Mount Bayou project that serves people in the rural Delta region of

Mississippi. Another outreach effort is the Matthew Walker Comprehensive Health Center, a neighborhood clinic offering health care services to poor families in Nashville. The College also coordinates the Middle Tennessee Breast and Cervix Cancer Screening Coalition, an effort that was expanded after the State received CDC funding. To support these types of programs, Meharry has increased its participation in collaborative partnerships; most recently, the College merged with Nashville General Hospital in an effort to increase its resource base.

Managed care has made significant inroads in the Tennessee marketplace because of the State's innovative health care program for its poor—TennCare was initiated in 1993 after the State received a waiver from the Federal Government. Thus far, the program has enrolled 1 million of the targeted population of 1.5 million Medicaid recipients and uninsured individuals. The program is based on a managed care philosophy; the State has contracted with 12 managed care organizations to provide comprehensive benefits on a prepayment basis. The second largest of these organizations is Access Med-Plus, a managed care company with a 12-year history in the State. Officials at Meharry have worked closely with Access Med-Plus to coordinate care for its needy clients, and have found the plan to be willing to participate in several outreach programs, including the purchase of a mobile mammography unit. They also are considering developing a model collaborative relationship to pursue cancer-related clinical trials. Given these initiatives, Access Med-Plus should be considered an example of a managed care organization that has a mature outlook of commitment to total quality care.

Key Points

- Underserved populations can be defined as those lacking access to adequate health care based on geographical limitations, inadequate health care facilities or providers, substandard or nonexistent health insurance coverage, or ineffective health care utilization by individuals because of their poor health screening behavior. Members of underserved populations are characterized by poverty, poor social support, and lower educational attainment. The institutions aiding the underserved often face their own difficulties, including a lack of adequate resources to meet the special needs of their clients.
- Managed care undoubtedly has impacted the delivery of health care services to cancer patients. However, some of the changes have been positive—for example, greater access to care for the underserved—and many of the perceived negatives are not as burdensome in reality as they are said to be:
 - While there is strict utilization review and nonpayment for inappropriate admissions, in reality most patients can be given chemotherapy in outpatient settings; also, most managed care organizations continue to pay for toxicity-related admissions if the patient is precertified and hospital stays are minimized
 - While participation in clinical trials and associated complications and hospitalizations are not covered under managed care plans, no effort has been made to distinguish appropriate patient admissions based on protocol versus standard treatment

- While laboratory testing associated with clinical trials is not covered, in reality, reasonable outpatient testing is allowed if providers use approved labs
- While expensive drugs are not covered, in reality, most standard chemotherapeutic agents are paid for as administered, and other expensive therapies can be used if prior approval is obtained
- While experimental treatments, agents, and complex protocol treatments are not covered, in reality, these therapies can be supplied by cooperative trials groups and the pharmaceutical industry
- While declines in revenue per capita may have a chilling effect on clinical trial accrual, in reality, the pool of potential participants may be broader given additional contracts to provide care
- While some fear that primary care gatekeepers may refuse to authorize needed specialty care, in reality, oncologists are considered primary caregivers or multiple visits to oncologists are allowed in appropriate circumstances.

Additional Research Needs and Other Recommendations

- Organizations dedicated to providing health care to the underserved must be safeguarded because they make essential contributions to addressing the problems of indigency and access to the health care system.
- Although institutions committed to aiding the underserved face numerous challenges in providing cancer care to these individuals, proactive efforts must be undertaken to overcome these hurdles:
 - Institutions must seek new funding sources to support additional professional positions to relieve investigators and support staff who are now overburdened with additional duties and limits on time spent per patient
 - Institutions must pursue affiliations and cooperative relationships with other cancer centers and private treatment facilities to expand the availability of otherwise limited therapies and treatment technologies
 - Institutions must pursue multigroup and interinstitutional protocols to overcome the scarcity of available cooperative group trials
 - Institutions must encourage participation in cooperative group protocols in the face of competition from commercial firms for patients eligible to be placed on clinical trials
 - Institutions must seek additional sources of support to address administrative challenges and shortfalls in available funding.
- Greater efforts must be initiated to work cooperatively with other organizations and providers to expand institutional resources; for example, specialized grants from NCI and NIH could support expanded professional staff and faculty at institutions caring for large numbers of underserved individuals.
- To increase clinical trial participation, particularly among the underserved, managed care organizations should make special arrangements to promote clinical trials to their members who develop cancer. Cooperative groups should design

- special clinical trials that provide additional support to address the unique problems of the underserved. Federal agencies should provide funding to support Phase I and Phase II studies.
- Additional efforts could be instituted to expand access to existing therapies. Cooperative groups should provide funds to cover expensive agents such as G-CSF. The pharmaceutical industry should provide products to investigators who are working with underserved populations.
 - Finally, Federal legislation should require managed care organizations to conform to policies implemented to assure uniformity of access to providers, off-label drugs, screening and prevention programs, and clinical trials.

Dr. Richard Payne
Intercultural Cancer Council

Discussion

The Intercultural Cancer Council (ICC) is a coalition of more than 30 private-sector organizations and leading experts addressing issues of concern to minorities, the medically underserved, and culturally diverse populations. Its members include representatives from the Nation's medical mainstream (e.g., the M.D. Anderson Cancer Center, the ACS, the American Public Health Association) as well as major groups and individuals specializing in minority medicine and health care for Hispanics, Native Americans, Asian Americans, Pacific Islanders, and African Americans. The ICC works closely with pivotal government agencies like NCI, CDC, and the Office of Minority Health at the NIH to promote its goal of developing and promoting policies and programs to address the fact that members of these populations have not shared equally in the advances made against cancer.

Minority groups and the medically underserved have higher incidence rates and lower survival rates from cancer than the national average. Several recent studies document that disparities in health outcomes are in part a function of race. It was reported recently that the probability of survival from age 15 to age 65 varied from 0.87 for white females to 0.62 for black males; the annual excess death rate was 374 per 100,000 for black males compared with white males, and 214 per 100,000 for black females compared with white females.

Factors relating to health care undoubtedly play a role in explaining these statistics. A study analyzing 20,000 patients hospitalized with colorectal cancer found that blacks more often are not admitted until their cancer is advanced, and they are less likely to receive certain therapeutic procedures. As a result, blacks have a 59 to 98 percent increased likelihood of dying in the hospital as a result of colorectal cancer. Blacks with localized disease were 41 percent less likely than whites to receive major colorectal therapeutic procedures and 27 percent less likely than whites to receive such therapy once metastasis had occurred. These data seem to indicate that the disparity in outcomes between blacks and whites with colorectal cancer may exist because blacks receive less aggressive treatment.

In another study of 2,235 patients with chronic medical illness, it was shown that declines in Medicare patients' physical health were more common in managed care plans (54 percent) than fee-for-service plans (28 percent). For patients with incomes less than 200 percent of the poverty level, physical and mental health outcomes also favored fee-for-service care even though managed care plans were favored in the nonpoverty groups. These results establish that policy makers should not base decisions on what works for vulnerable groups such as the poor and elderly on average outcomes for the general population in managed care organizations.

Finally, a study of 1,308 outpatients demonstrated that the rate of under-medication with analgesics for all patients was 42 percent. Minority groups however, were three times as likely to be undermedicated, with the under-medication rate for African Americans approaching 76 percent. Clearly, palliative care services are important for minorities, yet they often receive inadequate reimbursement in managed care plans. This may be because the consequences of poor pain management are not reflected in the measures typically used to assess outcomes—job and productivity losses, utilization of services, or excess mortality.

Key Points

- The emergence of managed care over the last few years has yielded many positive developments, including an emphasis on preventing disease and the development of tools for measuring variations in practice outcomes. However, rapid changes in anything as complex as the U.S. health care system can have unintended adverse consequences in vulnerable segments of the population. Unfortunately, managed care's emphasis on lowering costs may well occur at the expense of maintaining quality care, and it may contribute to the further erosion of access for vulnerable patient groups.
- Managed care also may negatively impact the care of minority and underserved groups by shifting Medicaid care from public to private institutions, thus compromising an important revenue base for public hospitals. This could have a disparate effect on the poor and working poor who may not have access to private facilities.

Additional Research Needs and Other Recommendations

- Policy makers cannot base conclusions about effective interventions for medically underserved populations on average outcomes for general enrollee populations in managed care plans. Instead, efforts must be undertaken to monitor the health outcomes of members of underserved and otherwise vulnerable populations of patients with chronic diseases, and these data should be used to support policy decisions.

- Additional efforts should be made to enroll minorities and the medically underserved in clinical trials so that important racial differences, like response to analgesics, can be discovered. The ICC supports the following recommendations from the recent conference on recruitment and retention of minority participants in clinical cancer research:
 - As Federal and State governments contract with managed care parties, they must mandate good clinical trials as covered services. The components that compose an appropriate clinical trial include therapeutic intent, approval by appropriate Federal agencies and regulatory bodies, Institutional Review Board approval, experienced and appropriately trained personnel, and a lack of a standard therapy superior to the trial being proposed.
 - More data must be collected on comorbidity in minority populations to determine whether its presence adversely affects participation in clinical trials.
- Managed care organizations should support outreach activities and provide preventive services to minority and medically underserved communities because they offer the best opportunity to provide cost-effective care. Since medically underserved patients tend to present with later-stage cancer, high-quality supportive and palliative care should be viewed as tertiary prevention practices and should be available through managed care plans.
- Managed care organizations should support professional education programs, medical schools, and postgraduate residency programs to improve the skills of physicians in providing primary, secondary, and tertiary prevention services.
- Managed care organizations should provide clinical care that is culturally competent and respectful of the cultural diversity of this society and the differing ethnic preferences for cancer care and preventive practices.

Drs. Trapido, Hargreaves, and Payne
Discussion Period

Key Points

- The definition of excessive costs depends in large part on who is defining the term; for example, palliative care may result in short-term cost increases, but does that mean that palliative care should be considered an excessive cost?
- Often, a conflict exists between what is best for an individual patient and what is appropriate for an institution concerned with operating in a financially sound manner in the face of decreasing revenues. Most providers, especially academic medical centers, have already implemented stringent cost-cutting measures such as increasing outpatient services, eliminating staff and departmental positions, and instituting critical pathways management. Yet, providers often complain that managed care organizations refuse to acknowledge these efforts by working cooperatively with them; instead, managed care representatives seem to focus on negotiating ever more inflexible contract terms.

- Representatives from different geographic areas varied in their perceptions about managed care's impact on care of the medically underserved. Meharry's positive experience may be due in part to the good working relationship that it has forged with Access Med-Plus, a managed care company that has been in the community for over 12 years.
- Other participants were not as pleased with the changes in the health care delivery system, and noted several drawbacks of managed care. For example, physicians must spend less time with each patient because revenues per patient have dropped under managed care. In addition, necessary follow-up care sometimes is compromised under managed care plans, and referrals to specialists can be problematic, resulting in treatment delays.
- Most participants agreed, however, that managed care has been detrimental to clinical research. Part of the problem is that as major academic institutions are forced to cut costs, their profit margins decrease, so that there are no funds left to support research. Thus far, managed care organizations have refused to shoulder any responsibility for supporting clinical trials, so that it may be necessary to enact legislation requiring such action. Some type of cost-sharing between the government, the pharmaceutical industry, and third-party payers—including managed care organizations—may be appropriate as long as it is possible to separate pure research costs from those associated with routine patient care.
- States will play a pivotal role in defining quality cancer care as they enter negotiations to enroll their Medicaid populations in managed care plans. The cost savings generated by moving Medicaid beneficiaries to managed care plans should be used to fund expanded health care initiatives rather than other public programs.
- Socioeconomic status and poverty have been shown to be powerful confounding factors in studies showing a difference in black/white mortality rates and other health care measurements. For example, blacks who live in urban environments that are not ghettos have mortality rates that are closer to the general population average.
- In the study showing differences in the outcomes of black and white patients with colorectal cancer, the authors concluded that it was not possible to ascertain precisely which factors accounted for the recorded discrepancy, although effects of diet, access to care, and prevention measures were likely. In the Appalachian population, it appears that older women receive less chemotherapy than men with a comparable stage of disease. This type of information is critical for designing effective cancer treatment, control, and prevention programs, and NCI should increase its funding of research addressing these types of social issues. It is not enough to review only incidence and outcome data; an individual's circumstances and social environment may be as important as medication in explaining a particular response.
- Free choice of provider was one of the primary strengths of the fee-for-service model. At this time, it is not clear whether managed care's efforts to limit access and choice have exacerbated the problem of providing culturally sensitive information to patients. It was noted, however, that managed care officials have learned that choice can be just as economical as channelization, so patients may

- begin to have more freedom to choose their providers as risk pooling and capitation emerge as trends for the industry.
- The fee-for-service system fostered physician/patient relationships in which decisions were based on the best interests of the patient rather than monetary incentives of the provider. Some participants suggested that this aspect of managed care must be improved, perhaps through the development of practice guidelines, so that physicians once again feel they can offer the best care to their patients.
 - Part of the reason that managed care has become such a force in the marketplace is that the fee-for-service system was generating spiraling health care costs that could not be sustained. On a positive note, managed care has forced providers to evaluate the cost-effectiveness of their treatment interventions and to base their decisions on scientific evidence.
 - Defining cost-effective, quality care is difficult in the absence of outcome research that allows comparisons to be made between different treatments rendered in different settings. Dr. Freeman pointed out the need to obtain such scientific data to support the findings and recommendations of the Panel because anecdotal information often is not persuasive to government officials. It may be ill-advised, however, to wait until a complete database exists to address some of the shortcomings of managed care that have been outlined in the testimony presented to the Panel over the past year. Certain changes to managed care practices are needed now, whether through regulatory oversight or through efforts to encourage large purchasers of health care to insist on coverage for complete quality care.

CLINICAL RESEARCH IN A MANAGED CARE ENVIRONMENT

Dr. Jeffrey Crawford
Duke University Medical Center

Background

At least partly as a result of managed care, Duke University Medical Center has in recent years experienced decreased total revenues and increased unmet costs, even as it attempts to maintain a vigorous clinical research program. In 1995 Duke had total revenues of \$805 million and total uncompensated care costs of \$245 million (including discounted fees, indigent care, and managed care). From 1990 to 1995, patient accrual to clinical trials was fairly consistent at about 1,000 patients each year. In 1996, however, there has been a significant decrease of 20 to 30 percent in the accrual rate through mid-September. It is not known how much of this drop is due to the impact of managed care, but the changing health care system probably is the major force behind this trend.

To address these developments, the Duke Health Network has taken a very aggressive approach to managed care contracting by seeking inclusion on the panels of as many insurers and managed care companies as possible. Duke also is following the lead of the Fox Chase Cancer Center in negotiating coverage for

clinical trials with individual managed care companies using the following relevant contractual language:

"The plan and the health care facility agree that the costs of medical care provided when a patient is entered on a clinical trial, as well as the costs of agents for labeled or unlabeled uses which might be part of the regimen, will be considered covered and reimbursable when all of the following are demonstrated:

- The treatment is provided with therapeutic intent aimed at improving patient survival or quality of life
- The treatment is provided pursuant to a clinical trial protocol approved by NCI, any of its cancer centers, cooperative groups or CCOPs; the Food & Drug Administration (FDA); the VA; or a qualified nongovernmental research entity as identified in the guidelines for NCI cancer center support grants
- The proposed therapy has been reviewed and approved by a qualified Institutional Review Board (IRB)
- The facility and personnel providing the treatment are capable of doing so by virtue of their experience or training
- There is no non-investigational therapy superior to the protocol treatment, and the available clinical or pre-clinical data provide a reasonable expectation that the protocol treatment will be at least as efficacious as non-investigational therapy."

Other organizations also are concerned about the negative impact that managed care is having on clinical trial research. The American Society for Clinical Oncology evaluated patient-oriented clinical research and found that in 1994, NCI spent over \$2 billion on research. Of that amount, \$339 million went to clinical trials, but only \$103 million of the \$339 million was directed to clinical treatment research. In 1994 NCI provided approximately \$935 million in support for investigator-initiated research through such funding mechanisms as ROIs, POIs, UOIs, and RFAs; clinical trials garnered only \$79 million, or less than 10 percent of the total amount. (NCI FY95 expenditures are provided on page D-47.)

ASCO believes that patient-oriented research grants differ inherently from basic research grants, and that the study sections reviewing NIH grants disproportionately favor laboratory research. To address this imbalance, ASCO recommended that the study sections be restructured so that clinical grants are reviewed appropriately. The Society also believes academic medical centers must take steps to better train clinical investigators and to guide them in the development of improved clinical research grant proposals. Finally, ASCO has urged NCI and NIH to increase funding for clinical research.

NIH has taken steps to address many of ASCO's recommendations, including the establishment of a Clinical Research Study Group and a Clinical Research Panel.

NCI also has created specific funding mechanisms for patient-oriented research, and the pay line has been increased for investigator-initiated grants; these positive changes are largely attributable to the efforts of Dr. Klausner, Director of the NCI.

Key Points

- It is critical to maintain and strengthen the infrastructure needed to support the talented young clinical investigators who will conduct clinical research in the future. This means that senior investigators must have the time and ability to mentor their junior associates through formal clinical research training programs. In addition, clinical trial coordinators, data management services, and computer resources must be available to support research efforts. None of these primary components can exist in the absence of adequate funding. In the past, the health care system paid the patient care costs of clinical trials; now, managed care organizations want to reduce or eliminate this support, to the detriment of research.
- Although industry could provide more support for clinical research and other important educational and outreach programs, a delicate balance must be maintained in order to preserve the independence and integrity of these activities.
- Steps should be taken to remove restrictions on patient access to clinical trials. NCI's recent agreements with the Department of Defense and the Department of Veterans' Affairs are important examples of the types of collaborative efforts that are needed. In addition, the pediatric oncology groups have undertaken a similar initiative with Blue Cross/Blue Shield. Under these arrangements, the routine patient care costs associated with participating in clinical trials will be covered by the insurer. Data to be collected will allow investigators to discover whether clinical trials really do cost more than standard care.

Additional Research Needs and Other Recommendations

- Managed care must allow patients to access innovative care at cancer centers. This will require centers to pursue an aggressive managed care contracting strategy.
- Academic medical centers must build community research networks so that clinical trials are conducted in the communities where patients live.
- Educational outreach must become a top priority so that consumers and employers begin to understand the intricacies of their insurance coverage and the need to reimburse clinical research.
- Investigators must take steps to lower the costs of conducting clinical research. This means designing trials that are less complex and incorporating only those tests that are necessary to yield critical clinical data. In addition, investigators must ensure that they complete the trials which they initiate; greater attention must be paid to setting realistic accrual rates and evaluating the impact of competing priorities.
- Perhaps the most critical threat to the long-term survival of clinical research is the lack of support offered to young investigators starting their careers; economics are

forcing them to spend more time in clinical practice as opposed to clinical research. Additional sources of funding (e.g., philanthropy, industry) must be identified and pursued if the necessary recruitment and training of young investigators is to proceed in the changing health care system.

Dr. Robert Warren
Lombardi Cancer Center
Georgetown Medical Center

Background

Georgetown University Medical Center and the Lombardi Cancer Center have instituted a number of initiatives to improve the quality of care they offer their patients. For example, the Center has cosponsored two symposia with the Xerox Corporation. Representatives from more than 50 managed care companies and 30 academic medical centers met to explore possible collaborations to foster quality cancer care. Academic medical centers that have established close working relationships with particular managed care organizations discussed how their relationships have evolved, the issues they have confronted in working together, and solutions to these obstacles to cooperative ventures. In addition, attendees focused on increasing clinical trial accrual and obtaining outcome data to assess medical interventions. It was clear from these two meetings that it is possible to combine the traditional mission of academic medical centers—research, education, and teaching—with managed care's emphasis on cost-effectiveness.

Referring physicians and medical directors of Kaiser Permanente recently met with Georgetown's bone marrow transplant team to discuss issues of mutual concern, especially problems in the referral process. The Kaiser Permanente representatives were receptive to the bone marrow transplant team's observation that earlier referrals often are more appropriate from both a medical and fiscal standpoint. As a result, the two groups were able to define a more consistent referral process. They also discussed patient education projects that could be launched jointly and the development of an enhanced data collection system. Based on the positive outcomes of this intense one-on-one meeting, representatives of two other managed care organizations have expressed interest in arranging similar sessions with Georgetown officials.

Georgetown also has created a Health Maintenance Organization Advisory Board. The HMO Advisory Board has worked with the breast cancer program's patient accession core to discuss ways to increase participation in clinical trials, especially among high-risk women who typically have limited access to such protocols; specifically, the members of the medically underserved patient population and HMO members. The managed care representatives have demonstrated a spirit of cooperation and have indicated their interest in collaborating in research on cancer prevention and control, diagnosis, and treatment. Among the issues that such collaborative efforts raise are:

- How can Georgetown utilize the managed care organizations' data on costs and quality of care to lower costs or improve patient care?
- What changes can be made so that managed care enrollees receive treatment through the managed care companies' contract hospitals, yet allow the Lombardi Cancer Center to capture data and enroll these same patients in Center trials? Discussions established that the managed care companies are concerned about "losing" their patients, but they are willing to share data at this point.
- Perhaps most importantly, how can managed care's operating principles and data best be integrated with the Lombardi Center's research initiatives so that better clinical trials are designed?

Another important area on which Georgetown has focused is improved case management technique. Rather than implementing a financial management model that tabulates inpatient costs, for the past 2 years Georgetown has used a continuum of care model. This approach involves creating a team of physicians, nurse-practitioners, fellows, nurse case managers, patient accounts specialists, and social worker case managers for each patient. Once a patient is admitted for treatment, an inpatient primary care nurse is quickly assigned to the team as well. The patient accounts representative coordinates outpatient precertification and inpatient financial issues. The nurse and social worker case managers coordinate care so that patients are shepherded through the entire inpatient and outpatient experience. This continuum-of-care approach is very popular with patients, and it also may be resulting in cost efficiencies.

Key Points

- Like other academic medical centers, Georgetown is committed to the goals of treatment, education, and research. As the health care system shifts from indemnity reimbursement to capitated provider contracts, however, it is becoming increasingly difficult to achieve these goals. Utilization management programs have proliferated in this environment, with the charge of establishing treatment criteria to determine whether treatment is reasonable and necessary, and whether it will benefit the patient.
- Thus far, most managed care companies refuse to cover clinical trials, although a few have been willing to discuss the possibility of reimbursing the patient care costs of individuals enrolled in certain Phase III trials. Lack of reimbursement has resulted in a decrease in the number of patients taking part in clinical trials, which leads to longer accrual times to complete trials and, ultimately, to fewer trials. In addition, over time it is possible that only people with indemnity insurance or those who can otherwise afford to pay for their health care out-of-pocket will be able to access clinical trials, thus eliminating a potential therapeutic option for members of underserved populations. While pharmaceutical companies have increased their support of clinical research, this trend raises its own issues, including the growing influence of commercial interests in the pursuit of scientific information. All of these developments could lead consumers to believe that

- providers are not committed to giving the best care to their patients or interested in improving available therapeutic options.
- Managed care's impact on the health care system will intensify as greater numbers of Medicare patients enroll in managed care plans. In the past, Medicare was a major source of funds for training programs, including residency and fellowship positions. Increased Medicare enrollment in managed care plans poses problems for the long term because managed care organizations are not providing support for training programs and other vital activities at this time.
 - Patients are concerned that they may not have access to state-of-the-art care under managed care, yet, the potential exists for managed care plans to utilize their on-site researchers and demographic data to provide excellent clinical trial support. Doing so may actually confer a marketing advantage to plans offering such coverage and to the institutions with which they contract.
 - Whether cutting-edge science can be conducted collaboratively with managed care organizations is an open question; many physicians have been reluctant to accept the degree of control that is imposed on them under most managed care contracts. Officials at Georgetown believe, however, that constructive collaboration is possible, and that it is the responsibility of academic medical centers to educate their managed care colleagues as to which clinical trials are appropriate for their patients. At the same time, it must be recognized that such issues as decreased costs and reimbursement rates, competition from community providers who can provide care for less than academic medical centers, and other market realities will influence future clinical research. In addition, managed care's need for outcome data will have a major influence on the planning of clinical trials, which must incorporate quality of life and cost-effectiveness measures.

Additional Research Needs and Other Recommendations

- Managed care organizations should provide access to clinical trials for their patients when the trials are reasonable, designed to answer relevant questions about the particular patient's cancer, and have been carefully reviewed by IRBs and the member institution.
- Managed care organizations should cover the routine costs of care for their patients who are enrolled in a clinical trial, as well as part of the actual costs of conducting the trial.
- Academic medical centers and other institutions must open a frank dialogue with their colleagues in managed care companies, both nationally and locally, to underscore the importance of clinical research and effective screening and prevention programs in advancing cancer treatment and care.

Dr. Robert Krance
St. Jude Children's Research Hospital

Background

St. Jude Children's Research Hospital was opened in 1962 to provide comprehensive medical care to children with catastrophic disease regardless of

their ability to pay, and to improve treatment through biomedical research. In addition to furnishing inpatient and outpatient care for the 300 to 350 new patients it accepts each year, St. Jude's also provides families with lodging and transportation to and from Memphis. The hospital depends on a powerful fundraising arm to help support its activities, since during the last year only about 47 percent of its \$80 million in charges was reimbursed. The hospital experienced a change in demographics during the years between 1991 through 1996: the percentage of insured patients declined (from 61 to 55 percent), and Medicaid patients increased (from 17 to 20 percent), as did uninsured patients (from 22 to 25 percent). This shift has led to a significant decline in reimbursement as private insurance reimbursement declined 5 to 10 percent, Medicaid payments decreased by 10 percent, and TennCare (Medicaid managed care in Tennessee) reimbursed only 17 to 40 percent of charges as opposed to the 30 percent that is typical for Medicaid payments.

Managed care has not yet had a particularly strong impact on St. Jude's operation because 80 percent of its patients come from either Memphis or the south central rural part of the country where managed care has not achieved high penetration. TennCare, however, is a powerful force at St. Jude's. Although there are many positive aspects of TennCare, its launch has been long and rocky, stretching over 2 years. It also has been underfunded, with the State relying on graduate medical education funds and free care from providers to finance a large portion of its share of the costs. Twelve managed care programs act as gatekeepers in the TennCare program, but only five operate statewide. Despite legislation mandating these TennCare managed care organizations to enter into contracts with St. Jude's, at the present time the hospital has successfully negotiated only one such contract.

St. Jude's faces additional challenges because of the relative scarcity of cancer in its patient population; there are 8,000 to 10,000 new cases of malignancy among children in this country each year, or approximately 12 to 14 cases per 100,000 children at risk. This small patient population means that it is difficult to accrue enough pediatric patients to maintain a vigorous clinical research program, and that pediatric cancer care is not a major concern for most managed care plans. In addition, St. Jude's has found that once pediatric patients have developed a relationship with a provider, they usually are unwilling to change providers. Finally, most children's hospitals share a fear that third-party payers believe any willing provider can furnish pediatric care.

Key Points

- Despite its strong fundraising abilities, St. Jude's ability to carry on basic and clinical research is expected to diminish in the next few years; at this time, the hospital is experiencing an absolute decline in reimbursement but a 42 percent increase in expenditures is predicted through the end of the decade. St. Jude has recently experienced third-party payer denial of all payment when some portion of a treatment is deemed "experimental." In addition, payment denials for patients

- being treated out of network amounted to 2 percent of charges last year; this percentage is growing.
- Managed care presents special challenges to a program like that at St. Jude's, which restricts its research and treatment efforts to a limited patient population. Inadequate patient accrual may be exacerbated under managed care, since patient care may be based first on cost considerations. Payers often are unaware of the benefits to children of being managed in a comprehensive pediatric cancer program.
 - Perhaps of greatest concern to St. Jude's officials is language appearing in managed care contracts that refuses reimbursement for any treatment provided pursuant to a Phase I or Phase II clinical trial, the experimental arm of a Phase III trial, or care that is delivered, or should be delivered, subject to IRB approval. This language effectively describes most of the care that St. Jude's provides to its pediatric patients.
 - St. Jude's has established three goals to fulfill its mission in the wake of managed care: to secure continued access to patients; to secure this access in a way that allows patients to be eligible for protocols; and to receive a fair level of reimbursement for its services. To maintain access to patients, St. Jude's has sought contracts with payers, but has found this approach to be highly labor intensive given the small number of pediatric cancer patients and the large number of managed care plans. St. Jude's also has developed affiliate relationships with small, nonuniversity-based pediatric programs and selected national organizations to boost its patient population base.
 - Additionally, St. Jude's is undertaking several steps to become managed care "friendly." For example, it is implementing a system that will segregate research costs from those attributable to patient care. The hospital also plans to boost its case management of patients so that payers understand exactly what portion of care is research oriented and what portion is routine patient care.
 - Despite all of these efforts, St. Jude's recognizes that it faces increasing levels of unreimbursed care in the future.

Dr. Georgia B. Vogelsang
The Johns Hopkins University

Key Points

- Although there have been anecdotal complaints about institutions' ability to accrue patients to clinical trials as a result of managed care, confirmatory data do not yet exist. Part of the problem in developing these data is that it is difficult for institutions to track patients who are never referred to them for medical care.
- In addition to refusing to cover clinical trial participation, managed care imposes other significant indirect influences on clinical research. For example, the precertification process to enroll patients on clinical trials has become enormously costly and time consuming. At Johns Hopkins, 70 percent of bone marrow transplant (BMT) patients are from out of town, and over 85 percent are covered by some type of managed care plan. The lengthy preapproval procedures of these plans mean that patients travel to Johns Hopkins to be evaluated, and then return

- home and wait for up to 3 weeks while their managed care plan decides whether the proposed treatment will be covered. This inefficient process increases travel costs, administrative time, and patient anxiety.
- Another difficulty arises from the lack of uniformity in the information managed care plans require in order to evaluate a proposed course of therapy; this forces institutions to individualize each patient's approval process, thereby increasing costs and time. Many plans also mandate that pretesting be conducted through the managed care company's network. This also increases costs for institutions like Johns Hopkins, which must hire additional personnel to recover the pretesting results and then confirm that they are correct and meet the institution's exacting standards. These additional costs support purely administrative functions rather than improved patient care.
 - These indirect results of managed care pose significant problems for providers. For example, the personnel costs associated with bringing a patient into Johns Hopkins for a bone marrow transplant have increased over 400 percent since 1992; they now account for over 3 percent of the total cost of performing a transplant. At the same time, the total cost of performing an allogenic transplant has dropped over 40 percent because of a comprehensive review of the transplant process to reduce costs while trying to maintain/improve patient care.
 - Managed care companies also are shifting many costs to patients; for example, many plans refuse to cover HLA typing for patients seeking a transplant. This means that unless the patient pays for the procedure out-of-pocket, he or she will not be able to have either an allogenic or unrelated donor transplant, thus making the patient ineligible to participate in any trial where these procedures are a therapeutic option. Limitations on outpatient coverage also impact treatment decisions and health care economics. Johns Hopkins has managed to achieve savings of \$20,000 per procedure by performing outpatient versus inpatient transplants; yet over 80 percent of managed care patients who request outpatient transplants are denied by their managed care plans because they do not have outpatient coverage.
 - Finally, follow-up of patients on managed care plans can be difficult, since many companies refuse to allow patients to return to the transplant institution after the procedure. Institutions must then hire additional personnel to recover necessary data from the follow-up providers. Unfortunately, certain technical data often are lost in follow-up since community providers do not have access to the sophisticated equipment or training available at cancer centers or research institutions.
 - At the same time, the emergence of managed care has brought certain improvements in patient care. There now is strict adherence to protocols, which was not always the case in the past. Providers have been forced to evaluate the cost-effectiveness of their treatment decisions, and emphasis has increased on collecting and analyzing outcome data, which, ultimately, should improve patient care because providers will have solid information on which to base patient management choices.
 - Importantly, the ability of institutions to continue to conduct "in-house" (i.e., institutionally sponsored) clinical research is being challenged by a combination

of higher costs to run clinical trials and reduced revenues coming into the centers. In-house research plays a critical role in the biomedical research infrastructure because it is where original ideas are developed to support applications for larger cooperative group studies or funding proposals to the NIH or FDA. At Johns Hopkins, in-house clinical studies are funded out of sums from the comprehensive cancer center and a bone marrow transplant project. Without this type of funding, the institution would be increasingly dependent on industry-sponsored clinical trials to support most of its in-house research efforts.

Drs. Crawford, Warren, Krance, and Vogelsang
Discussion Period

Key Points

- Trials meeting the specifications of the Fox Chase guidelines, which include studies other than NCI-sponsored trials, should be reimbursed by third-party payers. Peer review plays an important role in ensuring that only sound trials are covered.
- Participants agreed that clinical research is too important in advancing cancer treatment to depend on the marketplace or corporate altruism to support its continued existence. Instead, a number of financing alternatives were offered, including the establishment of a pool into which third-party payers, including managed care companies, would contribute a specified portion of their profits to support academic medical centers and clinical research. A second proposal emphasized establishing working relationships between institutions and specific managed care plans so that the risks and costs of clinical research would be equitably shared. Another alternative is Federal legislation requiring third-party payers to contribute to clinical research.
- It was pointed out that precious time is taken away from academic pursuits when medical staff and faculty are distracted by concerns about managed care's emphasis on the bottom line. This diversion from research-oriented tasks, when coupled with the increased administrative demands associated with managed care plans, may result in a significant decrease in productive staff hours.
- One of the positive changes that had been hoped for with managed care was a substantial reduction in paperwork. However, most participants agreed that their administrative duties had increased considerably under managed care. Although Johns Hopkins has experienced an increase in accruals to its transplant trials, the time required to take the patients through the process is increasing; at the same time, reimbursement from managed care organizations is decreasing, as is the amount that the institution can charge for each transplant and still remain competitive. Dr. Vogelsang estimated that each transplant admission requires several weeks and up to 20 to 30 percent of the team's time to prepare the necessary paperwork. These outlays of staff hours do not directly benefit the patient.
- Participants noted that managed care organizations' willingness to reimburse patient care for bone marrow transplant trials is atypical and driven by the high profile such transplants have gained after years of litigation and publicity. Patients

- enrolled in more routine studies are denied coverage consistently, and providers do not have the resources to challenge every denial. One strategy that might be pursued in this area is a national campaign to educate employers—the major purchasers of health care coverage—about the importance of clinical research for their employees and the advancement of health care in general.
- Dr. Krance noted that St. Jude's usually receives reimbursement for most children who are covered by a third-party payer even if treatment is rendered under a protocol. However, he is concerned about the future, particularly given the strong language that Blue Cross/Blue Shield has inserted in its contracts for TennCare and its managed care arm. Thus far, it does not appear that third-party payers find pediatric care enough of a problem to warrant instituting an auditing process, but this could change at any time. Pediatric cancer care also comes under attack because it often is rendered at children's hospitals, which are viewed as expensive health care alternatives.
 - One of the suggestions presented to improve the outlook for clinical research is to educate managed care officials about the benefits, on both an individual and a societal level, of clinical trials. Participants acknowledged, however, that this kind of effort requires an enormous commitment of time and resources.
 - An initial barrier to meaningful dialogue is the mutual distrust between representatives of managed care organizations and academic medical facilities. Often, the managed care officials fear that these institutions exist only to provide high-tech, high-dollar care that may not necessarily benefit the patient. Academic medical centers often are uneasy about managed care's emphasis on cutting costs; in addition, many of the institutions have been involved in relationships with managed care plans that have exploited the Center's reputation for high-quality care but have not resulted in patient referrals. With time and positive interaction, these attitudes of distrust can be broken down so that a discussion of possible collaborative efforts can take place.

INFORMATION DISSEMINATION

Ms. Carlan T. Graves
Duke University Medical Center
Cancer Information Service

Key Points

- The National Cancer Act mandates that information from cancer research be disseminated to the public, patients, and health care professionals. The Cancer Information Service is one avenue that NCI has chosen to meet this public information requirement. In today's changing communications and health care environments, it now is more important than ever to maintain the public's access to information from a truly impartial source.
- Communicating information effectively requires the development of messages that are customized to reach the intended population (e.g., minority and underserved groups, lower-literacy individuals, or the hearing impaired). Today's

- cancer information spans the continuum of care, from prevention, screening, and early detection through diagnosis, treatment, and clinical research.
- Personnel in the CIS office at Duke University have noticed several trends in the volume and types of calls they are fielding from patients utilizing the information line. For example, the growing influence of the resources available through the Internet—Medline, CANCER LIT, the PDQ database, and information about support and discussion groups—has led to an increase in calls from individuals who already possess a great deal of information about cancer. At the same time, the complexity of the questions asked has increased, and it takes longer to help these individuals sort through the variety of available information. Conversely, underserved patients seem to be falling further behind in the acquisition of important cancer information.
 - Managed care also has impacted the types of calls handled by Duke's CIS personnel. Many callers complain about delays in care, the inability to access a second opinion under their plan, or being returned to a primary care physician for follow-up care. Moreover, because more people now have access to information about clinical trials through the Internet, callers are complaining about third-party payers' refusal to pay for protocol treatment. Approximately one-fifth of the calls now result in PDQ searches for information about current clinical trails. More callers also are asking questions about home care concerns because they are experiencing shorter hospital admissions. Finally, patients are questioning the quality of information they are receiving from providers who are operating under "gag" provisions in their contracts with managed care organizations or who are paid on a capitated plus bonus basis.
 - Although it is clear that access to information has increased, it is still difficult to find impartial, scientifically based data and to locate information that patients and their families can understand easily. It is still difficult to implement effective outreach services to the underserved. Dr. Thomas Smith, Massey Cancer Center, has observed, "[A]s medicine looks to the bottom line, nobody is competing for those most in need—the elderly, minority, and uninsured patients. And this is who the CIS serves, and serves well."

Ms. Lynn Erdman
American Cancer Society

Discussion

To assess the needs of consumers for information about cancer, ACS recently conducted three studies focusing on public knowledge and perceptions, both about cancer and organizations providing cancer information, and specifically about services of the ACS. To meet identified information needs, ACS is updating its Infonet system to provide the public with a single reliable and comprehensive source of cancer information. Three working groups have been established to move the project forward: a content work group, a technology work group, and a product work group. At this time, the project is in the second of a three-phase process to be completed in 1998. An editorial board is in place, and several staff have been hired; in addition, ACS has negotiated with NCI to gain access to the

agency's databases. ACS also has developed a process to update this critical information, and a timetable for content development is in place. In January, the national call center will begin pilot testing, with California being the first of 12 field centers to be established.

State and local chapters of ACS also are working to improve information dissemination to the public. California, for example, has developed a broad-based action plan emphasizing patient advocacy, health promotion, outcome measures, and patient services; this plan is being shared with managed care officials in an effort to educate them as well as members of the public.

Key Points

- Outreach and information dissemination are crucial to the mission of the ACS. A recent focus group conducted by the American Association of Retired Persons (AARP) confirmed that consumers need and desire health care information. They lack adequate information about their health plans, are frustrated by the process of enrolling in these plans, often do not readily understand plan performance measures, and are skeptical about patient satisfaction ratings. Consumers want report cards that assess plan performance, but the information must be conveyed in ways that are meaningful to them.
- Cancer information is particularly important to consumers, as illustrated by the popularity of the ACS web site; it is one of the five most visited sites on the Internet today. The number of calls to the site has increased from 10,000 in September 1995 to 450,000 calls in October 1996.
- Many of these calls focus on problems associated with managed care: delayed referral; refusal to allow out-of-network consultations; failure to promptly diagnose and treat medical conditions; and inadequate follow-up care. It is clear that patients face great difficulties in navigating a complicated, frustrating, and ever-changing health care delivery system.
- To address consumers' need for more knowledge about managed care and its impact on cancer patients, ACS has developed an action plan that emphasizes the need to provide accurate, current, and comprehensive information to the public about all aspects of managed care. ACS has identified several steps required to address these informational needs, including:
 - Developing and maintaining a comprehensive information database on managed care
 - Educating and training call center customer representatives on how to respond to questions from the public
 - Developing and disseminating report cards on oncology care for the consumer
 - Developing a consumer manual to assist employees and employers in selecting plans that provide necessary oncology care services.
- In addition, ACS is implementing a program to provide the public with a single reliable source of information on cancer through its 1-800 number and on-line services. The revised Infonet will provide up-to-date cancer information as well as

- direct access to ACS programs and other available community services. Several databases will form the core of Infonet, including an updated version of the CRS database that includes information on clinical trials and cancer literature. Highly trained customer representatives will answer the calls, and provide user-friendly information to patients, their families, or the general public. If these individuals need local ACS services, they will be transferred to the appropriate local unit where representatives can direct them to resources within their communities.
- In designing appropriate information services, it is important to remember that 30 percent of the American public is functionally illiterate, and 20 percent are reading at the third- or fourth-grade level. This latter group obtains most of its information from television, so creating appropriate health messages for that medium is particularly critical.

Ms. Marion S. White

North Carolina Advisory Committee on Cancer Coordination and Control

Discussion

North Carolina has a long history of cancer control initiatives, beginning in 1946 with the establishment of a clinic at Duke that utilized then-new cervical cancer smear techniques. Other significant landmarks include a very early indigent care program and the presence of three of the 27 NCI-designated comprehensive cancer centers within the State. Additional expertise is provided by a strong ACS chapter and a cancer committee of the Medical Society. Many of the State's cancer control activities (e.g., Project ASSIST, the central cancer registry, and a vigorous breast and cervical cancer program) are directly attributable to support from several Federal agencies like the NCI and CDC.

In 1993, the North Carolina General Assembly created the North Carolina Advisory Committee on Cancer Coordination and Control (ACCCC) to coordinate the many cancer control activities within the State and stimulate further collaboration between the various program participants. Over a 2-year period, the ACCCC developed a comprehensive Cancer Control Plan (the Plan) describing action needed to reduce the burden of cancer in the State. The Plan is extensive, covering prevention, early detection, care, legislation, education, coordination, and evaluation, and more than 70 Statewide agencies and organizations have committed to its 188 strategies.

Among the Plan's immediate goals are activities (e.g., physician and public education, third-party payer negotiations, and a physician survey) to increase colorectal screening in the State. The ACCCC also is planning a roundtable to promote a statewide cancer control research agenda. In addition, the ACCCC has worked to educate the State legislature about cancer and the need for effective prevention, diagnosis, and treatment, and is currently drafting proposed language to require coverage of clinical trials and to prohibit employer and insurance discrimination against people with a genetic predisposition to cancer.

The continued viability of clinical trials is another area of concern for the ACCCC. One of its strategies to address this problem is to conduct an extensive needs assessment among practitioners to learn about their awareness of telephone information lines, clinical trials, support programs, and transportation services. This needs assessment will be completed by the end of 1997, and has the support of ACS, CIS, and the North Carolina State Division of Health Promotion. A second part of the strategy to preserve clinical research is to implement a statewide educational campaign focusing on the value of clinical trials in cancer prevention, early detection, and treatment. In addition, a regional conference on minority recruitment into clinical trials will be held next summer. Prior to the conference, the ACCCC will survey physicians to profile which providers currently participate in clinical trials, where they are they located, their specialties, whether they are members of minority groups, and their current patient population. The ACCCC also will conduct focus groups with minority individuals who have participated in clinical trials and those who have declined to identify significant differences between the two groups.

Key Points

- Consistent with national statistics, North Carolina has experienced a decline in mortality from lung cancer for both white men and black men beginning in 1989 and 1990, respectively; unfortunately, death due to lung cancer for women has increased during this period. Data for other types of cancer are too variable to discern clear trends at this time.
- Collaborative efforts, such as we have in North Carolina, can be very effective in cancer control and prevention programs as people come together and find common ground in moving an agenda forward. In addition to providing an opportunity for networking, collaborative efforts furnish a forum in which to address new and emerging issues with a creative synergy that often is not present when organizations work alone.
- Managed care has the potential to improve cancer care in many ways: by educating the public and health care providers about the disease; by providing better screening and early detection techniques to a large segment of the population; and by providing coordinated and high-quality care to people with cancer. However, there are also many problems with managed care, such as access to clinical trials.
- Almost 1 million North Carolinians do not have any type of health insurance, and their access to medical care is severely curtailed. Increasing access to health care and to insurance is a critical need, especially in those parts of the State with high rates of poverty, limited transportation services, and a shortage of health care providers.

Additional Research Needs and Other Recommendations

- Given managed care's increasing influence in the health care marketplace, greater efforts must be made to ensure that its representatives are brought into the

planning and implementation of activities to reduce the burden of cancer. New trials and treatment regimens will not yield the answers needed to make advances against cancer if people cannot enroll in the studies or take advantage of innovative therapies because of restrictive insurance policies.

- The Panel's final report should address issues of access for underserved populations.

Ms. Nancy Weaver Emerson
Duke Comprehensive Cancer Center
Duke University Medical Center

Key Points

- In addition to fighting an emotional and physical battle, today's cancer patients often find themselves fighting their insurance companies over policies that deny them quality care:
 - Outpatient mastectomies, which force women to return home with drain tubes still in place to immediately face the emotional and physical trauma one suffers after having had a mastectomy
 - Restrictive provisions regarding specialist and in-network care that can mean undergoing surgery in a local hospital with no surgical or medical oncologist on staff
 - A lack of supportive care that would help patients to better deal with this life-threatening illness, possible debilitating treatment, and resulting damage to their self-esteem
 - Gatekeeping mechanisms that sever the patient's established physician-patient relationship with an oncologist in favor of a new one with a primary care physician
 - Time-consuming preauthorization processes.
 - Insurers' refusal to cover clinical trials even though they might offer patients the best therapeutic option
 - Gag orders that restrict physicians from telling their patients about all of the available treatments that might benefit them
- California became the first State to pass legislation granting terminally ill cancer patients who have been denied experimental treatment an independent review by outside medical experts; the experts' decision is binding on the patient's plan or insurer. The purpose of the bill was to stem the flow of millions of dollars going into court settlements rather than health care and to ensure that treatment decisions are based on medical science instead of corporate profits. Any patient whose physician certifies that he or she has a terminal condition which has a high probability of causing death within 2 years is eligible for the expert review when a health plan denies treatment recommended by a physician who has determined that standard therapies would not be appropriate or effective. The legislation benefits patients who will have the comfort of knowing that treatment decisions are being made by an independent panel of experts who have no conflicts of interest. Third-party payers will benefit from reduced litigation.

- Unfortunately, it often appears to patients that managed care companies are not really lowering the costs of medical care. Instead, it seems that costs are being shifted to patients and their families who sometimes are forced to take drastic actions (e.g., taking out second mortgages on their homes or ending a marriage so that a spouse qualifies for Medicaid) to receive the treatment that they and their physicians believe offers the best therapeutic option.
- Society must begin to answer difficult questions like the following if it is to ensure that all people receive quality cancer care:
 - Is it right to allow insurers to drag their feet about making treatment decisions while a cancer patient's health continues to deteriorate to the point that his or her life cannot be saved?
 - Is it right for insurers to decide what is best for a cancer patient when a knowledgeable physician has recommended what he or she believes will best serve the patient?
 - Is it right that patients are denied access to promising clinical trials after they have exhausted standard treatments?
 - Is it right that patients are not told about the best treatment options?
 - Is it right that families are forced into financial difficulties during a time of crisis while insurers play a waiting game?
 - Is it right that teaching institutions that train tomorrow's health care providers are facing dire financial straits because of changes in the financing and delivery of health care?
- The President's Cancer Panel has the opportunity to make a difference to the more than 1 million individuals in this country who will be diagnosed with cancer this year. The panel can put the "can" in cancer by suggesting needed changes in the way we do business today.

Ms. Graves, Ms. Erdman, Ms. White, and Ms. Emerson
Discussion Period

Key Points

- The evolving health care system, including the emergence of managed care, has increased the need for accurate, up-to-date, comprehensive information about cancer, which, in turn, increases the demands on information specialists. Many information services are handling a growing volume of calls, and the time needed to answer each call is becoming longer as people ask more sophisticated questions. Information specialists must possess a wide range of communication skills, since they talk to people with literacy problems as well as Ph.D.s who have already gained a large body of information from the Internet.
- While the Internet clearly provides the opportunity to expand the information available to the public, it is important to realize that at this time there is no quality control mechanism built into this information channel. This can sometimes result in the need for clarification and correction by information specialists. Additional resources to support more information technicians and phone lines, as well as ensuring that providers are able to spend sufficient time with patients to answer

their questions, would greatly assist information services in meeting the needs of the public for cancer information.

- Information service providers now are being asked to convey extensive medical information to patients who have been discharged relatively quickly following treatment. This trend raises a number of troubling issues, including whether NCI's support for these information services may, in fact, be subsidizing medical care costs that really are the responsibility of insurers. Similarly, many costs have been shifted to families who now are responsible for providing an unprecedented level of home care.
- The recommendations of the President's Cancer Panel will receive more attention from policy makers if the hurdles to quality care that have been described throughout its meetings are portrayed as systematic problems impacting society at large rather than anecdotal evidence of specific individuals' problems. The Patient Advocate Foundation may be able to assist the Panel in effectively gathering data to confirm managed care's impact on quality cancer care.
- Participants acknowledged that the uninsured population presents a growing problem that probably cannot be solved in the absence of a universal health care system; however, it is unlikely that a move in this direction will be politically viable in the near future. Dr. Freeman noted that the Panel is concerned about the lack of universal access, especially for patients facing a deadly disease which will kill them if they are not treated in a timely manner. It was suggested that progress on this front could occur if a coalition was formed of labor unions, employers, and other organizations for which health care benefits are a major concern.

CLOSING REMARKS

Dr. Harold Freeman

In his closing remarks, Dr. Freeman noted that:

- Testimony during the four regional meetings of the Panel has established that the United States is undergoing a rapid revolution in the health care delivery system. Managed care already has penetrated 75 percent of the market in the western part of the country, and it is making rapid inroads into the eastern markets as well. This growth is attributable to the fact that the United States could not continue to support double-digit rises in health care expenditures.
- Managed care has the potential to improve patient care in many ways: an increased emphasis on cost-effective therapy, the development of better outcome data and guidelines to assist providers in making difficult treatment decisions, and greater protocol specificity.
- To date, however, managed care companies have been driven principally by cost containment, so that managed care at this stage of its evolution is really managed cost, and that outlook can present some disadvantages and challenges in securing quality care. Managed care's short-term focus on the bottom line sometimes interferes with making the long-term commitment to infrastructure that is necessary if the Nation is to continue to offer the best medical care in the world. In order to preserve this country's place as the leader in cutting-edge technology,

- we must continue to support the academic medical centers and clinical trials that lead to improvements in patient care against a disease like cancer. All too often, however, patients have found it difficult to participate in clinical trials because their managed care plans refuse to cover such treatment. At this time, it appears that accrual rates are dropping in some areas of the country, an unhealthy trend that cannot be allowed to persist.
- Other issues were raised concerning managed care's impact on quality cancer care. Many institutions have experienced a significant decline in reimbursement for their services while their costs in providing care continue to increase. The preauthorization requirements of managed care companies differ from plan to plan, requiring institutions to devote additional, valuable staff time to paperwork rather than patient care. Often, members of the most vulnerable underserved populations--the elderly, the poor, and minorities--are the individuals who suffer the greatest impact in this changing world.
 - Ultimately, ethics, morals, and values related to both quality and efficiency are tremendously important in addressing difficult issues like the following:
 - Will managed care evolve and mature so that its apparent dangers are relatively short-term phenomena that will give way to long-term solutions?
 - What is the role of NCI in providing sufficient support for clinical research?
 - Who, ultimately, will bear the cost of clinical care that is associated with research?
 - What steps can be taken to increase access to clinical trials in underserved populations?
 - What steps can be taken so that the uninsured also have access to quality health care?
 - It is difficult to assess definitively either the benefits or the disadvantages of managed care at this time, especially since its impact in a particular region seems to correlate with market penetration, and this varies widely throughout the country. It is clear, however, that managed care has modified the traditional doctor-patient relationship and transferred the responsibility for making most decisions into the hands of CEOs who are reporting ultimately to stockholders. This change does not appear to be resulting in better care of patients.
 - Speakers have suggested the great benefit that can emerge from opening dialogues with managed care officials and educating them about the importance of maintaining quality cancer care, including access to clinical trials. While this approach does indeed hold out promise for the future, it must be noted that it is very time consuming, especially given the many managed care plans that currently exist throughout the country. Other speakers have suggested the need for legislation to regulate some of these issues, an approach that may be necessary given a market that seems to have no conscience.
 - The Panel has appreciated hearing the various viewpoints expressed throughout its four meetings, and will distill this information into a final report to President Clinton.

NATIONAL CANCER INSTITUTE CLINICAL TRIALS

**(DOLLARS in THOUSANDS)
FY 1995 Actual**

	Non-AIDS		AIDS		Total	
	No.	Amount	No.	Amount	No.	Amount
Research Grants Research Proj:						
Noncompeting	205	\$56,243	7	\$2,811	212	\$59,054
Admin. Supp.						
Competing	141	55,645	3	771	144	56,416
Subtotal	346	111,888	10	3,582	356	115,470
SBIR/STTR	3	254			3	254
Subtotal, RPG	349	112,142	10	3,582	359	115,724
Research Centers						
Spec/Comp.	11	22,279			11	22,279
SPORES	4	4,964			4	4,964
Subtotal	15	27,243	0	0	15	27,243
Other Research						
Coop. C1. Groups	151	74,882	1	310	152	75,192
Other	0	0			0	0
Subtotal	151	74,882	1	310	152	75,192
Total RGs	515	214,267	11	3,892	526	218,159

R&D Contracts	10	6,549	6	4,759	16	11,308
Intramural		28,997		44,081		73,078
RMS		0		1,488		1,488
Control						
Subtotal, Control		80,784		0		80,784
Construction		0		0		0
Total, NCI	525	330,597	17	54,220	542	384,817