PRESIDENT'S CANCER PANEL
Where Are We Today?

July 30, 1996
Seattle, Washington

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 was to begin an in-depth exploration of managed care mechanisms and issues affecting the conduct of clinical research.

Sixteen speakers described institutional, economic, and medical issues and barriers in conducting clinical cancer research and securing payment for associated patient care costs. Discussions focused on geographic and market issues specific to the greater Northwest and California, and on the experiences of Community Clinical Oncology Programs (CCOPs) in the region. Cost and patient management issues were also presented from the perspective of managed care providers.

Opening Remarks

Dr. Harold Freeman
Chairman

In opening the meeting, Dr. Freeman indicated that:

- The purpose of the meeting was to explore the process of bringing cancer advances to the public as it is affected by managed care. The meeting represents the first of a series of four meetings on this subject, which will examine how to maintain the capacity of clinical investigators to conduct research, maintain outreach activities and research dissemination, and improve the availability of quality health care nationwide.
- Enrollment in managed care plans has increased steadily since the 1970s. Recent years have seen an explosion in managed care enrollment; currently, more than 58 million Americans are managed care enrollees. Enrollment growth in these plans is likely to continue.
- In addition to the conversion of traditional fee-for-service health coverage to managed care mechanisms, proposals have been made to convert Medicare into a managed care system, and Medicaid conversion into managed care is already proceeding.
- Managed care is profoundly changing not only the way medicine is practiced, but the way clinical research is conducted. Dr. Freeman expressed his view that managed care is essentially market driven, focusing primarily on promoting cost containment with relatively less focus on research findings and their translation into practice. Application of research findings has historically been the means by which medical care has been improved.
- Many research institutions are already being affected by managed care. Many third-party payers refuse to allocate money to permit patients to participate in research clinical trials or to reimburse for costs associated with investigational or experimental therapies. The policies of managed care plans concerning clinical research protocols and reimbursement for clinical care vary considerably and

change frequently, resulting in new fiscal and administrative burdens for research organizations. In addition, financial incentives are shifting cancer care from major cancer centers into the community, where there is less control over quality and less reporting of clinical outcomes.

- The Panel continues to be concerned that economics that favor managed care and its emphasis on cost containment may sacrifice access to quality medical care and ultimately impede the ability of the research community to translate research results to the public benefit.
- The war on cancer cannot be won from the laboratory alone. Cutting-edge therapies cannot be developed without testing them in humans. Clinical research on all aspects of cancer prevention and care must continue to be supported, as must patient access to investigative clinical trials and the application of research findings to the public.
- It is hoped that this series of meetings will continue the positive dialogue that has been opened by the National Cancer Institute, from which payers, providers, and, ultimately, recipients of care will benefit.

Director's Remarks

Dr. Richard Klausner
Directror, National Cancer Institute

Dr. Richard Klausner noted that:

- Because our preventive and therapeutic interventions for cancers of all types remain largely inadequate, a research-based approach to oncology is essential. Effective models for clinical research and information exchange cannot be divorced from the settings in which patients are located, their access to care, and the care for which payment is available.
- Despite concerns about the impact of managed care on clinical research, the realignment of health care mechanisms also holds opportunities for creating partnerships that both solve the relevant financial issues and ensure that academic centers survive, that the organization of medicine that has yielded so much progress in past decades is preserved, and that population-based and patient research is continued and even expanded.
- Over the past year, the NCI has taken an increasingly active role with providers and payers of all types to identify issues and barriers to the participation of managed care organizations and other payers in the national research program.
- Much of the clinical and cost information about patients in trials is lost or collected in ways that make it impossible to determine accurately added costs, if any, associated with trials or to reliably aggregate patient data. It is essential that we begin to do a better job of collecting patient information to move beyond anecdotal data on clinical care associated with clinical research. Discussions such as the one planned for this Panel meeting are crucial to discern potential responsibilities, opportunities, and options for answering these questions, ensure that clinical trials are simple and accessible, and guard against the loss of cancer care advances because of short-term financial incentives.

- Despite the differences that now exist, it is reasonable to believe that continued communication among payers, providers, and the research community will produce some agreement that quality care cannot be dissociated from the issue of optimum outcomes, and that optimum outcomes for diseases like cancer cannot be attained without research. It also is reasonable to believe that managed care plans that offer optimal, cutting-edge care—including care provided through clinical trials—will enjoy a competitive advantage.
- One of the partnerships now being forged is that between the NCI's distributed research system (e.g., the cancer centers, Community Clinical Oncology Programs, and cooperative clinical trials program) and the Department of Defense, which is the provider-payer for 8.3 million people in the United States. As part of this partnership, NCI and the DOD have agreed to work together to gather data necessary to answer some of the key questions about added incremental costs associated with clinical trials participation. In addition, a major effort will be made to dispel misperceptions and improve communication with providers about clinical research, and make it easier for providers to participate.

Welcome

Dr. Robert Day
Director, Fred Hutchinson Cancer Center

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

- He concurs with Dr. Klausner's observation that we lack information about marginal costs in clinical research trials. Moreover, we lack an accurate profile of clinical trial participants compared with the general population of patients with cancer. Such a profile needs to be developed, perhaps by assessing current and changing patterns of care among newly diagnosed cancer patients, to determine whether people are receiving the benefit of clinical trials and the most advanced cancer management strategies.
- In 1993, the legislature of the State of Washington enacted a sweeping health care reform package similar to that proposed nationally by the Clinton Administration. Dr. Day and others at the Fred Hutchinson Cancer Research Center worked with the committees that designed and implemented the legislation to emphasize the importance of continuing support for patient care costs associated with clinical trials and for research education costs. The legislation was largely repealed in 1995, with no resolution on the issues of research and education costs. These issues remain and it will be important for those in academic medicine to remain ready to work with the evolving health care payment mechanisms to ensure the viability of these components of the health care delivery system.
- Under Dr. Klausner's leadership, the NCI has instituted major efforts to work with Federal insurers (e.g., DoD, the Health Care Financing Administration); the outcomes of these efforts will greatly influence the future actions of health care payers of all types throughout the country.

PRESENTATION HIGHLIGHTS

EXPERIENCES IN THE GREATER NORTHWEST

Where are we today?

Dr. Frederick R. Appelbaum
Fred Hutchinson Cancer Center

Background

Unlike most cancer centers, the Fred Hutchinson Cancer Research Center is solely a research-based organization; as such, nearly all patients at the Center are entered onto clinical trials. Those not eligible for available trials are typically referred to other institutions for treatment. Research at the Hutchinson Center is focused principally on marrow transplantation and related antibody-based therapies and adoptive immunotherapies.

Key Points

- Because of the inadequacy of existing cancer prevention and therapeutic outcomes, clinical research is necessary and reliance on research conducted in Europe or by pharmaceutical companies is unacceptable.
- In a study conducted at the Hutchinson Center more than a decade ago comparing marrow transplantation with experimental chemotherapy for the treatment of acute myelogenous leukemia (AML), 15 percent of eligible patients could not receive treatment under the study solely because their third-party carriers refused to pay. All of these patients were to be entered on the marrow transplantation (i.e., more costly) arm of the study. While transplants are now accepted treatment for AML, payers are now refusing to cover participation in marrow-transplant studies for other malignancies. Over a third of marrow transplanted AML patients in another study who were eligible for subsequent therapy with interleukin-2 (IL-2) were not treated because their third-party carriers refused coverage. In a recent survey of 75 patients receiving transplant consultations at the Hutchinson Center, 68 were determined to be eligible for the procedure; however, the payers for 12 of these patients refused to permit transplantation at the Hutchinson Center (but did cover the procedure performed elsewhere) and the payers for 12 others refused transplantation at any location because of the patients' presenting disease. Taken together, these data suggest that 10 to 25 percent of patients who would be eligible for a study are not allowed onto the study at the institution of their choice because of third-party carrier issues. The underlying issue appears not to be cost per se, but the reluctance of the health plan to pay more for a procedure than its competitors; thus, the plan may allow the procedure, but insist that it is provided at the lowest-cost facility.

- Clinical trials costs associated with patient registration, data monitoring, and unique research laboratory tests are normally covered by grants or drug companies and are not the concern of third-party carriers. Patient care costs of trials that may exceed the cost of care for standard therapies for specific diseases comprise the financial barrier to broader clinical trials participation, and we have inadequate data on these costs. The Hutchinson Center developed a methodology to estimate these costs for all types of clinical research in the State of Washington and found that the average differential inpatient cost per case on trial in 1993 was approximately $5,400. This figure, multiplied by the number of patients on trials, represents approximately a 0.5 percent increase in total statewide health costs over treatment with conventional therapies. Costs of this magnitude need not be an impediment to access to trials if all payers share in them equitably.
- Payers will be more likely to be amenable to shouldering these costs if they are assured that clinical studies are methodologically sound, informative, and efficiently run. In addition, it is the responsibility of the research community to inform the public of the value of clinical research studies so that the public will demand the inclusion of such studies in health benefit plans.

Discussion

Discussion following Dr. Appelbaum's presentation included additional key points:

Key Points

- It cannot be known with certainty that patients denied access to a clinical trial are being denied a medical good or benefit. Clinical research, by nature, asks a question about the efficacy of one intervention compared with another. Studies are not done in the absence of such a question. Every sound clinical trial should provide the opportunity to advance the quality of care, since prior evidence and the review process should assure that the experimental treatment is as good as or better than the best conventional therapy for patients at a particular stage of disease.
- In a Phase II study, the question is whether there will be response where there has been none with other drugs or a response as good as what is hypothesized with the experimental treatment. In Phase I studies, there is no standard therapy that is effective for that patient. It should also be noted that with the development of predictive animal models and therapies (e.g., immunotherapies) that do not follow the classic dose escalation scheme, the lines between Phases I, II, and III are becoming less distinct.
- Regarding the survey of patients whose insurers refused to permit transplantation at the Hutchinson Center, those that received transplants did so at institutions that typically do not publish research studies. As a result, treatment, outcome, and cost data on these patients are probably lost.
- Patients are more likely to be refused entry into a study if the experimental therapy stands out, e.g., requires a second hospitalization or is very different from conventional therapy.

- The Hutchinson Center receives support from pharmaceutical companies for some of its studies. Many other studies involve therapies developed using in-house reagents, and thus have no pharmaceutical company support. Although industry has a significant role to play in academic clinical research and the relationship between industry and academia is an important one, it must also be recognized that pharmaceutical companies are highly focused on rapid drug approval. As a result, they take a very narrow approach to the conditions for which they will allow a drug to be studied and the toxicities and unusual outcomes they will investigate. Therefore, overreliance on pharmaceutical company-sponsored research is unwise.
- It is a growing problem that while patients are appropriately becoming more involved in decisions regarding their care, experimental treatments are being seen as the best treatment when clinical trials have yet to demonstrate that this is so. Patients are demanding coverage from their payers for experimental treatments; bone marrow transplantation for breast cancer is a prime example of this situation. It is in the interest of payers and researchers alike to effectively and quickly provide the answers to these efficacy questions by supporting the conduct of research; it is the only way the struggle between payers, participants, and providers can be resolved.
- When patients are not allowed on clinical trials or when the rate of refusal is high, three key changes are likely to occur. First, the time required to complete trials will be lengthened. Second, the mix of patients entering clinical trials is likely to be skewed toward those in higher socioeconomic groups because they are able to pay out-of-pocket and/or they are successful in fighting their insurers to secure treatment. This shift may result in clinical trial results that are not applicable to the general population. Finally, the type of clinical trial being conducted may shift; trials in which the experimental arm is easily identified by the payer from the standard treatment will be avoided.
- Dr. Appelbaum estimated that, as Director of the Clinical Research Division at the Fred Hutchinson Cancer Research Center, he spends at least one-third of his time addressing third-party payer, cost, and related issues so that researchers at the Center can continue to carry out clinical trials. At present, there is a strong move among managed care plans of different types to establish a negotiated global fee to cover all transplant-related services; treatment costs for approximately one-quarter of the transplant patients at the Center are paid for in this way.
- Like other centers, the Hutchinson Center is reducing inpatient stays and providing more treatment in the outpatient setting. Dr. Appelbaum noted the added burden this shift places on the patient and the patient's family members, who typically become the patient's caregivers in these circumstances.
- To appropriately track patients on trials conducted predominantly or exclusively in the outpatient setting, and related costs, data collection mechanisms will have to be strengthened.

Dr. Oliver W. Press

University of Washington

Background

The University of Washington is a regional medical school that relies heavily on several key affiliations to accomplish its service and academic missions. Clinical practice and research are conducted at several sites, including the University of Washington Medical Center, the VA Medical Center, Harborview Medical Center, Children's Hospital Harbor View, and the Fred Hutchinson Cancer Research Center. The catchment area of the University of Washington includes 28 percent of the land mass of the United States, and includes the States of Washington, Alaska, Montana, and Idaho; Wyoming will be added next year. Because of its regional focus, the University of Washington has been ranked the number one medical school in the country for primary care. Since its inception, the School of Medicine has also had a major focus on basic biomedical research. As of fiscal year 1995, the University of Washington ranked sixth in both the number and dollar value of National Institutes of Health (NIH) research grants awarded, excluding awards to Hutchinson Center-based School of Medicine faculty.

The Medical Center supports about 1,200 faculty; of these, most are in the traditional clinician scientist career pathway, but there are 158 full-time research faculty. A newer career path, the clinician educator (80 percent of time spent treating patients, 20 percent spent teaching), is receiving increased emphasis and is expected to grow as competitive pressure for greater clinical activities intensifies.

In addition, the School of Medicine has about 1500 students, of whom approximately half are medical students. The School of Medicine also supports approximately 950 residents and an equal number of fellows split approximately evenly between basic science and clinical departments.

Key Points

- Like most major medical schools, the University of Washington is highly dependent on research grant funding and patient care revenues to carry out its academic mission; though a State institution, only 9 percent of funds come from State sources. There also is increasing pressure to maintain patient care funding levels in the face of intensifying competition. Attending physicians are being called upon to spend more time in direct patient care, which curtails time available to apply for grants.
- Outpatient visits to the cancer center for cancer care of all types have been increasing over the last several years; in contrast, inpatient care, as reflected by revenue, has flattened and declined slightly over the same

period. This is believed to reflect a shift to outpatient cancer care rather than reimbursement constraints.

- Over the last 5 years, the payer mix for inpatient care has been relatively stable--approximately half commercial insurance, 15 percent Medicaid, 27 percent Medicare, and a small percentage of self-pay. Of these patients, 56 percent are managed care plan participants. This percentage has also remained stable over the past 5 years, but managed care patients are more stringently managed than previously (e.g., a change from prior authorization and retrospective review to capitation for the Medicaid population).
- The Seattle-area health care marketplace is in a period of rapid consolidation, evidenced by the emergence of several integrated provider systems and consolidated multispecialty clinics and physician groups. Few unaffiliated independent primary care physicians remain in Seattle.
- Most of the insured lives in the Seattle area remain in large preferred provider organizations (PPOs), but the State's largest employers increasingly are pressuring employees to choose the more strictly managed health plans. Managed care enrollment in the Seattle area is estimated at 70 to 80 percent.
- Changing attitudes of the insurance and managed care companies has had a significant effect on the conduct of clinical research at the University of Washington. Payers contend that payment for patients on trials should come from the trial's sponsor, as should ancillary tests and procedures performed in the course of the trial, even if the test is part of standard care. In addition, they contend that medical education and training should not be part of costs they pay, and despite local cost analyses showing otherwise, that academic medical centers are inherently expensive because they use newer technologies and are engaged in research and teaching. It is particularly difficult to get approval for participation in Phase I and II trials.
- These prevailing payer attitudes create a dilemma for clinical research: NIH grants do not cover patients' clinical costs, nor does support from many of the smaller pharmaceutical companies. In addition, patients who have chosen the lowest-cost and most restrictive health plans while healthy resent restrictions on access to the newest protocols and technologies once they develop cancer.
- Changing payer attitudes are also reflected by the decline in patient approvals from 95 to 65 percent over an 8-year period for a radiolabeled antibody treatment for lymphoma, despite publication of major papers demonstrating the treatment's efficacy. These refusals mean that more eligible patients must be evaluated to achieve the same accrual rate; further, some eligible patients are told they cannot participate because the University is not one of the health plan's preferred providers.
- It is becoming increasingly difficult for academic physicians to excel as clinicians, researchers, and teachers. They are under pressure from their institutions to generate more revenue through direct patient care, and are

under pressure from managed care plans to see more patients in less time. This dynamic and increased paperwork burdens limit time for laboratory research. Academic physicians with clinical responsibilities are finding it more difficult to compete for research funding against full-time laboratory researchers. In this scenario, teaching suffers most, since no one wants to pay for it and there are few incentives for achieving excellence.

Discussion

Discussion following Dr. Press' presentation included additional key points:

Key Points

- Accrual to NCI-supported trials has remained steady; however, we lack accurate data on how much additional time and effort is required, because of payer restrictions, to maintain accrual rates. These data, and detailed information on the reasons for denial of coverage for different trials, are needed to support negotiations with payers.
- In many cases, the extent of negotiation with the payer required to get approval for participation in a trial has more to do with the type of protocol (e.g., if there is an unusual or expensive aspect of the treatment) than the type of payer (e.g., managed care versus indemnity). Some managed care organizations routinely deny coverage for any treatment that can be recognized as experimental. In one trial cited by Dr. Press, the company making the agent under investigation (an antibody) has decided to design the trial using a lower dosage that requires less inpatient time (and thus less difficulty from insurers concerning coverage) even though it has been shown that higher doses produce higher overall and complete response rates and longer remissions of disease. Similarly, only indispensable ancillary tests are now included when designing clinical trials, because it is recognized that other tests, while desirable, will not be paid for by insurers.
- It was also noted that differential cost data for trials do not exist because they have not been needed in the past; fiscal discipline imposed by managed care may have the positive benefit of forcing researchers to examine priorities and economic tradeoffs.

Dr. Peter O. Kohler

Managed Care and the Oregon Health Sciences Center

Background

The population of Oregon is approximately 3 million; by 1996, enrollment in managed care plans of various types had reached 1.34 million. Managed care enrollment in the Multnomah County/Portland metropolitan area is estimated at 80 to 90 percent. Oregon has one of the lowest inpatient utilization rates in the country, consistent with lower rates in the Greater Northwest compared to other regions.

Oregon Health Sciences University (OHSU) is a traditional academic health center that includes a medical school, hospital, nursing school, dental school, allied health programs, and various research institutes. It is the only academic health center in Oregon, drawing much of its patient population from Portland, but with a statewide presence. Much of its primary care is provided to the indigent population of the Portland metropolitan area and OHSU serves as a crucial part of the health care safety net for the State. OHSU has always specialized in pediatric oncology and treats about 70 percent of pediatric cancer cases in the State. It also maintains a network of teaching arrangements.

Increasing managed care enrollment and passage of the Oregon Health Plan (with the resulting loss of revenue from the Medicaid population served by the center, replaced by a growing patient population from among the working poor) demonstrated that the center needed to realign its role in the marketplace to continue successful operations. Administrative functions were consolidated, but unlike similar activities in other States, the University hospital and other organizational components were retained. Collaboration with the Oregon Health Plan to provide service to Medicaid patients, participation in statewide consortia, development of a statewide clinic network, and cooperation/competition with other programs have also been undertaken. Finally, the University was restructured to form a public corporation, though its mission remained unchanged. It has gained greater fiscal accountability and independence, simplified decisionmaking, and a more business-like culture.

Key Points

- Though wide variation exists, some managed care plans are committed to research. OHSU has worked closely with plans to convince them to participate in clinical research. Among certain plans, a concept of "managed research" is emerging that reflects the perspective of those at risk. Criteria that might increase the willingness of plans to participate in at least some clinical studies include: external review by NIH or a similar independent body/group, quality standards for studies, a prioritized selection process for study participants (which requires definition), and possible risk assignment to the research institution.
- Definitions of managed care organizations vary, but the key variables are the source and magnitude of risk and the responsible payer.
- Oregon Health Sciences University is at risk for its capitated business (primarily Medicaid patients) and can make decisions to authorize participation in clinical trials; for its managed care business (82 percent of revenue), the health plan is at risk and must authorize entry onto clinical studies.
- As has occurred in other health markets, the escalation of the managed care presence in Oregon has resulted in health care institutional change at all levels and the formation of strategic alliances between several large payers and providers.
- OHSU has had to reduce its length of stay to remain competitive, despite the fact that it provides a high volume of trauma care and is the solid organ transplant

facility for the State. Still, some payers in the metropolitan area are deflecting patients away from the center.

- Graduate medical education and indirect medical education payments, which have been tied to acuity of care, are at risk and are likely to continue to decrease. Federal legislation has been proposed to create a trust fund to support medical education at academic health centers, but its passage is unlikely at this time because of the perception that there are too many physicians and because academic health centers have not adequately made the case that they provide sufficient added value.
- In addition to the negative effects of managed care on clinical research previously cited, Dr. Kohler anticipates that it will become more difficult to attract young investigators into research careers. OHSU is making a particular effort to recruit young scientists, young physicians, and Ph.D.s into clinical research and clinical trials.
- The political arena adds uncertainty to the future of managed care since legislators tend to respond to the pressures of the moment.
- OHSU is also establishing statewide networks for trials, other cooperative agreements (with community providers), and partnerships with private foundations, medical technology and pharmaceutical companies, integrated health networks, and others. Also under consideration are increasing use of the World Wide Web for research and information purposes and emphasizing translational research.
- It remains to be seen how far the pendulum will swing in the direction of capitated managed care. Dr. Kohler predicted that there will be a backlash against managed care plans unconcerned with quality. He believes that new knowledge gained through the conduct of clinical trials can be made a requisite component of quality care and become a competitive advantage for the better managed care organizations.

Additional Research Needs and Other Recommendations

- Health care providers should reinforce public demand and media attention concerning quality of care under both managed care and indemnity payer systems.
- Future needs include: increasing NCI funding for translational research to bring the benefit of discoveries to the public, mandating access to clinical trials, where appropriate, establishing clinical research training as a cornerstone of all oncology programs, and developing systems to secure and manage data produced in networked centers.

Discussion

Discussion following Dr. Kohler's presentation included additional key points:

Key Points

- Public support for the NIH budget is strong and is likely to remain so. For this reason, a viable career path for young clinical investigators is probable, despite the impact of managed care on clinical research. Greater promotion of the value of clinical trials will help ensure the continued flow of intellectual talent into clinical research. It is increasingly the case, however, that young people are being forced to choose between a career in laboratory research and one in clinical medicine; it is becoming far more difficult to do both.
- At the University of California, Los Angeles (UCLA), a deliberate decision has been made to move away from the expectation that each faculty member should excel as a clinician, researcher, and teacher (the "triple threat"). Instead, UCLA fellows now spend 5 years at the institution; in addition to board eligibility in hematology oncology, fellows must choose between clinical research, health services research, and basic research and are awarded additional degrees in the area they pursue. It is hoped that academicians will thereby become more specialized and more competitive in the market.
- In moving away from the "triple threat" responsibilities of individual research, faculty responsibilities, and clinical care, care must be taken that individuals still exist who have the breadth of training (e.g., in both laboratory and clinical areas) to conduct translational research.
- Programmatic organization of a cancer center can help to ensure cross-fertilization of ideas, recognition of translational opportunities, and a team approach to conducting translational research. To be successful, however, cooperative efforts must be rewarded as much as individual successes.

COMMUNITY CLINICAL ONCOLOGY PROGRAM EXPERIENCE

Dr. Paul L. Weiden
Community Clinical Oncology Program
Virginia Mason Medical Clinic, Seattle

Background

Virginia Mason Medical Clinic (VMMC) was one of the original CCOPs funded in 1983; it covers metropolitan Seattle, western Washington, and Alaska. Changes in VMMC in the 13 years since its inception reflect changes in the health industry. It has grown from a largely downtown referral specialty practice (a group practice partnership) with three locations and 110 physicians to a regional specialty and primary care practice with 25 facilities and 354 physicians practicing as employees of a not-for-profit corporation. VMMC has a strong independent residency program and a long tradition of clinical research.

A recently concluded agreement between VMMC and Group Health Cooperative of Puget Sound will result in Group Health becoming part of the Virginia Mason CCOP in 1996. Shifting institutional alliances in recent years, however, threaten other established relationships.

Key Points

- In 1983, compensation of physicians at Virginia Mason depended only one-third on physician productivity; fully one-third was based on physician participation in clinical research, publication, and other activities that brought credit to the medical center. In 1996, productivity has all but eclipsed professional achievement valuation.
- Although the potential patient benefit of studies conducted under the Community Clinical Oncology Program is generally superior to the Phase I studies conducted in collaboration with a local biotechnology company, compensation of investigators, research support staff, and patients participating in the industry-sponsored studies is vastly greater. This creates a fiscal bias toward industry-supported studies.
- The design of pharmaceutical company clinical studies is often driven more by Food and Drug Administration requirements and limitations related to FDA approval than science.
- All CCOP studies may not be perfect, but they generally are high-quality science. Frequently, however, the most interesting science involves submission of extra blood or tumor samples; NCI generally does not give additional CCOP credit for the additional work required to support good science in this manner.
- Clinical cancer research must provide value if it is to survive as part of the clinical practice of medicine, particularly in the private sector. When appropriate in focus and design, it has the potential to improve outcome and provide increased service to patients, but it must be done with less cost.
- Managed care has affected VMMC at an institutional level (e.g., shifting alliances, corporate emphasis on value) more than at the level of individual patient provider decisions. At the same time, the corporate emphasis on value has led to decreased utilization and inpatient lengths of stay.
- For-profit health care providers may be less likely than not-for-profit providers to be concerned about clinical research. This distinction may be more important than whether a payer is a managed care or indemnity plan.

Additional Research Needs and Other Recommendations

- Since all health plans benefit from improved knowledge regarding therapeutic effectiveness, mandate direct research support by all health insurance plans (perhaps 0.5 percent of total premiums).
- Provide adequate grant support to physicians, support staff, and perhaps patients involved in clinical research to reverse the current monetary bias favoring industry-supported studies.
- Eliminate excessive and costly tests for patients participating in NIH-sponsored protocols.
- Minimize unnecessary and costly administrative requirements (e.g., Institutional Review Board (IRB) requirements; Office for Protection From Research Risks (OPRR) requirements; grant application and data-reporting requirements).
- The original goals of the CCOP remain viable and appropriate in 1996 and must remain part of the evolving managed care environment.

Dr. H. Irving Pierce

Northwest Clinical Oncology Program

Background

The Northwest CCOP consists of a consortium of 39 physicians and 11 community hospitals in four counties in southwest Washington and the Kaiser Permanente hospital in Portland, Oregon. The CCOP serves a population base of approximately 500,000 people in the State of Washington, and 375,000 people in the metropolitan Portland area. It is affiliated with four research bases, including the Southwest Oncology Group, the M.D. Anderson Cancer Center, the National Surgical Adjuvant Breast and Bowel Project (NSABP), and the University of Rochester, which together provide access to approximately 120 clinical treatment and prevention studies. Annually, the CCOP places 60 to 75 patients on treatment studies and another 100 on prevention and control studies.

In 1994, physicians in Tacoma, Washington, and the Pierce County Medical Bureau reached an agreement for reimbursement for services provided in Phase III clinical trials. Prerequisites for reimbursement include trial approval by the FDA, NIH, cooperative research groups, or CCOP; approval by a qualified IRB; evidence that no clearly superior noninvestigational treatment exists; data demonstrating reasonable expectation that the protocol treatment is at least as efficacious as noninvestigational therapy; and assurance that the facility and personnel providing treatment are qualified to do so by virtue of experience and/or training. Phase I and II studies are not included in this agreement, and coverage for off-label use of certain chemotherapeutic drugs is decided on an individual basis. The Pierce County Medical Bureau has recently joined the larger, regional Benchmark Groups, and it remains to be seen if this agreement will be extended to the other member organizations.

Key Points

- The insurability of patients with cancer remains a topic of concern among oncologists nationwide. Cancer is inordinately expensive to treat, complications are rampant, and limited treatment success means sometimes prohibitively expensive treatment is provided over a longer duration.
- Physicians must be continually aware of costs and must streamline, consolidate, and sometimes limit care they provide (including diagnosis and treatment) based on what the insurer will allow.
- Factors affecting CCOP physicians' ability to accrue patients to clinical trials include lack of community physician interest in clinical trials, lack of an available protocol for a given disease condition, lack of patient interest in experimental treatment, and concern that treatment provided under clinical trials will not be covered by insurers.

- Though there is increasing concern about payer participation in clinical trials as managed care and capitated contracts expand in the Pacific Northwest, lack of coverage (except for bone marrow transplantation for breast cancer and certain other conditions) has been a relatively small problem compared with other regions of the country. The limited impact of managed care seen to date may lie in the fact that approximately half of cancer patients in the region are covered by Medicare; with the rise in Medicare managed care arrangements, however, this may change.

Dr. Scott M. Browning

San Diego Kaiser Permanente

Background

Kaiser Permanente is a nonprofit staff-model HMO managed in large part by physician partnership. Its mission is to provide high-quality, accessible health care to its members, but clinical research is not a mandate of the plan. The Kaiser plan in San Diego currently provides health care for approximately 380,000 people in the San Diego region. Among this geographically stable and health-oriented population, there are approximately 1,600 new cases of cancer each year. Oncologists at the plan have been participating in clinical trials since the 1970s, but lacking institutional support, with increasing difficulty. For this reason, Dr. Browning applied for a CCOP grant to acquire research support staff and permit interested plan oncologists to remain involved in clinical research.

Key Points

- The CCOP based at San Diego Kaiser Permanente was funded in 1989. After several years of satisfactory accrual to treatment and cancer control clinical trials, several factors and events caused a dramatic drop in accruals in 1994, leading to suspension of the CCOP's funding.
- The problems experienced by the San Diego CCOP illustrate some of the constraints associated with conducting clinical research in an HMO environment. Specifically, the paramount importance of cost considerations caused the IRB at Kaiser to deny the opening of new Phase III trials and require that certain agents be provided at no cost by the research base. In addition, Phase I and II trials were not allowed. These restrictions coincided with suspension of the NSABP, resulting in relatively few open trials available to offer to patients, but extended follow-up of patients already enrolled on Phase III clinical trials. Further, the NSABP suspension created negative publicity, the need for multiple mailings to patients, and other activities that adversely affected the CCOP.
- In addition, the health plan restructured in response to competitive pressures, resulting in greater patient loads for physicians and reduced discretionary time which had been and continued to be the only time available for participation in clinical research. In addition, cancer control patients were no longer permitted to be seen during regular clinic hours and clinic personnel were prohibited from assisting in the care of these patients.

- Follow-up data are currently being submitted for over 500 patients; however, except for participants in the Breast Cancer Prevention Trial, the CCOP is funded only for new accruals. It is necessary to devote one full-time data manager to follow-up, leaving little staff time for new accrual work. Funding the data manager's position required the reduction of an RN position to part-time, curtailing support for physicians participating in the trials.
- The increasing complexity of Phase III trials coupled with reductions in ancillary research staff has created a negative incentive to placing patients on trials.
- Physicians who participate in clinical trials outside of an academic environment do so on a volunteer basis, and deserve a supportive relationship with the NCI and research bases. Dr. Browning likened clinical research outside of a university setting to an orphan that everyone wants to see grow up but no one wants to feed.

Dr. Keith S. Lanier

Columbia River Oncology Program (CROP), Portland

Background

The Columbia River Oncology Program (CROP) has been a CCOP participant for 10 years. Its primary research bases are the Southwest Oncology Group (SWOG) and the NSABP. CROP has also been a member of the M.D. Anderson network for many years and in the last 18 months has also joined the Radiation Treatment Oncology Group (RTOG), and the Pediatric Oncology Group (POG). Within the CCOP, which has participation from a number of hospital systems in Oregon and Washington, several thousand new cancer cases are diagnosed each year. Although the CCOP's accrual relative to other CCOPs is high, its accrual relative to the cancer cases in the geographic area is low. Overall, approximately 20 percent of clinical trial participants are in managed care plans, though this varies widely among hospitals.

Key Points

- Currently, approximately one patient per month refuses clinical trial participation based on cost. Some patients are paying for trial-related tests out-of-pocket; Dr. Lanier reiterated Dr. Appelbaum's observation that this cost shifting to the patient may skew the profile of patients who participate in trials.
- Bureaucratic delays in getting approval for participation on a trial are sometimes so long that the patient becomes ineligible for the study because of disease progression or other changes. A more subtle form of treatment delay is related to gatekeeper delays in referral to specialty providers. Approval for expensive procedures (e.g., marrow transplantation) is not particularly difficult to obtain from managed care providers in the Portland market, with the exception of the Oregon Health Plan; contract language is often the barrier encountered rather than medical indication or appropriateness of the procedure.

Additional Research Needs and Other Recommendations

- Managed care can provide quality control for cancer treatment trials. Clinical researchers need to work with physicians on the boards of managed care organizations to educate them about the potential benefits of clinical research participation.
- Clinical trials should be the standard of care; we need to work to make this a reality. To do so, trials must be relevant, scientifically sound, conducted at minimum cost, and include appropriate follow-up. It is also necessary to provide support for costs related to research procedures, genetic studies, and shipping, handling, and procurement.
- Data on cost differences between clinical trial costs and standard therapy must be developed.
- The value of clinical trials needs to be promoted with employers and advocacy groups. Greater leadership and guidance from the NCI is needed to help promote clinical trials and ensure that they are continued.

Discussion

Key Points

- Dr. Klausner indicated that activities have been initiated to reduce bureaucracy and burdensome regulations in NCI operations, increase the flexibility with which resources can be deployed, and increase accountability. For example, an evaluation of the Cancer Centers Program is under way, and programmatic changes are expected that will acknowledge and support the unique capacities and expertise of each center. In addition, a committee headed by Dr. James O. Armitage (involving the community, managed care, clinical trials participants, and others) has been convened and charged to develop implementable recommendations to address issues of incentives and disincentives for clinical trials at all levels. The recommendations are to address simplification, bureaucracy, infrastructure needs, compensation/volunteerism issues, and the evolving health care environment, among others. The group has, for example, been asked to look at the historic institutional separation of cancer centers and CCOPs to determine if changes (e.g., consolidation) are possible and desirable. These and similar activities addressing other Institute operations will rely to a greater degree than previously on input from the research, health care delivery, and consumer communities. Soliciting this input means that while change will be rapid, it will not occur overnight. Nonetheless, the NCI is cognizant that the clinical trials system must evolve to remain viable in the managed care environment.
- It is also recognized that informed consent paperwork has become decreasingly informative as it has become more voluminous, but simplifying it is beyond the sole discretion of the NCI or NIH.

- Typically, 1 to 2 months elapse from the time a protocol reaches the CCOP director to the time it can be activated. Variations in this period are due to differing IRB review processes and structures. It was noted that OPRR requirements prohibit IRB approval of protocols outside of the State in which the IRB is located, even if for multi-State institutions/organizations; this causes considerable duplicative work and expense. One speaker indicated that because the IRB that reviews protocols at his organization includes appointed members from each of its consortium hospitals, it is able to centrally approve and activate protocols for all CCOP participating physicians.
- Optimism or negativity about the future of clinical research in a managed care environment may be affected by experience to date—those who have experienced negative repercussions may believe the situation must improve, while those relatively unaffected thus far (observing the plight of those in the first group) may view the future with greater trepidation.
- The extent and strength of physician leadership within managed care organizations may prove to be a highly important variable affecting clinical trials participation in the managed care environment. The availability of clinical research advocates in key governmental positions may also affect the stance toward clinical research at statewide or regional levels.
- Speakers expressed hope that the attention being focused on the issues of managed care and clinical research will lead to increased

PERSPECTIVES FROM MANAGED CARE

Dr. Simeon A. Rubenstein

Group Health Cooperative of Puget Sound

Background

Group Health Cooperative of Puget Sound is a 620,000 member-owned cooperative, with approximately 430,000 members in western Washington, and the remainder in central and eastern Washington. Priorities are established by members in concert with the plan's Board and include primary prevention (with an emphasis on smoking cessation), early detection (particularly early detection of breast cancer), and treatment of acute and chronic illness, including clinical trials.

The plan currently participates with SWOG and the Children's Cancer Study Group (CCSG), and is also active in applied (effectiveness) research, cost-effectiveness research, and quality-of-life research.

Key Points

- Managed care plans can be categorized into three types: (1) assemblers--that put together a makeshift package of contracted services and sell it at a low price to young, healthy employee groups; (2) utilization managers--plans in which virtually all procedures require prior permission from a plan manager who has little medical knowledge and is focused on utilization control; and (3) those

designed to improve health--organized systems that apply systematic approaches to improve individuals' health and manage cost in a way that is satisfying to both customers and providers.

- The prevailing view of cancer among nononcologist physicians, patients, and payers--that it strikes unpredictably, is treated with short-term therapies by specialists, and that research focuses on basic science and new cures--is giving way to an understanding that cancer is partially predictable, and has become a chronic illness in many cases, and that the research focus has expanded to include health services research on primary prevention, early detection, and treatment of chronic diseases.
- The marketplace seems to be evolving toward a greater emphasis on care provided locally. Patients do not seem to want to travel to regional centers for care. There are sufficient numbers of specialists in satellite locations to provide this care, and information technologies will continue to make it easier to provide care from network locations. These technologies will also continue to increase patient access to state-of-the-art treatment and other information. In addition, locally provided care allows patients to maintain social and family support that are critical to quality of life and, possibly,length of life.
- Effective systems of care are organized as systems, are multidisciplinary (including the personal physician), employ common information systems that track all outcomes for a large population, enhance research opportunities by linking funding and delivery, implement active prevention and screening outreach programs, and provide the opportunity to work with other research institutions with complementary assets and interests.
- Group Health Cooperative believes that primary prevention smoking cessation programs are as important a part of its cancer care as therapies for clinically evident disease. It has found that effective patient follow-up and provision of full coverage for program costs have increased participation and the 12-month quit rate among participants. In addition, the program has proven economical in terms of cost per year of life saved.
- Similarly, the plan's breast cancer detection screening program actively engages women members beginning at age 40; data are collected on incidence rates relative to the nonmember community and tumor size. To monitor program quality, data are also collected on program performance by location and by model (e.g., staff versus network), and are the basis for program improvements.
- There are significant overlaps in the interests and agenda of managed care organizations and academic medical centers or cancer centers. Collaborative efforts (for example, in research or medical education), however, must meet the self-interests of each participating organization.

Additional Research Needs and Other Recommendations

- Seed money is needed to help initiate joint efforts in research or medical education. These joint efforts could take advantage of existing population-based databases of managed care organizations and expertise complementary to skills and expertise that are strengths at NCI and the cancer centers.

Dr. Allen B. Bredt
Kaiser Permanente

Background

The Kaiser Permanente Medical Care Program (KPMCP) is a non-profit HMO with national enrollment of 6.6 million members in 16 States and the District of Columbia. Its medical staff includes over 9,000 physicians and 12 separate medical groups across the country. The physicians in each medical group direct both patient care and the operation of the medical group. While the details of the health care delivery system in each location may differ, the scope of services and basic philosophy of care are consistent.

Kaiser's mission is to provide high-quality, cost-effective care, and improve members' health outcomes. The plan is socially and professionally obligated and committed to residency, fellowship, and provider training. Its research activities are focused on contributing to knowledge about how best to deliver high-quality, accessible health care and to collect data demonstrating improved health outcomes. The plan also has a commitment to community service.

In California, Kaiser has 2.3 million members each in southern and northern California, and 500,000 members in Oregon. Together, this population experiences 20,000 to 22,000 new cases of cancer annually.

Key Points

- Kaiser is proud of its quality, information, and utilization management, which it believes enable the plan to improve the processes of care, education of providers, and information systems, and ensure that the right care is provided at the right time in the right place.
- Cancer care provided at Kaiser plans is consistent with its mission as an organization. Measuring the effectiveness of cancer care is an emphasis at the plan, not only to assess outcomes but for planning and designing improvements. Patient and physician education are emphasized to support shared decisionmaking. Participation in clinical research, when appropriate and available, is one component of the plan's comprehensive cancer care program.
- Cancer research is considered important at Kaiser, and substantial resources are devoted to it. The organization participates in research at many levels--intramural studies funded by Kaiser or grants from philanthropic and other groups, CCOP and cooperative group (e.g., SWOG, Northwest Cooperative Oncology Group [NWCOG]) participation, collaboration with local universities and cancer centers, and referrals to NCI intramural studies.
- Attitudes toward the conduct of clinical research, however, vary somewhat between components of Kaiser Permanente. In contrast to the less-positive experiences in southern California described by Dr. Browning, Kaiser's NWCOG believes that cancer care is best delivered through a research clinical trial setting,

is able to support most of these activities in-house, and feels that if done appropriately, clinical research can pay for itself.

- Collaboration with academic medical centers depends on finding commonalities in organizational missions; these commonalities can be springboards for ongoing relationships and improved and expanded research efforts.
- Cancer cases among Kaiser enrollees in California comprise approximately 15 percent of all new cancers in California. This population, coupled with physician interest in research, provides the seeds for potential collaborative efforts. In northern California, however, there have been problems in attempts to collaborate with the CCOP and NSABP, which have sapped the enthusiasm of some of the plan's research-oriented physicians.
- For decades, virtually all of Kaiser's California and Oregon pediatric cancer patients have participated in research protocols. This model has been quite successful; the reasons for this success need to be explored to determine how it can be adapted to adult cancer care.
- For conventional care, resource allocation at Kaiser is guided by a recognition that resources are limited and the requirement that a proposed treatment is both effective and as effective and cost-effective as alternatives. In addition, treatment choice should maximize health outcomes of all members while still being in the best interest of the individual patient and possible within resource constraints. Extrapolated to cancer care, these resource allocation principles dictate that as stewards of the premium dollar, the plan is obligated to provide access to high-quality, effective care and improve the health of all members. As a nonprofit HMO, this means embracing well-designed Phase III trials that address important research questions and are efficiently run. Phase I and II trials can be considered, but since efficacy has not been established, funding for them should come from a source other than the premium dollar.

Additional Research Needs and Other Recommendations

- NCI and the President's Cancer Panel can help foster clinical cancer research in the managed care environment by identifying areas of mutual interest to the NCI, the academic institutions, and the managed care providers. Studies should address the most important clinical questions of mutual interest, and cost issues should be considered carefully. In addition, situations must be avoided in which patients referred to an academic center for a study on an important clinical question are diverted into lower-priority, more expensive, and less carefully controlled trials.
- The NCI and KPMCP could initiate collaboration on one or two clinical trials of mutual interest that may foster networking and provide a springboard for more ambitious future efforts.
- In an era of limited resources, NCI should continue to direct and coordinate the cancer research agenda, including more focused priorities and elimination or consolidation of duplicative, expensive, and poorly accruing trials. At the same time, care must be taken not to squelch spontaneous, basic research that provides the basic discoveries that lead to clinical interventions.

- If less cancer care will be delivered in academic medical centers in the future, we will need strategies to make cancer care easily and widely available and ensure that research that is conducted is meaningful. This will require reevaluating the entire structure of cooperative groups, CCOPs, academic medical centers, and HMOs to develop a reasonable plan--developed with thought, collaboration, and compromise by all--for clinical research that fits the current health care market place.

Dr. Peter McGough

Medalia Health Care

Background

Medalia Health Care is a joint venture between the Sisters of Providence and Franciscan health systems. Medalia is a large medical group focused on primary care; it does not have specialists on staff, but seeks to be the first point of contact with the health care system and the coordinator of care across settings. Serving 400,000 patients in the Puget Sound area through 40-community based clinics, Medalia employs 295 primary care physicians. It accepts full risk for capitated enrollees.

Currently, 25 percent of enrollees are in capitated managed care, with most of the remainder in some form of managed fee-for-service plan. Regardless of the patient's payer, Medalia's goal as a coordinator of care is to ensure that each patient gets the right care at the right time. The primary care physician role is that of guide and advocate, and medical decisionmaking is maintained at the level of the physician and patient as often as possible.

Key Points

- One of the potential benefits of managed care is its emphasis on prevention and early detection (e.g., mammography for breast cancer detection), and the coordination of care once disease is detected, including active care management and support programs. Challenges of managed care, however, are its ability to truly control costs through innovative approaches to care (not just doing the same thing with less money), to address issues of funding for research and clinical trials, and to achieve clinical collaboration for the benefit of patients.
- Critics of managed care express concern that it can delay and obstruct care. Such a strategy is self-defeating, since delayed care results in poor outcomes and greater costs.
- Managed care goes beyond early diagnosis to address prevention. A U.S. West analysis suggests that medical interventions of all types account for only 30 percent of health outcomes, and the most overwhelming determinants of health outcome involve lifestyle issues (e.g., smoking, exercise, seat belt use). Effecting changes in lifestyle behaviors requires patient education, which is supported by managed care. These issues are not addressed by indemnity insurance except in the context of underwriting (e.g., lower rates for nonsmokers).

- In coordinating cancer care, Medalia strives to make early diagnoses, get the patient to the best care (available through a broad referral network of local and regional resources, including cancer centers and academic medical centers), stay with the patient and family, and coordinate the continuum of care.
- Active care management and support is another important aspect of managed care that involves identifying patients with special needs (for example, cancer patients with comorbid conditions) and improving the way care is delivered to them by empowering patients to make better use of resources. This is done through patient education, community involvement and support programs (e.g., hospice), broad use of providers, and evolving care guidelines.
- With the rapid pace of change in health care and shift of control away from physicians, hospital, or health planners, it is crucial that collaborative and creative dialogue takes place to address issues, including: ways of balancing resources for prevention and treatment; enhancing patients' quality of life while still assuring fiscal survival and cost control; improving data systems and information sharing for providers and patients; simplifying protocols; and addressing the need for research and education on compassionate approaches to care for the dying patient.

Additional Research Needs and Other Recommendations

- Funding for research should be extracted across the board from total premiums; if all payers benefit from improvements in care that result from research and education, all should participate in their cost.

Dr. Frank Senecal

Medalia Health Care

Key Points

- Major advances in cancer treatment (e.g., acute lymphocytic leukemia [ALL] in children) have occurred because of the progression of small advances made in successive research studies. This progress cannot be allowed to decline or cease, but is threatened in the current health care environment.
- Limited available cost data at Medalia indicate that treatment provided in several cooperative group clinical trials is substantially higher than the cost of standard therapies. Even cost differentials in the range of $2,500 per patient are significant for the oncologist who is at risk in a capitated environment, and it is the oncologist who makes the decision as to referral to trial.
- In addition, profit margins are narrowing. In the last 18 months, reimbursement for patients on stem cell transplant trials have shrunk to $1,200. Requests for transplant coverage are seldom refused, in contrast to several years ago. Dr. Senecal indicated that the plan physicians have become better able to predict which patients will be approved and payers have a better sense of when they should not refuse coverage.
- The cost of chemotherapy drugs will be a major deterrent to accrual in the coming years, and it is doubtful that these costs can be supported in the health care system, particularly for drugs for which response rates are relatively low and

extension of survival is moderate. Data management costs will also be an increasing issue in patient referral to trials.

- Although managed care has had little impact to date on clinical trials participation in the Tacoma/Seattle area, it can be expected to have a negative impact in the future. It will be necessary to educate payers to the value of clinical trials. Education notwithstanding, for-profit plans are likely to refuse to allow their enrollees to participate in clinical research.
- Other barriers to trials are the gatekeeper model of managed care and oncologists' increasing responsibilities for patient care and related paperwork. The additional time and effort needed to introduce patients to a trial and collect the additional data are a deterrent, particularly if personal income will be at risk because of higher costs associated with the trial.

Discussion

Key Points

- If we expect managed care and other payers to support research and development, the research community must ensure that clinical trials are cost-effective. Increased contribution to Phase III clinical research addressing important clinical questions would answer key research questions more quickly (e.g., is marrow transplantation effective treatment for breast cancer) because we would have the financial resources and patient base to conduct the trials.
- Limited response rates to some of the newer chemotherapy drugs are daunting, particularly in view of their cost. In the future, however, we will be better able to identify subsets of patients in whom response is most probable and multidrug combinations that will improve response rates, thereby making use of these agents more cost-effective.
- With an understanding of current barriers to clinical research in an evolving managed care environment, we should focus on identifying collaborative models based on complementary resources and shared issues, needs, and goals. Aspects of these models may be adaptable at a national level. An undeniable reality is that mechanisms or relationships established to support clinical research, if they are to be self-sustaining, must satisfy the self-interest (e.g., research, public visibility) of the participating organizations in addition to benefiting the patient.
- New clinical pathways developed as a result of research can take years to implement on a widespread basis. Participating in trials allows an organization to implement such algorithms most quickly (because they have already been doing it) and may confer the market advantage of offering state-of-the-art care years before competitors are able to do so.
- Research provides the discoveries that lead to greater efficiency (e.g., better surgical techniques that reduce operating room costs and lengths of stay; methods of information exchange that reduce the need for office visits). This should be a major motivation for payers and providers to support research and must be better articulated.

- The market is beginning to respond to patient pressure for greater choice of provider. This market backlash against restrictive plans has been part of the impetus behind some provider group mergers and the growth of point-of-service (POS) health plans. Experience to date (principally in the eastern United States) is that POS plans are no more costly than restrictive plans. Similarly, clinical trials in the managed care setting could prove sufficiently economical if they are carefully designed and implemented, ensuring that they focus on important, answerable questions, are ethical, and are cost-effective. As evidenced by recent surveys and Congressional support for the NIH budget, clinical research is valued and supported by the public. As patients become more knowledgeable and able to advocate for their care, they will increasingly demand of competing providers the care they believe is of value.
- It was suggested that a next step in the dialogue on these issues is to determine how and with whom to structure formal discussions to establish new collaborative models for conducting clinical research in the managed care context. NCI or other grant funding may be needed to launch these models that can then be used as examples of win-win relationships for implementation or adaptation across the country. Dr. Klausner indicated that the recently established agreement with DoD is just such a model.
- Care must be taken to guard against clinical "carve-outs" that fiscally pit one type of medicine or one disease against another (e.g., cancer care versus heart bypass surgery). Similarly, despite the attraction to find a cure for cancer, research and support must also continue for preventive interventions. These needs dictate a whole systems approach to structuring the health care system to best serve patients.

Closing Remarks

In his closing remarks, Dr. Freeman noted that:

- The war on cancer was declared on December 23, 1971, by Richard Nixon; at that time, President Nixon thought the war could be won in 8 years. We are, however, still fighting the war, and are now doing so in an evolving system of managed care.
- Speakers have expressed differing views as to whether managed care interferes with clinical research; the Panel will reach conclusions about this question as it continues its deliberations.
- Definitions of managed care also vary; in particular, the distinction between for-profit and other forms of managed care and the impact of physician leadership on plan policies and operations; these issues warrant further discussion.
- We need better data on the differential cost of care in clinical trials compared with conventional therapies. In addition, we need to revisit the definitions of Phase I, II, and III trials so that it is clear what we are asking payers to fund.

- It is of concern that under the current system, people in the higher socioeconomic strata are more likely to participate in clinical trials; this may skew research results and represents a social inequity.
- Responses to the managed care marketplace have included consolidation, collaboration, consortia, flexibility, and the formation of new corporate entities. There is a serious question, however, that individual human destiny can be addressed under the same market-driven system that manages commodities.
- Other issues that merit further discussion include delays in patient care under managed care systems (both delay in referral to specialists and delay in initiating care under a clinical trial), care of the indigent in a system in which cost shifting is no longer possible, and physician training.
- It is not clear that managed care is here to stay. The American public may eventually reject managed care as too restrictive and unresponsive to individual needs.
- Dr. Freeman noted that according to Senator Brock Adams, military R&D over a recent 28-month period had exceeded research and development for all of science for the last 100 years. It remains to be seen if the nation will be willing to make the investment in research that is needed, and who will contribute (either through funding or individual effort) to supporting the research enterprise.