

OPPORTUNITY:

Revitalizing the NIH
Clinical Center
for Tomorrow's
Challenges

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Executive Summary

BACKGROUND

The Warren Grant Magnuson Clinical Center is the core clinical research facility at the National Institutes of Health (NIH) and is the largest center of its kind in the world. A recent study of NIH described the Clinical Center as “a unique and invaluable resource for the direct clinical application of new knowledge derived from basic research.”¹ The Clinical Center provides protocol-specific patient care in support of the intramural research programs sponsored by most NIH Institutes. The Clinical Center also serves as a resource for training clinical investigators.

Clinical Center patients are drawn from a nationwide patient referral base to participate as research volunteers in NIH-sponsored protocols. In FY94,² 72,200 inpatient-days and 73,400 outpatient visits occurred at the Clinical Center. This represents approximately 50 percent of the research days and 27 percent of the research outpatient visits supported by NIH throughout the United States. The Clinical Center supports a portfolio of approximately 1,000 active protocols. A heavy emphasis on Phase I and Phase II clinical trials and on studies of the pathogenesis and natural history of disease distinguishes the research mix at the Clinical Center from that of teaching hospitals, where emphasis is more on Phase III and IV clinical trials. On occasion, investigators from outside NIH are permitted to use the Clinical Center.

ISSUES

The Clinical Center is at a critical point in its history. The translation of bench research to clinical practice in areas such as genetic and immunologic therapy will accelerate in the next decade, placing demands on the Clinical Center to respond quickly to new protocols and new approaches to treatment. At the same time, changes in the external environment have already decreased the traditional flow of referrals from physicians to the Center, and patient loads for inpatient and outpatient care have declined in recent years. The Clinical Center

¹ *Report of the External Advisory Committee of the Director's Advisory Committee, National Institutes of Health*, a report of the National Institutes of Health Intramural Research Program, November 17, 1994, p. 1.

² The most recent complete data available.

needs new relationships with insurers and patients to facilitate recruitment. A steady change in consumer expectations of healthcare is influencing clinical research as well. Patient willingness to accept long hospital stays and to return to the Center for long-term follow-up is decreasing. New approaches, such as the use of telemedicine to broaden access of patients to protocols, will become critical.

Rising costs in both bench and clinical research have contributed not only to the decrease in inpatient census of the Clinical Center, but they have also led to questions about the value received for each dollar spent at the Center. Given the tenor of Congress, these cost pressures can only be expected to increase in the future. For example, with less funding, episodic crises — such as the recent and sudden cuts in NIH travel budgets, which provide funds needed for patients to participate in protocols — can be expected to be the norm rather than the exception.

Finally, the Clinical Center itself urgently needs physical renewal. The physical plant, built in the 1950s, is barely able to sustain modern practice in either patient care or research because of inherent weaknesses in systems such as air handling and utilities.

In an effort to reduce the costs and improve the efficiency of government programs, the Vice President's Reinventing Government II initiative designated the NIH Clinical Center as an organization to be critically reviewed and reengineered to improve its effectiveness and efficiency. An NIH Clinical Center "Options Team" was created by the Secretary of the Department of Health and Human Services to perform that review. This report summarizes the Options Team's findings, conclusions, and recommendations.

The NIH Options Team evaluated Clinical Center functions in the broadest sense possible, exploring everything from the Center's governance, structure, and strategic direction to the details of day-to-day management, information systems, and benchmarking. This evaluation included a series of visits to health facilities and to government-owned organizations throughout the country to learn how other institutions have dealt with the problems the Clinical Center now faces.

External advisors met with the Options Team in a two-day retreat held in Annapolis, Md., in October 1995. These same advisors also served as hosts to various team members during visits to their institutions. The recommendations contained here reflect the particular emphases placed by the external consultants on the Option Team's observations.

MAJOR RECOMMENDATIONS

The recommendations that follow propose that the Clinical Center undergo significant change to improve efficiency and to ensure that the Center flourishes into the next decade. The Center must be nimble enough to respond rapidly to

new initiatives, cost-effective enough to undertake these changes with fewer resources than it has today, and innovative enough to serve as a national core of clinical research in the information age. To achieve these goals, the Clinical Center must change the way it is governed, funded, and managed.

The Options Team and the external consultants agree that the following recommendations are the most important for the Clinical Center to address now:

- ◆ A clear and logical governance structure should be developed for the Clinical Center that draws on the expertise of leaders of outside organizations and reflects the interests of the Institutes, which are the clients of the Center. A Board of Governors should be created to oversee the Clinical Center. The Board's responsibilities should include annual budgeting and strategic planning as well as oversight of operations. The majority of this Board and the chair should be individuals from outside government; the remainder of the Board should be representatives of NIH Institutes. Appointments to the Board should be made by the Director of NIH upon the recommendation of Institute directors and the Director of the Clinical Center.
- ◆ The Clinical Center should have a clearly defined budget of its own. The budget should be as stable as the NIH budget as a whole.
- ◆ The Clinical Center should have a means of retaining reserves from year to year. The Center should also be permitted to charge insurance companies for some services and to solicit donations. The new budgeting process should include methods to (1) ensure that all Institutes have continued access to a baseline level of activity at the Center, (2) permit Institutes that improve the efficiency of their protocols to increase their overall activity, and (3) permit outside investigators to use the Clinical Center.
- ◆ As one of its first official actions, the new governing Board of the Clinical Center should direct development of a strategic plan with clear and measurable objectives. The plan should serve as the keystone by which managers can allocate and distribute resources. Clinical Center management should immediately begin to develop the background information upon which such a plan can be based.
- ◆ The Clinical Center should have more flexibility to improve its efficiency and effectiveness, particularly with regard to the procurement of goods and services, management of personnel, and use of operating savings. The Options Team evaluated several structural approaches as the means for obtaining such flexibility, including continuing to operate the Clinical Center as a Federal organization, converting it to one of several types of federally sponsored organizational arrangements, and managing the Center by contract. The Options Team and external consultants recommend that the Clinical Center be designated a "Reinvention Laboratory," a Federal demonstration site in which reduced regulation, enhanced local autonomy, and improved Federal personnel and procurement practices are combined.

The Options Team also recommends that the Center do the following:

- ◆ Actively seek funding for a new Center facility that will be more efficient to run and maintain and that will permit more efficient use of staff.
- ◆ Explore increased contracting out of individual Clinical Center functions.
- ◆ Invest in integrated information systems that provide real-time information for managers about costs and human resources.
- ◆ Adopt an ongoing program of benchmarking, integrated with the strategic plan adopted by the new Board of Governors.
- ◆ Establish new methods for recruiting patients to protocols.

The body of the report contains additional recommendations, background information, justification, and methods for implementation.

Contents

Chapter 1. Background	1-1
Issues: Why Change the Clinical Center?	1-1
Study Methodology	1-2
Overview	1-2
The Options Team and External Consultants	1-3
Subcommittee Methodology	1-4
Organization of Report	1-5
Chapter 2. General Description and Characteristics of the Warren Grant Magnuson Clinical Center	2-1
Overview	2-1
Physical Characteristics	2-1
Budget	2-2
Patient Activity	2-4
Full-Time Equivalent Staff Members	2-6
Training	2-6
Research Protocols	2-6
Sources of Funding — Past and Present	2-7
Chapter 3. Primary Recommendations: Structural Improvements for the Clinical Center	3-1
Overview	3-1
Clinical Center Governance	3-1
Budgeting	3-4
Planning	3-5
Chapter 4. Achieving Clinical Center Flexibility	4-1
Overview	4-1

Contents (Continued)

Reinvention Laboratory Proposal	4-1
Procurement	4-2
Personnel	4-4
Clinical Center Renewal	4-6
Contracting Options	4-7
Chapter 5. Secondary Recommendations: Operational Improvements for the Clinical Center	5-1
Performance Measures and Benchmarking	5-1
Information Systems	5-2
Public Information	5-3
Patient Recruitment	5-3
Charging for Clinical Care	5-5
Appendix A. Options Team Members and External Consultants	
Appendix B. Summary of Site Visits Conducted by the Options Team	
Appendix C. Institute Leadership Interview Survey Findings	
Appendix D. Alternative Organizational Forms for the Warren Grant Magnuson Clinical Center Flexibility	
Appendix E. Charging for Clinical Care: Report from Michael McGarvey, M.D.	

Illustrations

1-1.	Timeline of Options Team Activities	1-3
2-1.	FY95 Clinical Center Budget	2-2
2-2.	Percentage Change in NIH Intramural Program versus Clinical Center	2-3
2-3.	Clinical Center Patient Activity from FY85 to FY95	2-5
3-1.	Existing Governance Structure	3-2
3-2.	Proposed Governance Structure	3-2

Tables

2-1.	Selected Inpatient Cost Factors	2-4
2-2.	Clinical Center Program Characteristics	2-5
2-3.	Full-Time Equivalent Staff Compared to Workload	2-6
2-4.	Protocols by Type	2-7

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valuable insights on the relationships between managed care and clinical research.

During the development of this report, NIH staff visited 30 organizations both inside and outside of the Federal government. Staff of these organizations willingly gave their time and shared their experience in ways that greatly enriched the whole Team's understanding of good management. Organizations visited were Alaska Native Medical Center; Baltimore Veterans' Affairs Medical Center; Barnes Hospital; Boston Children's Hospital; Corporation for National and Community Service; Dana-Faber Cancer Institute; Duke University Medical Center and Health System; Emory University Hospital System; Fairfax Hospital; Federal Home Loan Mortgage Corporation (FREDDIE MAC); Frederick Cancer Research and Development Center; Henry M. Jackson Foundation for the Advancement of Military Medicine; John Dempsey Hospital, University of Connecticut; John Hopkins Hospital; Logistics Management Institute; Massachusetts General Hospital; Mayo Clinic; Mount Sinai Hospital; National Institute of Standards and Technology; National Library of Medicine; Phoenix Native Medical Center; University Hospital — SUNY Health Science Center at Syracuse; University of California — San Francisco; University of Chicago Hospitals, Illinois; University of Maryland Medical Center; University of Michigan Hospital; U.S. Army Medical Research and Materiel Command; Walter Reed Army Medical Center; and Clement J. Zablocki Veterans' Affairs Medical Center.

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Finally, I would like to thank the most important people of all: the Clinical Center's patients. Although I met only a few of them, I was uniformly impressed by their courage in undertaking unknown risks in the hope of helping others as well as themselves. This report is for them.

Helen L. Smits, M.D.
Deputy Administrator
Health Care Financing Administration

CHAPTER 1

Background

ISSUES: WHY CHANGE THE CLINICAL CENTER?

The Warren Grant Magnuson Clinical Center (the “Clinical Center”) is the core clinical research center of the National Institutes of Health (NIH). It is the largest center of its kind in the world and has a history of great accomplishment.

For several reasons, the Clinical Center is a truly unique national resource. Among these reasons are the special blend of basic science, clinical research, and clinical care expertise located on the NIH campus among Institute and Clinical Center staff; the distinctive culture of NIH’s intramural environment that over the past four decades, has fostered some of the finest and most important clinical research conducted in the world; and the experienced, collaborative Clinical Center infrastructure — ranging from science-based nutrition services to molecular biology support — that has grown and flourished in the Clinical Center since its creation. Combining these resources with the Center’s critical mass of specialized and costly technologies, such as scanners, facilitates cost-effective performance of certain types of research. These unique cultural and technological aspects of the Clinical Center are clearly of value to NIH.

The Clinical Center, however, is at a critical point in its history. Rapid and profound changes in three areas — research, healthcare, and the congressional and external environments — have resulted in a very unstable setting. This is specifically illustrated by the following facts:

- ◆ The translation of bench research to clinical practice in areas such as genetic and immunologic therapy will accelerate in the next decade, placing demands on the Clinical Center to respond quickly to new protocols and new approaches to treatment. At the same time, a steady change in consumer expectations about healthcare is already influencing clinical research: patient willingness to accept long hospital stays and to return to the Center for long-term follow-up is decreasing.
- ◆ The manner in which healthcare is provided in the United States is changing, both dramatically and rapidly. This changing healthcare landscape has an impact on the recruitment and retention of patients for clinical research studies in all centers, including the Clinical Center. Changes in the external environment have already decreased the traditional flow of referrals from physicians to the Center, requiring new relationships with insurers and patients to facilitate recruitment. New approaches, such as the use of telemedicine to permit distant physicians to provide protocol-based care, will become critical to success.

- ◆ In an era in which increasing attention is being paid to fiscal conservatism and a balanced Federal budget, the NIH budget is receiving more scrutiny than ever before. Rising costs in both bench and clinical research have led to a reduced census at the Clinical Center in recent years and to ongoing questioning by the Institutes about the value received for each dollar spent at the Center. Given the tenor of Congress, these cost pressures can only be expected to increase in the future. For example, with less funding, episodic crises — such as sudden cuts in Institute travel budgets that provide funds needed for patients to participate in protocols — can be expected to be the norm rather than the exception.

The Clinical Center lacks the means to manage efficiently in this volatile environment. Governance of the Center is unclear, with multiple committees providing oversight. Controversial cost-cutting measures, such as consolidation of floors, have been achieved only slowly and with difficulty. The budget process for the Clinical Center, in which money flows through the Institutes, has proved confusing and frustrating for both Center and Institute staff members. The Clinical Center also faces a series of very serious barriers to managerial efficiency in areas such as personnel, purchasing, and contracting. Approvals for efficient practices as simple as atypical work schedules have often been impossible to obtain. Finally, funds generated through Clinical Center efficiencies in recent years have not necessarily been available to reinvest in Center activities or to be used for intramural research.

A final and significant concern is that the Clinical Center urgently needs physical renewal. The current plant, built in the 1950s, is barely able to sustain modern practice in either patient care or research because of inherent weaknesses in systems such as air handling and utilities.

The Clinical Center should become the most effective biomedical research organization possible. It must be nimble enough to respond quickly to change and efficient enough to deliver more and better clinical research with diminishing resources. Savings from a more efficient Clinical Center should contribute to the construction of a new building and to the purchase of capital items needed to improve efficiency further.

STUDY METHODOLOGY

Overview

Early in 1995, the Department of Health and Human Services (DHHS) undertook a reexamination of the Clinical Center's structure and organization in response to Vice President Gore's Reinventing Government II (REGO II) initiative. A proposal to contract out the management of the Clinical Center at NIH was included in the DHHS proposals and sent forward to the Vice President's office as one way to address the critical need for a new Clinical Center facility.

The Secretary of the Department of Health and Human Services then charged an internal “Options Team” from NIH, and an associated committee of external consultants to explore DHHS’ earlier proposal in detail and make recommendations on the best future for the Clinical Center. The timeline of the Options Team’s activities is shown in Figure 1-1. The Secretary specifically charged the Options Team to explore a wide range of options rather than focusing exclusively on contracting out. This report is the result of that effort.

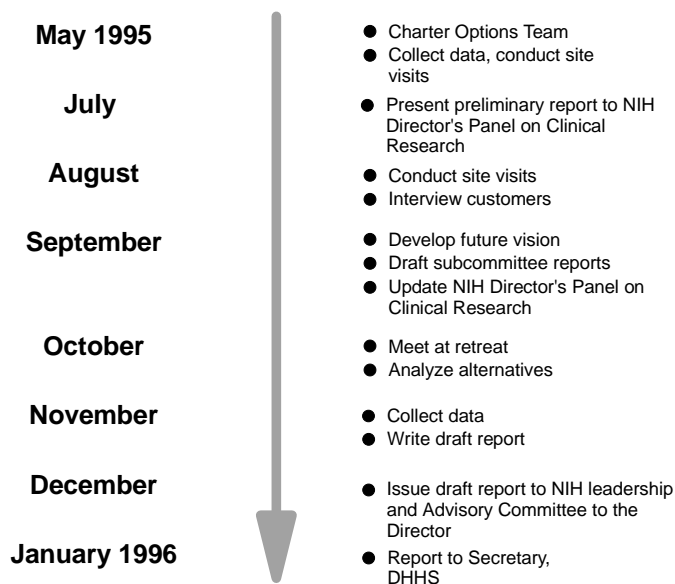


Figure 1-1.
Timeline of Options Team Activities

The Options Team and External Consultants

The Options Team had 16 members. All of those members were from NIH except for Dr. Helen L. Smits, Deputy Administrator of the Health Care Financing Administration, who served as Chair. Mr. John Finan, President of Barnes Hospital in St. Louis, Mo., served as Chair of an associated committee of 12 external consultants, preeminent leaders representing academia, academic medical centers, and the health insurance sector. Members and their affiliations are listed in Appendix A.

The primary goal of the Options Team was to develop methods for improving the efficiency of Clinical Center operations without compromising the quality of scientific researcher patient care. The secondary goal of the Options Team was to consider the designation of the Clinical Center as a Reinvention Laboratory and to find ways to generate funds through operational savings. Reinvention Laboratories are Federal demonstration sites in which streamlined procedures and reduced personnel and procurement practices are combined to increase local autonomy and improve efficiency.

Seven subcommittees of the Options Team were formed to study various topics concerning the current and future mission of the Clinical Center and the methods by which the Clinical Center can function most effectively. The subcommittees identified obstacles (e.g., procurement and personnel) to conducting clinical research and to carrying out efficient hospital operations. They visited medical centers around the country to learn from others about how to improve Clinical Center operations.¹ The subcommittees and their missions were as follows:

- ◆ *Governance* assessed the Clinical Center's governing structure in terms of meeting customers' needs and functioning effectively while responding to emerging changes and challenges.
- ◆ *Information and Reporting* identified management information and administrative reporting systems and the related training needed to support maximum cost-effective performance.
- ◆ *Budgeting* identified the most appropriate way to measure Clinical Center management performance and fiscal control.
- ◆ *Benchmarking* identified performance indicators used by other research institutions to improve the Clinical Center system of measuring its operating performance.
- ◆ *Options as a Federal Entity* assessed the limitations and reduced flexibility the Clinical Center faces because of Federal regulations regarding procurement, personnel, contracting, and so forth.
- ◆ *Reinvention Laboratories* identified model organizations of the reinvention process in the government and evaluated the feasibility of the Clinical Center serving as such a model.
- ◆ *Vision* evaluated a spectrum of options to assess which organizational alternatives would allow the Clinical Center to operate most efficiently to carry out the Clinical Center's mission.

Subcommittee Methodology

Each subcommittee followed a similar four-pronged methodological approach to derive data to address their particular missions. First, they conducted literature reviews to facilitate their understanding of hospital governance, management, budget, and contracting issues. In addition, they highlighted problems facing academic medical centers.

¹Many of the external consultants hosted the Options Team subcommittees at their home organizations. Several of the consultants also made individual visits to the Clinical Center to meet with staff and observe operations firsthand.

Second, subcommittee members interviewed departmental managers within the Clinical Center. Their questions addressed such issues as productivity measurement, efficiencies sought, data needs, and suggestions for improving the information system.

Third, the subcommittees visited a variety of governmental, academic, and private-sector organizations. They conducted interviews at academic medical centers to learn about their governance structures, budgeting methods, performance measures, and information systems. They identified the objectives of the organizations, the activities in which they are involved, and lessons that would be of significance to the Clinical Center. Several subcommittees also visited government hospitals, government corporations, and businesses with special ties to the government to learn about their governing structure, financial status, and personnel and procurement systems. They measured the information they obtained against the needs and demands of the Clinical Center. (Appendix B presents a brief synopsis of the site visits.)

Fourth, the subcommittees interviewed the leadership of the Institutes that regularly use the Clinical Center. They asked the Institute Directors and Scientific and clinical directors to discuss the operations of the Clinical Center and the types of improvements they would like to see. In addition, Dr. Michael Gottesman, NIH Deputy Director for Intramural Research, and Dr. Philip Chen, NIH Associate Director for Intramural Affairs, were interviewed. A synopsis of their responses is found in Appendix C.

On October 10 and 11, 1995, the Options Team, including its internal members and external consultants, met in Annapolis, Md., to present and evaluate their findings. Immediately following those discussions, the external consultants met privately to develop an independent assessment and to develop their recommendations. Those recommendations were presented to the entire Options Team and helped form the basis for this report.

ORGANIZATION OF REPORT

The remaining chapters of this report present the following: a description of the Warren Grant Magnuson Clinical Center (Chapter 2), the Options Team's primary recommendations for structural improvement of the Clinical Center (Chapter 3), recommended actions for achieving flexibility (Chapter 4), and a number of specific management issues and proposed solutions (Chapter 5). Supporting information is provided in the Appendices.

CHAPTER 2

General Description and Characteristics of the Warren Grant Magnuson Clinical Center

OVERVIEW

The Clinical Center's mission is to provide the patient care, services, and environment needed to initiate and support the clinical research sponsored by the individual NIH Institutes. Fifteen of the 18 Institutes have active clinical research programs at the Clinical Center.

The Clinical Center has a long, distinguished history of significant accomplishments in clinical research. Accomplishments from the Center's protocols include development of innovative chemotherapeutic strategies for treating childhood leukemias and disorders of the immune system, development of the artificial heart valve, and development of Azidothymidine (AZT) for the treatment of HIV infection. Laboratory studies, currently at the molecular level that are expected to move rapidly in the future, relate to a wide spectrum of trials involving gene therapies to treat several forms of genetic diseases such as hemophilia, cystic fibrosis, adenosine deaminase (ADA) deficiency, and chronic granulomatous disease of childhood, as well as malignancies. Basic studies within the Clinical Center and surrounding NIH research laboratories seeking to develop a new class of synthetic vectors required for successful gene therapy are expected to permit the start of many new clinical protocols.

PHYSICAL CHARACTERISTICS

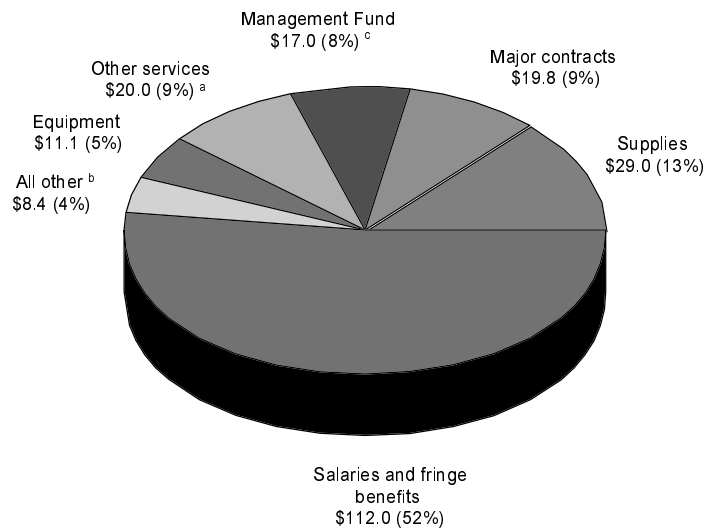
The Clinical Center was opened in 1953, and an adjacent ambulatory care facility was opened in 1981. The Clinical Center was designed with laboratories proximal to patient care units for close collaboration and quick transfer of knowledge between basic science and clinical medicine. Initially, each Institute was assigned to particular Clinical Center patient care units. The number of beds allocated to each Institute was, and still is, a function of physical space, style of research programs, and anticipated special needs of patients. At one time, the Clinical Center housed 540 beds. Currently, the Center has 359 beds open, a number that has declined over the past several years due to shorter lengths of stay, a shift to the outpatient setting, decreasing admissions, and recognition by management that patient care unit consolidation would improve efficiency. A patient care unit consolidation plan is currently being implemented

resulting in the creation of multi-Institute shared wards. Upon completion of the current phase of the consolidation plan, 325 beds will be open. Plans exist for the development of a new hospital with 250 beds.

BUDGET

The Clinical Center does not have a separate congressional appropriation; NIH Institutes pay the Center for services provided. The Clinical Center's budget is developed annually to support the intramural clinical research mission of NIH. NIH assesses each of the Institutes for the resources needed to operate the Center. Each year money is transferred from each Institute's appropriation to the Management Fund, a portion of which is distributed to the Clinical Center to pay its bills. The allocation methodology for the assessment of each Institute's contribution to the Clinical Center budget is complex. In the past, changes in assessment formulas have been temporally associated with downswings in the Clinical Center's utilization.

The Clinical Center's FY95 budget was \$217,300,000. About 52 percent of the budget supported the salaries of the approximately 2,000 full-time equivalent (FTEs) personnel working at the facility. A breakdown of the major components of the budget is provided in Figure 2-1.



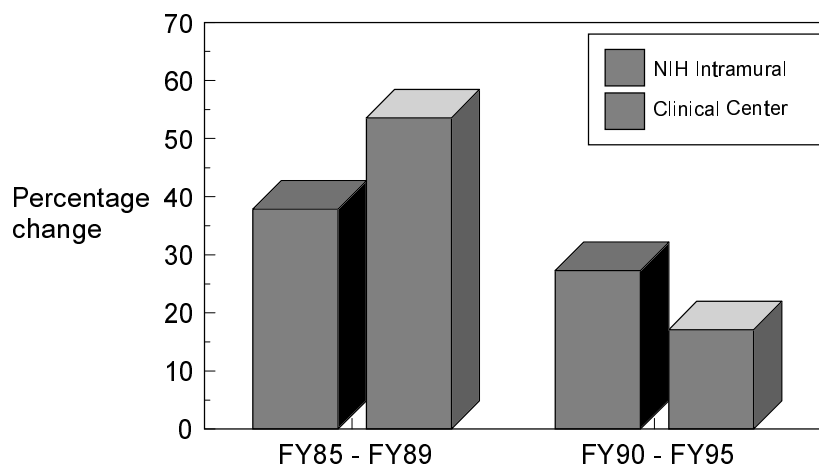
^a“Other Services” includes such items as renovations, patient care unit upgrades, consultants, contract lab tests, temporary services, NIH services and supply fund, interagency agreements, maintenance contracts, and automated data processing services.

^b“All other” includes travel, training, printing, transportation, rental, and biomedical engineering.

^cThe Management Fund is supported by contributions from the Institutes to support the services of NIH (e.g., utilities, grounds, maintenance, and mail services).

Figure 2-1.
FY95 Clinical Center Budget

In recent years, the Clinical Center has focused on controlling its rate of spending relative to the size of the NIH intramural program. Between FY85 and FY89, the Clinical Center budget grew by 53.6 percent compared with the total intramural program increase of 37.9 percent,¹ while between FY90 and FY95, the intramural program increased by 27.3 percent and the Clinical Center's budget increased by only 17.1 percent.² (See Figure 2-2.) This slower rate of increase of Clinical Center costs compared to the rate of increase of the NIH total intramural program costs was brought about by new efficiencies at the Center and by decreased census. Some Institutes, believing that Clinical Center costs were inappropriately high, admitted fewer patients, resulting in unstable utilization.



Note: Percent changes are based on the annual budget figures, which are not adjusted for inflation.

Figure 2-2.
Percentage Change in NIH Intramural Program versus Clinical Center

The Options Team compared the cost per patient-day at the Clinical Center to the cost per patient-day at other Maryland hospitals. Maryland was selected due to its rich hospital database as well as the geographic, economic, and demographic similarities between Maryland hospitals and the Clinical Center. Compared to the average cost per patient-day for all Maryland hospitals, the cost per planned patient-day at the Clinical Center was 8 percent greater in FY89 but 19 percent greater in FY94. Despite that growth, the cost per planned patient-day at the Clinical Center in FY94 compared favorably with other academic medical centers in Maryland. (See Table 2-1.)

¹From FY85 to FY89, NIH's intramural program budget grew from \$639,851,000 to \$882,417,000 and the Clinical Center's budget increased from \$113,059,000 to \$173,706,000.

²From FY90 to FY95, NIH's intramural program budget grew from \$975,871,000 to \$1,222,862,000 and the Clinical Center budget increased from \$187,456,000 to \$216,625,000.

Table 2-1.
Selected Inpatient Cost Factors

Site	Program	Length of stay (days)	Charges per inpatient-day (dollars)	Total charges per discharge (dollars)
Clinical Center	All inpatients (planned for FY94)	9.8	1,557	15,259
Johns Hopkins Hospital (JHH)	Inpatients (excluding oncology)	6.8	1,363	9,269
University of Maryland Hospital	All inpatients	7.4	1,679	12,422
All Maryland hospitals (including JHH and the University of Maryland, excluding the Clinical Center)	All inpatients	5.5	1,087	5,979
Clinical Center	National Cancer Institute inpatient	8.7	1,924	16,658
Johns Hopkins Hospital	Inpatient oncology	8.7	2,600	22,618

PATIENT ACTIVITY

Clinical Center patients are drawn from a national patient referral base to participate as research volunteers in Institute-sponsored protocols. In FY95, 64,389 inpatient-days and 68,383 outpatient visits occurred at the Clinical Center, with approximately 20 percent of the outpatient visits in day hospitals. The Clinical Center inpatient census has declined steadily since 1988. Outpatient activity increased from FY89 to FY91 and then declined. (See Figure 2-3.)

Factors contributing to the declining census include elimination of the provision of routine care to protocol patients and the elimination of protocols that enabled patients to receive non-research-based medical care. These latter, which are known as “omnibus” protocols, were terminated after a recommendation was received from the Inspector General of DHHS that no patients be admitted exclusively for routine care. The new policies mean, for example, that an ambulatory patient seen in the Mental Health Institute who develops pneumonia cannot be treated for that pneumonia at the Clinical Center and that a patient who requested Clinical Center treatment for an unusual illness could not be admitted to the Clinical Center in the absence of a specific, preexisting protocol. Also, the Clinical Center’s increased use of day hospital visits over the past few years has contributed to the reduced inpatient numbers. In addition to a decreased number of admissions, there has been a dramatic decrease in the average length of

stay over the last two decades. (See Table 2-2.) Finally, some Institutes have been forced to cut travel budgets, thus reducing the number of patients able to use the Clinical Center.

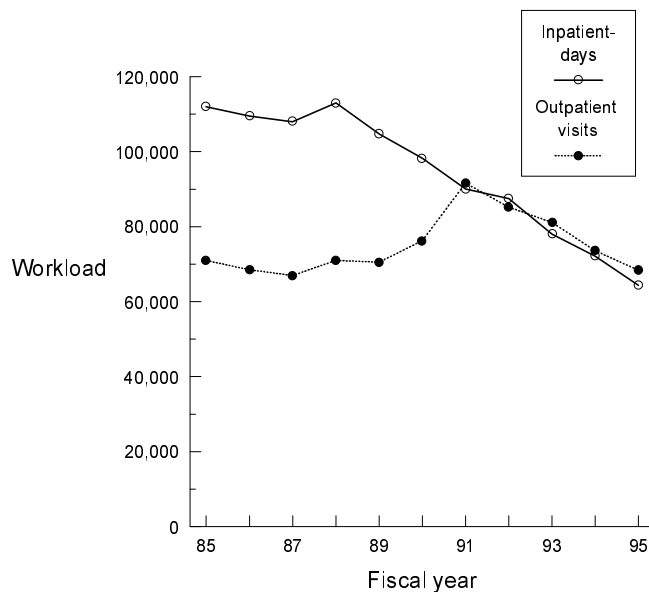


Figure 2-3.
Clinical Center Patient Activity from FY85 to FY95

Table 2-2.
Clinical Center Program Characteristics

Characteristic	FY75	FY85	FY95
Beds	504	496	359
Average daily inpatient census	314	307	176
Admissions	4,939	8,757	6,871
Average length of stay (days)	23	13	9.7
Outpatient visits	45,000	70,135	68,383
Active protocols	1,068	1,110	1,143

The precipitous drop in the length of stay combined with the increase in outpatient interactions suggests that the level of scientific activity in the Clinical Center has not diminished appreciably; rather, the mechanism by which care is provided has changed, reflecting national trends.

FULL-TIME EQUIVALENT STAFF MEMBERS

During the past few years, the Clinical Center's staff levels have been reduced by 337 positions to parallel the reduced patient activity levels. (See Table 2-3.) This 15 percent reduction in FTEs from 2,226 in FY92 to 1,889 at the beginning of FY96 represents a \$19.2 million savings in personnel costs. Streamlining plans are underway to consolidate patient care units and flatten the administrative structure to promote efficiencies and reduce further FTE requirements.

Table 2-3.
Full-Time Equivalent Staff Compared to Workload

Measure	FY92	FY93	FY94	FY95
Bed days	87,521	78,048	72,167	64,389
Outpatient visits	85,215	81,127	73,353	68,383
FTEs	2,226	2,080	2,077	1,889

TRAINING

At the beginning of FY96, approximately 1,200 physicians had patient care credentials at the Clinical Center, including 230 Clinical Associates in training. Most of these credentialed clinical investigators were employed by the individual NIH Institutes or centers; 134 were employed by the Clinical Center. In addition, approximately 80 medical residents rotated through the Center's patient care units from local teaching institutions to provide them with exposure to the unique clinical, ethical, and personal issues that arise in clinical research. The Clinical Center recently developed and began offering a curriculum in clinical research to ensure that investigators are well-trained in the broad issues of clinical research, including epidemiology, biostatistics, ethics, and law.

Clinical Center physicians and support staff work closely with, and are fully integrated into Institute clinical research projects, collaborating with Institute staff and extramural clinical investigators. The relationships among the professional staff members (i.e., physicians, nurses, and pharmacists) of the Clinical Center and the Institutes' investigators are collaborative and interdependent.

RESEARCH PROTOCOLS

All care provided in the Clinical Center is delivered within the context of the active clinical research protocols, including approximately 45 Investigational New Drug protocols approved by the Food and Drug Administration. The number of active protocols has remained relatively stable over the past 20 years,

increasing from 1,068 in FY75 to 1,143 in FY95. These protocols include clinical trials, natural history protocols, screening protocols, and training protocols. A percentage breakdown by protocol type is shown in Table 2-4. Of the active clinical trials, 85 percent are Phase I and Phase II studies. The emphasis on protocols of natural history or disease pathogenesis, Phase I and II clinical trials, is unique at the Clinical Center and, as such, complements the extramural clinical research portfolio, which contains primarily Phase III and Phase IV clinical trials. All protocols are reviewed formally twice each year for resource utilization and yearly for clinical safety and the quality of science.

Table 2-4.
Protocols by Type

Type of protocol	Percentage
Clinical trials	47
Natural history	50
Screening	2
Training	1

Note: Data from 1,143 active protocols in FY95.

SOURCES OF FUNDING — PAST AND PRESENT

From the opening of the Clinical Center in 1953 through FY84, each Institute's annual assessment for the Clinical Center was based on the number of beds it was allocated. That method was straightforward and provided predictability of costs to the Institutes during periods of stable bed assignment and stable utilization. However, over time the Institutes' bed use was variable; as resources became more constricted and healthcare costs escalated, inequities in that system began to emerge.

In FY85, the cost-allocation system was redesigned to "pay for use" so that Institute assessments would reflect resource utilization more accurately. Each quarter, Institutes were allocated a share of Clinical Center costs on the basis of the proportion of services delivered in the immediate past quarter. This new cost-allocation system was better than the previous approach, but quarterly fluctuations in actual obligations began, and the ability of the system to provide good budget planning data deteriorated.

The Institutes were concerned that Clinical Center obligations were increasing at a greater rate than intramural research budgets between FY85 and FY89. Concomitantly, during that period, the Clinical Center regularly had to ask for supplemental midyear funding. In FY90, the system was revised so only annual adjustments could be made to Institute allocations. The budget-allocation system was revised to its current approach in FY93 to allow Institutes to influence their cost assessments through planned patient volumes. The FY90 through FY95 period saw a reversal of the previous five-year experience; the Clinical

Center's budget growth trailed the NIH intramural program by 10.2 percent as shown in Figure 2-2.

Despite these revisions, several impediments to accurate planning still exist, which contribute to inefficiency in the system. These impediments include imprecise investigator patient-volume estimates, difficulty with patient recruitment, problems funding patient travel, difficulty determining prospective and retrospective protocol costs, and a lengthy protocol approval process. Since Institutes pay for what they plan, not what they use, inefficient planning often results in unused resources.

CHAPTER 3

Primary Recommendations: Structural Improvements for the Clinical Center

OVERVIEW

The Options Team reviewed the operations of many medical centers, hospitals, and research institutions to identify their best practices for ensuring operational productivity and fulfillment of mission. The Team concluded that the Clinical Center can operate very well if it makes the changes described in the following subsections:

- ◆ Governance
- ◆ Budgeting
- ◆ Planning.

Chapter 4 is devoted to achieving flexibility at the Clinical Center with the discussion focusing on the procurement, personnel, and contract management functions of the Clinical Center.

CLINICAL CENTER GOVERNANCE

Issue

Currently, Clinical Center governance is structured around a series of NIH committees. (See Figure 3-1.) This structure leads to a lack of clarity in how decisions are made. One result has been delays in implementing important cost-saving measures. In addition, the Clinical Center has no formal access to the experience of external experts in hospital and research management, making the transfer of knowledge about new approaches slow and difficult.

Solution

A clear, logical governance structure should be developed for the Clinical Center. (See Figure 3-2). This new structure should draw on the expertise of leaders from outside organizations and reflect the interests of the Institutes.

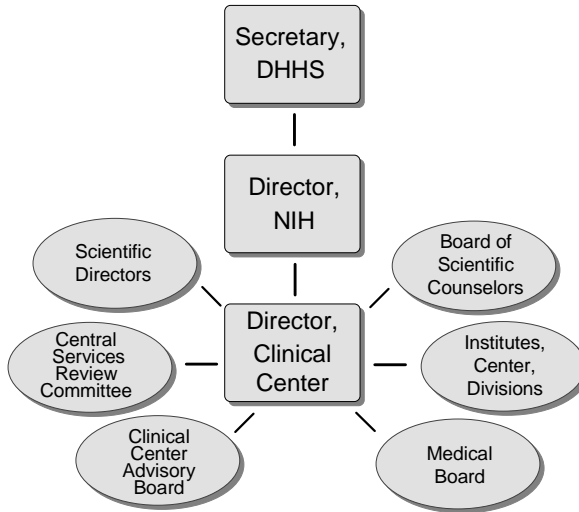


Figure 3-1.
Existing Governance Structure

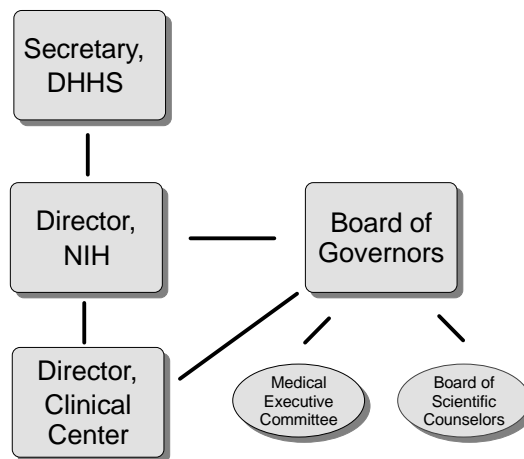


Figure 3-2.
Proposed Governance Structure

- ◆ A Board of Governors (the “Board”) should be appointed by the NIH Director on the basis of recommendations made by Institute directors and the Clinical Center Director.
- ◆ The Board’s membership and structure should be as follows:
 - ▶ The Board should consist of 15 members: 9 nongovernmental and 6 governmental employees.
 - ▶ Governmental members should be NIH but not Clinical Center employees. The only exception to this principle should be the Clinical Center’s Director, who should serve on the Board as an *ex officio* member. Board members from NIH should be selected to ensure broad representation of the Institutes.
 - ▶ External Board members should be selected for their expertise in healthcare governance and management and clinical research.
 - ▶ At least one Board member, either external or internal, should be a registered nurse.
 - ▶ The Board Chair must be an external appointee.
 - ▶ Meetings should be held every other month.
 - ▶ The Board should create committees as necessary to govern effectively.
- ◆ The Board would have several important responsibilities. It should do the following:
 - ▶ Approve a strategic plan.
 - ▶ Approve an annual operating budget and plan.
 - ▶ Make recommendations to the NIH Director about the hiring; performance, including termination issues; and compensation of the Clinical Center Director.
 - ▶ Serve as an advocate for the Clinical Center.
 - ▶ Annually review the clinical services of the various Institutes and report to the NIH Director on the planning and performance of those services.
 - ▶ Receive and review the annual report of the Clinical Center’s Board of Scientific Counselors.

- ◆ An Executive Committee of the Board should be structured to do the following:
 - ▶ Meet during the months when the Board does not meet.
 - ▶ Have full Board authority, except in functions related to the approval of the strategic plan or annual operating plan.
 - ▶ Consist of both external and internal members of the Board of Governors.

- ◆ A Medical Executive Committee should replace the existing Medical Board, and it should be accountable to the Board of Governors for privileges, credentials, and other functions assigned by the Board. This Committee should do the following.
 - ▶ Recommend clinical and managerial quality improvement initiatives to the Board.
 - ▶ Recommend credentialing and privileging actions to the Board.

BUDGETING

Issue

The Clinical Center's budget process is unwieldy. The budget is first appropriated to individual Institutes, transferred as part of the NIH Management Fund to NIH's central administration, and then transferred to the Center. As is the case with all other government operations, the Clinical Center must spend its entire budget within the fiscal year; no carryover is allowed. A complex formula was recently put in place that permits an Institute to reduce its activity at the Clinical Center, thereby achieving some reduction in the amounts paid for Center support. Cost reductions achieved at the Center in recent years have been returned to the general management account at NIH, although not necessarily returned to the intramural research programs. The arrangement provides no incentives to increase efficiency on the part of either the Institutes or the Clinical Center, and it provides no way to encourage increased use of the Center so as to lower unit costs. The current formula also makes future Clinical Center funding far more unstable than funding of NIH as a whole.

Solution

The Clinical Center should have a clearly defined budget of its own from which the majority of its revenues should be derived. Ideally, the Clinical Center's budget should be no less inherently predictable than the budget of NIH as a whole. To improve continuity and stability, allow savings in operating expenses

to be retained and reinvested within the Clinical Center from year to year. To achieve greater flexibility, permit any needed reprogramming between budget categories. Permit the Center to charge insurance companies for some services and to solicit and accept donations. Develop a method for ensuring that all Institutes have continued access to a baseline level of activity at the Center. Permit Institutes that sharpen their forecasting and improve the efficiency of their protocols to increase overall activity.

With the new budget mechanism the Institutes will be guaranteed access to Clinical Center resources based on their historical use of its facilities. To provide incentives for efficiency, Institutes should be encouraged to reduce protocol costs in exchange for increased access to Clinical Center resources. To increase Clinical Center use by the Institutes, excess Clinical Center capacity should be available through an Institute-generated protocol review process. There should also be a method by which outside investigators can be granted the right to perform protocols at the Clinical Center.

PLANNING

Issue

The Clinical Center lacks a strategic plan describing how it will respond to long-range Institute needs, extramural pressures to reduce costs, and competition from alternatives to intramural research.

Without such a plan, decisions that have long-lasting consequences or require long lead-times, will be untimely if they are made at all. Lack of timely decision-making will delay Institute initiatives that depend on the Clinical Center and waste opportunities that benefit the Institutes. One previous effort to write a strategic plan took place in 1990; the resulting document was never finalized, was not used to guide decision-making, and was almost entirely unknown to Clinical Center management.

Solution

As its first action, the Board of Governors should direct the development of a strategic plan for the Clinical Center. Scientific policy and strategy are established by the individual Institutes and the NIH Director. A strategic plan for the Clinical Center defines the ways in which these policies are translated into a unified operational whole.

The plan must include a description of the external and internal pressures faced by the Clinical Center. This includes the current costs of clinical research, trends in Institute funding, public and congressional expectations of clinical research, and trends in cost and outcomes in extramural clinical research. An honest evaluation of the Clinical Center's current strengths and weaknesses will be

essential. The plan should assess the kinds of extramural clinical research that might be best completed at the Clinical Center as well as the question of whether or not some Clinical Center activities should be transferred to external settings.

The strategic plan should describe the major strategies that the Clinical Center will pursue in the next few years. It should be made operational through the development of specific goals and objectives, which can be used to measure management's success in moving the organization forward. A completed plan should be widely distributed. Reevaluation of the plan should be undertaken on a regular basis.

CHAPTER 4

Achieving Clinical Center Flexibility

The Clinical Center needs a great deal of flexibility to operate productively. With greater flexibility, the Center would be better able to implement the many productivity improvement recommendations made in this report. To this end, Reinvention Laboratory status and contracting are discussed.

OVERVIEW

One of the charges to the Options Team was to examine organizational structures that could be adopted by the Clinical Center to provide increased flexibility to ensure efficiency. A subcommittee of the Options Team evaluated a complete spectrum of legal and structural options. Some of the options studied included maintaining the status quo structure, complete privatization, and fully contracted management and operation of the Clinical Center.

Many of the options studied included several variations on a particular theme. For example, under privatization, the Options Team considered five suboptions: government-sponsored enterprises, wholly owned government corporations, employee stock ownership programs, franchising, and Federally Funded Research and Development Centers. Detailed analyses of all the options studied are provided in Appendix D.

Of the options reviewed, the Team rejected options involving full privatization of the Clinical Center or complete contracting out. The Team also rejected the “status quo” option of leaving the Clinical Center fundamentally untouched because greater flexibility and responsiveness is needed to meet future research needs. The Options Team focused on designating the Clinical Center as a “Reinvention Laboratory.”

REINVENTION LABORATORY PROPOSAL

As a result of its analyses, the Options Team recommends Reinvention Laboratory status as superior to the other options. Successful reinvention could facilitate the changes necessary to realize Clinical Center operating efficiency while preserving the current institutional/organizational scientific and clinical research culture. Status as a Reinvention Laboratory also could be used as a bridge to some more radical organizational change, should such a change become necessary.

While the Team felt that three other model structures — the wholly owned government corporation model, the Federally Funded Research and Development Center, and a partial outsourcing model — would provide reasonable structural flexibility for the Center, the Team recommends that the Clinical Center and NIH learn more about the benefits and risks of operating under these structures before adopting one.

The Options Team recommends that the Clinical Center be designated a Reinvention Laboratory immediately.¹

- ◆ The Clinical Center should develop sensitive, specific, and effective performance measurement systems to chart organizational progress, identify opportunities for improvement, and provide solid data upon which reinvention successes can be marketed.
- ◆ In light of both the impermanence of delegations of authority and the concerns about the potentially ephemeral nature of the reinvention process, the Clinical Center reinvention proposal should focus on obtaining legislative changes.
- ◆ The Clinical Center should identify strategically placed advocates to support its reinvention proposal.

The Clinical Center's Reinvention Laboratory proposal focuses on three major support functions: procurement processes, personnel processes, and the financing mechanisms for the construction of a new Clinical Center facility. The Reinvention Laboratory proposal is currently being refined and revised with the assistance and input of NIH and DHHS executives.

Procurement

ISSUES

The Clinical Center's procurement system is time-consuming, labor-intensive, costly, and slow to change. The contract and subcontract award process is cumbersome and unresponsive to a research and development environment. Specific problems are related to small purchases, low competition thresholds, and sole-source award requirements. Although some of the needed changes may require legislative action, many others can be accomplished through relaxation or removal of regulations, guidelines, and directives promulgated at various levels within the Executive Branch and its agencies.

¹The Options Team surveyed major internal NIH customers to identify those customers' perceptions regarding the major obstacles to operating efficiently under Reinvention Laboratory status. With the assistance of the Clinical Center's senior staff, the Team drafted a Reinvention Laboratory proposal to address identified obstacles to efficiency. That proposal focuses on the development of performance measures that can be used to quantify success.

SOLUTIONS

Although the Reinvention Laboratory proposal deals extensively with procurement system changes, the Options Team recommends increasing the flexibility, accountability, and responsiveness of the procurement process. The Team believes that the Clinical Center needs to take better advantage of alternative methods of contracting — such as “best value” contracting methods, credit cards, “prime vendor” services contracts, and blanket purchase agreements — to do two things: The first is to reduce the cost of the goods and services the Clinical Center acquires as well as the cost of the acquisition cycle of identifying, ordering, receiving, distributing, and paying for goods and services. The second is to increase the responsiveness of the procurement process, both in terms of the time needed to acquire necessary supplies and services and in terms of reducing the administrative workload the procurement process places on the Clinical Center staff.

The most significant cost savings appear possible in the procurement of supplies. Almost all other U.S. hospitals use cooperative buying consortia to pool their purchasing power: Many academic medical centers save money by using the University Health Systems Consortium for purchases. Other government hospitals, such as those in the Departments of Defense (DoD) and Veterans Affairs, use the power of legislative mandates to ensure that vendors offer them the lowest prices. In contrast, a substantial amount of the supplies consumed by the Clinical Center are acquired from the local retail market. The Center needs to take better advantage of its purchasing power to obtain lower product prices.

Commercial distribution of supplies should also be pursued by the Clinical Center to further reduce its costs. Under just-in-time delivery contracts with vendors, warehouse and inventory costs can be reduced significantly. Several companies offer to deliver supplies directly to ordering units in other hospitals, thereby reducing the hospitals’ material-handling costs. There are many other opportunities for the Clinical Center to develop innovative partnership arrangements with distributors and manufacturers. For example, the Center should learn about the risk-sharing contracts that several academic medical centers recently have entered into with vendors that have resulted in cost savings.

Several departments within the Clinical Center have started contracting with a prime vendor for supplies. The Clinical Center should perform a before-and after comparison of costs under the prime vendor program. Other government organizations have obtained savings in three areas: one-time inventory savings, ongoing savings from reduced materials management overhead costs, and ongoing savings from a large reduction in the number of local purchases made. Annual savings in those other government organizations of 5 to 15 percent of the total supply budget are common. If the prime vendor program can also be shown to save money and improve service at the Clinical Center, then such arrangements should be encouraged and expanded.

The Clinical Center has another significant opportunity to reduce the cost of supplies by improving awareness within the Clinical Center of available

contracts and sources of supplies and services. For example, DoD hospitals using prime vendor contracts also use a sophisticated electronic catalog that comparison shops for them. By comparing like items from different sources or in different package sizes, those hospitals have achieved significant savings in purchasing supplies. NIH could use DoD's electronic catalog as a tool to reduce its supply costs. Making information more accessible to users in the Clinical Center can encourage savings through economies of scale.

The Options Team also believes that the Clinical Center should give managers more authority to contract or place orders with vendors. Often, the department managers are more aware of offered values than are the procurement staff members. The Team recommends that NIH issue credit cards to department managers in the Clinical Center, allowing them to expedite purchases, take advantage of savings offered by vendors, and greatly reduce paperwork. Studies have shown that the average cost to place a purchase order through the normal procurement process is between \$100 and \$250 per order — a cost that can be eliminated for the majority of the Clinical Center's purchases through the use of credit cards. The Options Team believes this to be consistent with its earlier recommendation to develop mechanisms for the management of budgets at the departmental level. It should provide department managers with the authority to operate effectively and accountably within their budgets.

Changes in procurement practices have brought significant benefits to public and private hospitals around the Nation. The Clinical Center needs to adapt those practices to its own environment to begin reaping the same benefits. Many of these benefits extend beyond the purchase price of the products being used and include increased staff efficiency, reduced record keeping, lower supply inventories, and improved service. The Clinical Center's Reinvention Laboratory proposal provides specific details of the needed changes and the appropriate level at which they should be made.

Personnel

ISSUES

The government's personnel system is so complex that managers and employees find it difficult to understand. It is so fragmented that they have difficulty making the system support their needs. Although the government's personnel system is structured to provide fair, consistent rules for employees and managers, it undermines the Clinical Center's efficient operation.

The processes associated with classification, pay, recruiting, hiring, evaluating, promoting, and terminating are too lengthy, duplicative, inflexible, cumbersome, documentation laden, and nonresponsive. The existing Federal compensation system is relatively rigid, and the pay system lacks flexibility. Department managers are given little decision-making authority and flexibility, and the system does not permit rapid responses to changing labor market conditions and research needs. Many processes require multiple levels of approval,

add unnecessary costs, and decrease staff satisfaction and productivity. Processes that should be relatively simple, such as hiring temporary employees or keeping term employees for the duration of a research protocol, are overly complex or impossible.

SOLUTIONS

In the Clinical Center's reinvention proposal prepared by the Options Team specific actions to improve the personnel system are detailed. Briefly, the Reinvention Proposal calls for the Clinical Center to obtain delegations of authority from both NIH and DHHS, waivers from existing regulations, legislative relief, and status as an Office of Personnel Management Demonstration Project. Those actions will allow the Clinical Center to implement several improvements. First, the Clinical Center could use alternative pay systems — such as those allowed under Title 38 of the United States Code — to improve the hiring and performance management of patient care staff and adjust the pay for clinical professionals.² For example, the Clinical Center could enable clinicians who oversee Senior Executive Service employees to participate in Title 38; allow dentists to participate in the Title 38 mechanism; and improve the recruiting, retention, and compensation of selected staff members.

Second, the Clinical Center could use employee appraisal systems like those in use at other Demonstration Project sites to adjust compensation based on performance, not tenure (abolishing the within-grade system); adjust the performance appraisal period consistent with the nature of the position; and simplify the amount of paperwork associated with the process. The Clinical Center should also consider alternative processes for evaluating employee performance.

Third, the Clinical Center could recruit for and staff its activities using the Center's mission, budget, and performance requirements to determine staffing levels and specialty mixes. This capability would also allow the Clinical Center to hire term employees for periods beyond the current four-year limitation (for the duration of a particular research protocol, or other mission need). Greater authority should also be given to expand the use of flexible working hours and the conditions under which off-site work is appropriate.

Fourth, improving the processes by which grievances and disciplinary actions are handled could increase a manager's ability to take timely disciplinary action and to consider alternative forms of discipline not currently authorized by legislation.

The Options Team's recommended changes are partially attainable within existing statutory and regulatory parameters. Some of them involve delegations of authority to the Director of the Clinical Center, authority which previously

²Title 38 of the United States Code is directed at the Veterans Administration. However, provisions are authorized for use by NIH through legislation, Pub. L. 100-607; by registered nurses and allied health specialists; and by physicians through a delegated agreement with the Office of Personnel Management.

resided at the DHHS or NIH levels. Legislative changes would allow the Clinical Center to design an alternative personnel system specifically suited to its uniqueness. The Options Team believes that these goals can be achieved without compromising the principles of fairness and consistency that underlie the existing personnel system. In fact, experience at other institutions suggests that simplifying personnel systems may actually improve their fairness, consistency, and efficiency simultaneously.

Clinical Center Renewal

ISSUE

The Clinical Center's 40-year-old physical plant is increasingly inadequate for the conduct of clinical research; it requires replacement. Funding for the replacement of the structure, which will cost an estimated \$380 million, is uncertain at this point. Limited funds have been appropriated for design studies, but actual construction funding has not been approved or appropriated by Congress.

NIH would like to use funds generated by increasing the Clinical Center's efficiency to pay for some of the construction of the replacement facility. Unfortunately, the Clinical Center, as a government organization, does not have the ability to carry savings forward from one fiscal year to the next, nor does it have the flexibility to use savings originally appropriated for Clinical Center operations to finance a construction program.

SOLUTION

The Options Team recommends that the increased flexibility gained under the Reinvention Laboratory program include the ability to carry savings forward from one fiscal year to another. The Team also recommends that the program include the capability to use funds saved in one accounting classification, in this case, Clinical Center operations and management, to finance another accounting classification — such as construction of a new Clinical Center. The draft initial reinvention proposal circulated by the Clinical Center did not include a description of these points, but the current version, does include these points.

Questions about the appropriate size and capacity of the replacement facility, its precise cost, and other planning issues are being studied concurrently with the REGO II effort and will be presented in a separate report.

CONTRACTING OPTIONS

Issues

Contracting out the operations of the Clinical Center was proposed by DHHS in early 1995. The Department's proposal reflected growing concerns about the Clinical Center's operational cost efficiency. Initially, contracting appeared to offer some potential for relief because it has been widely viewed as more efficient than in-house government operations and because it has worked with some degree of success in the government. According to proponents of contracting, contracted operations are more cost-effective, more responsive, and more flexible than many government organizations. However, good contracts for complex government functions are difficult to write and require significant expertise in contract administration.

Elements of Successful Privatization

According to the *Harvard Business Review*³ and other expert sources, a successful privatization initiative must satisfy several prerequisites:

- ◆ First, the organization performing the contracting action must clearly understand its tasks, conditions, and standards if it is to generate a usable statement of work.
- ◆ Second, the privatization must be accompanied by clear, measurable performance objectives understood and agreed to by all parties.
- ◆ Third, the process being considered for privatization should have clearly delineated resource inputs and outputs.
- ◆ Fourth, the flow and variability of the work being considered for privatization should be measurable, predictable, and, if possible, controllable.
- ◆ Finally, the function to be contracted out should usually consist of a function that is not mission-critical or that could not be considered part of an organization's "core competency." The exception to this prerequisite is found in those companies whose survival is so imperiled that contracting out their core competency is the only remaining option.⁴

Contracting out has been applied with some success in government organizations. The Department of Energy's (DOE's) massive laboratory network provides one notable example because it involves the outsourcing of complex research and development functions and it illustrates the tightly interwoven

³Richard Peisch, "When Outsourcing Goes Awry," *Harvard Business Review*, May - June 1995, pp. 24-37.

⁴Paul Strassman, "Outsourcing: A Game for Losers," *Computerworld*, August 21, 1995.

collaboration possible between government and contractor personnel in some outsourced operations. It should be noted, though, that DOE's approach has been the ongoing target of criticism by the General Accounting Office and others in recent years.

"Firewalls" erected to prevent abuses of government power have created significant inefficiencies in government operations, but it is not at all clear that the pressure to contract for services can, in and of itself, remedy this. The same pressures exerted to accommodate competing political interests have found their way into Federal contracting practices. Because the government, by design, chooses even-handedness and open competition over efficiency, the contracting process itself introduces costs and inefficiencies.

Even the most efficient contractor will incur substantial costs as a result of government contracting practices; costs that are ultimately passed on to the government. Thus, direct comparisons of Clinical Center operations with private-sector organizations (when such comparisons are even possible) must be adjusted.

Studies of Federal contracting practices have estimated that they add at least 5 percent, and as much as 25 percent, to the cost of a typical contractor's activities. To accurately predict costs of privatizing the Clinical Center, one would need to obtain cost data for the proposed contractor and then adjust it upward by 5 to 25 percent to account for the expected additional cost for that contractor operating under Federal rules.

Another factor limiting the ability of contractors to transfer the efficiencies in their own private-sector operations to the provision of government healthcare services is that even private-sector firms are bound by many of the same practices that make a government organization inefficient. While contractors enjoy more flexibility with regard to staffing and procurement, they are not free to maneuver as widely in these areas as private-sector organizations dealing with each other. For example, government acquisition regulations, in addition to dictating that the government purchase supplies and services from a certain number of small or disadvantaged businesses, also require that government contractors follow similar procedures. In fact, the regulations also require that contractors monitor and document their compliance with these procedures, thus introducing additional overhead requirements.

PRIVATIZATION AND NIH

Of the five prerequisites noted, only one (workflow predictability) is satisfied at the Clinical Center. Because the clinical workload at the Center is protocol-driven, workload is relatively controllable; however, the fact that investigators at the 15 individual Institutes using the Clinical Center determine patient accession means that workload control is, by definition, highly decentralized. Therefore, even this one element of successful privatization that is present at the Clinical Center is not easily monitored or regulated on a central

level. Furthermore, because the Clinical Center is engaged in basic research about diseases and treatments that are largely unknown, the knowledge base about the long-term progress of a protocol is discontinuous and incomplete. In part, because of the complexity of research programs, developing clearly understood tasks and conditions and explicit performance criteria could be even more difficult at the Clinical Center than it is for most other government functions.

The fact that the Clinical Center is physically, organizationally, and culturally a part of NIH makes clear delineation of resource inputs and outputs difficult. The Clinical Center provides housekeeping, central sterilization, and other support services to the NIH campus, while the NIH infrastructure supports a wide range of Clinical Center needs. The range and scope of these interwoven operations makes it virtually impossible to know without extensive analyses who pays for what within the Clinical Center. For example, laboratories in the Clinical Center are physically located on the property of the Center, but are actually owned by the Institutes using them. Moreover, staff may be funded by one or several of the Institutes, engineering and support services provided by the NIH Central Services Fund, housekeeping paid for by the Clinical Center, and supplies funded by an individual research protocol, except for media and glassware used in the lab, which is once again an expense borne by the Clinical Center. This interweaving exists at the very highest levels, where Clinical Center operations are financed by the pooled resources of the Institutes, down to the very lowest levels, where even office supplies are drawn from a variety of funding sources. In fact, even intellectual activities are interwoven, as in the case of protocols that are performed jointly by Clinical Center and Institute researchers. The intricate intertwining of functions and responsibilities, which is the result of 30 years of co-evolution, has produced extraordinarily productive research efforts. It has also produced an organization that would be very difficult to document in developing a statement of work.

Finally, the issue of core competency and the Clinical Center's importance to NIH research objectives needs further exploration. Two issues present themselves: First, the Clinical Center is not a typical 250-bed hospital; the protocols carried out at the Clinical Center represent the most basic and difficult biomedical research work in the world. No other institution in the world operates clinical research facilities even remotely approaching the Clinical Center's in terms of scale, complexity, and ambiguity. Although a variety of healthcare organizations manage complex hospitals and other patient care settings, the Clinical Center's research functions dwarf the patient care aspects of its operation. Since no other organization in the government, private sector, or academia manages a clinical research function of such complexity, it is not now possible to determine whether another organization could do a better job of managing the Clinical Center in a privatized setting.

The second issue concerns the importance of the Clinical Center's functions. Because the Clinical Center is investigating more basic scientific questions than other generalized clinical research facilities, it represents the "seed corn" of the American medical establishment. The fundamental medical breakthroughs that have made American medicine unique in all the world have been achieved, in

large measure, because of the fundamental investigative output of the Clinical Center. Whether all or part of the Center could be privatized is not at issue; in theory, all government functions can be privatized. Instead, the question is about the risk of privatizing such a basic and fundamentally important function as the Clinical Center in a setting where many interrelated research activities would remain within the government. Do the potential efficiencies of privatization justify risking productive biomedical research and the American medical enterprise?

SOLUTIONS

Because the Clinical Center's operations and external relations do not meet the criteria for successful privatization initiatives, the Options Team does not recommend that large-scale privatization be pursued at this time. The issue of privatizing the entire Clinical Center was clearly and explicitly proposed, reviewed, and rejected by all participants in the REGO II study process, including the external consultants. The REGO II analysis revealed privatization to be less desirable than other options, and rejected it.

Further analysis to determine the feasibility or economic desirability of contracting for even limited functions is due to lack of data. Instead, NIH leaders should attempt to identify selected Clinical Center functions that are not directly linked to its core competency of biomedical clinical research and to develop a contracting strategy for those noncore functions.

CHAPTER 5

Secondary Recommendations: Operational Improvements for the Clinical Center

The Clinical Center can take several actions to assess and address internal operational improvements. During the past several years, the Clinical Center has focused on quality improvements and steps have been taken to implement change. Department managers have looked for ways to improve efficiency and to reduce costs; many have been successful in doing so.

Implementation of the recommendations that follow would help bolster and integrate managers' efforts. Most of the recommendations can be undertaken immediately within the current structure of the Clinical Center.

PERFORMANCE MEASURES AND BENCHMARKING

Issues

The Clinical Center should use performance measures to gauge overall efficiency and to demonstrate that NIH customers are receiving value for their expenditures. Managers need to be held accountable for their performance; workload and productivity indices can be used as the criteria for assessment.

Solutions

The Clinical Center should develop performance measures and benchmark work processes with a cost accounting system designed to provide support for tying costs to performance. Two types of benchmarking should be used. Internal benchmarking permits an organizational unit to assess its performance over time. Benchmarking against units at outside organizations is also worthwhile, especially when similar functioning units are compared.

An incentive system should be developed whereby efficiency is recognized and rewarded. Reinvesting a portion of saved resources to expand or enhance research and/or the work environment can provide a strong motivation to supervisors and staff to improve performance.

The output from these efforts will provide the Clinical Center mechanisms to demonstrate to NIH Institutes that they are receiving value for their money.

Benchmark standards will result in the ability to measure quality and costs. Caregivers and supervisors will be able to manage resources on the basis of reliable and valid data. Clinical Center leaders will receive cost and performance information and have a means to promote accountability. Moreover, they will be able to link clinical research outcomes to financial performance.

INFORMATION SYSTEMS

Issues

The Clinical Center is a world leader in computerizing clinical data. It falls short, however, of having an information system that provides managerial and financial data needed by managers. Those managers need information that is timely, relevant, accurate, and clear for informed decision-making, which is imperative to increased efficiency and enhanced productivity.

Investments in information technology have not been sufficient to build the infrastructure necessary for integrating clinical research outputs with data about resource allocation inputs. The data currently provided are retrospective and difficult to use in making operational decisions. Timely information about performance and costs is not available. The architecture of the computer system is outmoded and cannot effectively integrate data between and among departments.

Solutions

The Clinical Center should complete a detailed and comprehensive information systems plan. The plan should focus on economic costs and benefits and identify efficiency improvements that may help finance system improvements.

Line managers should specify information needs and help design systems that meet their requirements. They should define the data elements necessary to measure whether or not performance and financial objectives are being met.

A strategy must be developed that ensures the integration of information. Information about performance indicators should be shared across departments. A resource allocation methodology or template should be developed to allow clinical research resource demands to be arrayed. This would permit meaningful analysis of resource consumption by operational research staff and Clinical Center management.

A substantial increase in the investment for information technology must be made. While a detailed plan must be undertaken, the Options Team expects that a five-year investment of \$9 million to \$14 million is needed to develop administrative and management information systems. A significantly larger staff within the information system department also will be needed.

The Clinical Center's information technology staff should participate in the assessment of all major information projects from the development of proposal requests through evaluation of the technology and feasibility of the project. Staff should assess a proposed technology's compatibility with existing and planned information architectures. Moreover, emphasis must be placed on how effective the project would be in meeting organizational information goals.

Clinical Center leaders will benefit from the expanded capability of a new information system. They will be able to gather and use information that is relevant and indicative of departmental efficiencies. Interdepartmental evaluations can be undertaken, with concomitant increases in flexibility and accountability. Decisions about resource allocation will be enhanced by timely, relevant, and usable data.

PUBLIC INFORMATION

Issues

The outstanding work of the Clinical Center is not being communicated to those outside NIH in an effective manner. The public, insurers, and referring physicians must be informed about the ways that the Clinical Center promotes the highest standards for conducting research and training clinical researchers. Dissemination of the Clinical Center's accomplishments will enhance patient recruitment and heighten research interest. Effective communication is essential to encourage other researchers to participate and collaborate in NIH-sponsored studies.

Solutions

Internal and external communications should be enhanced. Particular emphasis should be placed on communicating the Clinical Center's successes to the public rather than exclusively to the scientific community. Collaboration with consumer organizations, oriented toward specific diseases or toward improved consumer choice in healthcare, should be a major element in the communications strategy. The public information office should be responsible for conducting surveys of NIH scientists, staff, patients, and other customers to provide feedback to Clinical Center leaders.

PATIENT RECRUITMENT

Issues

Traditionally, recruitment of patients into clinical protocols has been the responsibility of individual Institutes. NIH specialists, many of whom have

received training at the Clinical Center in the past, have worked with their colleagues in academic medicine to disseminate information about existing protocols and to encourage patient referral. There is a widespread perception at NIH that this traditional physician-based referral system does not work as well as it once did. While many well-known protocols and well-known researchers still receive more than sufficient referrals, other excellent and important studies have languished for lack of patients, despite significant efforts by the researchers to recruit patients.

A variety of reasons for the decrease in referrals to Clinical Center protocols has been explored. These include decreased referrals from academic centers because of the growth of managed care, a reluctance of academic physicians to refer patients in a fiercely competitive environment, and decreased willingness by patients to travel long distances or to remain hospitalized for long periods to receive care.

The DHHS Inspector General also raised concerns about the patient recruitment practices of some Institutes. A recent study of the National Heart, Lung, and Blood Institute questioned the cost of cardiac surgery provided to research patients as an inducement to participate in trials. This same Inspector General report also noted that a large proportion of patients in some protocols are foreign nationals; it recommended that a special policy be adopted with respect to these patients.

Solutions

The Options Team recommends the following:

- ◆ In the modern healthcare world, patients often make referral decisions on their own or with advice from their insurers. Therefore, the public should be directly informed about the availability of the Clinical Center and the risks and benefits of participation in its research.
- ◆ Managed care plans are likely to be very conservative about referrals to the Clinical Center because of the fear of liability. They do not wish to be seen as pushing patients toward research merely to save money. Education of managed care case managers and medical directors about ethical referral practices could increase referrals.
- ◆ Because the general practicing medical community, even in nearby areas, has little sense of what the Clinical Center is and what it does, the Center needs to establish a clear public image to encourage medical practitioners to refer their patients to the Center.
- ◆ Managed care plans of all types may be more comfortable referring patients if they have a contract with the Clinical Center. These agreements could establish the duties of a managed care plan after the patient's initial treatment.

- ◆ The development of shared research protocols, in which techniques such as telemedicine are used for follow-up, could increase referrals from academic physicians. Patients are likely to view such arrangements as more convenient and attractive.
- ◆ The Clinical Center has an outstanding reputation with patient advocacy groups interested in some of the diseases being studied. The Clinical Center staff can learn from these advocacy groups how best to approach other consumer organizations in ways that will enhance referrals.

CHARGING FOR CLINICAL CARE

Issue

Should the Clinical Center charge patients and insurance companies for some of the services it provides? The Inspector General of DHHS recommended doing so in a recent report. Similar recommendations were made in an earlier report by the General Accounting Office. These reports recommended that legislation be proposed to permit the Clinical Center to bill for services received by patients in the control arm of randomized clinical trials. Their rationale was that routine care was provided and should therefore be covered by insurance.

Solutions

To obtain views on the issue of charging patients, the Options Team met with Dr. Sandra Harmon-Weiss, Senior Vice President of U.S. Healthcare, Inc., and with Dr. Michael McGarvey, Senior Vice President of Blue Cross and Blue Shield of New Jersey, an external consultant to the Options Team. Dr. McGarvey also discussed the issue informally with several other Blue Cross and Blue Shield vice presidents and submitted a report to the committee, which is included as Appendix E. Several Options Team members also visited with senior staff and the billing office at Walter Reed Army Medical Center. Walter Reed recently began billing for insured individuals also eligible for CHAMPUS.

The external consultants and the Options Team unanimously agreed that the patient charging arrangement suggested by the Inspector General would be unacceptable because it would conflict directly with key principles of clinical research. Patients in all arms of a clinical trial are studied using protocols designed to provide scientific information. The testing and supervision offered to patients receiving “standard” care is determined by the needs of the clinical trial, not of the individual patient. Therefore, clinical research does not parallel routine or standard care in any sense, and insurance companies will not pay for it.

Patients who agree to participate in clinical research accept a number of risks. They must be willing to give up control and choice with respect to treatment, must accept additional testing to support research goals, and must often

face entirely unknown dangers from new and untried treatments. Patients who participate at the Clinical Center must often also accept the inconvenience of traveling long distances for treatment. Asking them to accept financial risk as well would create a sense that patients in a standard treatment arm are not getting the real benefits of research. Such an arrangement could markedly decrease the willingness of insured patients to participate in research because of the risk of loss of insurance and the burdens of paying coinsurance and deductibles out of pocket.

We recognize that, in a period of diminishing resources, identifying additional funds for the Clinical Center will be critical to its continuing function. The right to retain income and donations for Clinical Center and NIH use should be sought. The arrangement at the Department of Defense, in which insurance money is shared between the billing hospital and the overall clinical service, could serve as a model.

During the discussions about charging for clinical care, several innovative ideas surfaced that should be much more acceptable to patients and their insurers than traditional fee-for-service billing. These include the following:

- ◆ Charge a flat fee to all insured patients admitted to certain predefined protocols. The fee should be somewhat lower than would be paid for care at another institution, and all coinsurance and deductibles should be waived.
- ◆ Charge, on an annual basis, insured patients admitted to “natural history” protocols.
- ◆ Write contracts with insurers in which they agree to contribute a fixed amount to a Clinical Center fund for every patient admitted to a Clinical Center protocol.
- ◆ Write capitation contracts with large insurers in which the Clinical Center agrees to accept patients with certain rare diseases. These patients are followed in natural history protocols.

In all instances, charging arrangements should be simple and straightforward, avoiding the complexity and the cost of traditional fee-for-service billing. Patients without insurance should never be disadvantaged in terms of acceptance into protocols. Insured patients should be forgiven the payment of out-of-pocket expenses. Patient confidentiality should be carefully protected, and individuals who request that their participation in research not be revealed to their insurance companies should have these requests honored. Finally, control of who is and who is not admitted to a protocol must remain with the patient and the researcher. Patients must be free to refuse research treatment and researchers must be free to reject those who do not meet protocol criteria or who are judged inappropriate for a given trial.

APPENDIX A

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and External Consultants

Options Team Members and External Consultants

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APPENDIX B

Summary of Site Visits Conducted
by the Options Team

Summary of Site Visits Conducted by the Options Team

Each of the seven subcommittees of the Options Team visited a number of organizations outside NIH in order to develop a sense of how they operate in today's environment. The subcommittees incorporated the knowledge gained during the site visits in their deliberations. The formulation of subcommittee recommendations was influenced by this insight. A summary of each visit is attached.

Contents

Alaska Native Medical Center (ANMC) — Anchorage, Alaska	B-7
Baltimore Veterans' Affairs Medical Center — Maryland	B-8
Barnes Hospital — St. Louis, Missouri	B-9
Boston Children's Hospital — Massachusetts	B-10
Corporation for National and Community Service — Washington, D.C.	B-11
Dana-Farber Cancer Institute — Boston, Massachusetts	B-12
Duke University Medical Center and Health System — Durham, North Carolina	B-13
Emory University Hospital System — Atlanta, Georgia	B-14
Fairfax Hospital — Falls Church, Virginia	B-15
Federal Home Loan Mortgage Corporation (FREDDIE MAC) — Washington, D.C.	B-16
Frederick Cancer Research and Development Center — Maryland	B-17
Henry M. Jackson Foundation for the Advancement of Military Medicine — Rockville, Maryland	B-18
John Dempsey Hospital, University of Connecticut	B-19
Johns Hopkins Hospital — Baltimore, Maryland	B-21
Logistics Management Institute (LMI) — McLean, Virginia	B-22
Massachusetts General Hospital — Boston	B-24
Mayo Clinic — Rochester, Minnesota	B-25

Contents (Continued)

Mount Sinai Hospital — New York	B-26
National Institute of Standards and Technology (NIST) — Gaithersburg, Maryland	B-27
National Library of Medicine (NLM) — Bethesda, Maryland	B-28
OP Demonstration Projects — Washington, D.C.	B-29
Phoenix Native Medical Center — Arizona	B-30
University Hospital — SUNY Health Science Center at Syracuse — Syracuse, New York	B-31
University of California — San Francisco	B-32
University of Chicago Hospitals — Illinois	B-33
University of Maryland Medical Center — Baltimore	B-34
University of Michigan Hospital — Ann Arbor	B-35
U.S. Army Medical Research and Materiel Command (MRMC) — Fort Detrick, Maryland	B-36
Walter Reed Army Medical Center — Washington, D.C.	B-37
Clement J. Zablocki Veterans' Affairs Medical Center — Milwaukee, Wisconsin	B-38

Alaska Native Medical Center (ANMC) — Anchorage, Alaska

Meeting date: 12 June 1995

Participants: Dr. Richard Mandsager, Director

Subcommittee: Reinvention

Major objectives as a Reinvention Laboratory:

Redesign the procurement and personnel systems to be flexible and responsive to customers and staff.

Conduct customer surveys.

Become competitive in cost and quality.

Activities undertaken:

Personnel:

Restructured pay schedule.

Waived recruitment, relocation, and retention regulations.

Implemented alternative work schedules and maxi-flex time.

Administered customer surveys without agency-level approval.

Procurement:

Use credit cards for micropurchases.

Raise sole-source approval threshold.

Authority to approve and initiate personal services contracts.

Themes and advice:

Obtain legislation changes initially.

Differentiate between agency-level and site-level policies.

Identify a “champion” at agency level to fight for you.

Measurement systems and strategies are critical success factors.

Have innovative and creative management prior to reinvention.

Baltimore Veterans' Affairs Medical Center — Maryland

Meeting date: 7 August 1995

Participants: Sharon Warren, Reinvention Coordinator Chief of Nursing

Subcommittee: Reinvention

Major objectives as a Reinvention Laboratory:

- Provide efficient and effective managed care.
- Increase patient satisfaction.
- Establish mission-driven teams.
- Develop performance-based measurement.
- Redesign committee structure.
- Overlay a matrix on the organizational structure.
- Develop technology projects.

Activities undertaken:

- Reorganization and job design of nursing staff.
- Realignment of support services.
- Use of technology for nursing staff.
- Improvement of the recruitment process.
- Introduction of a nursing case management model.
- Decentralization of nursing service division.
- Development of patient-focused care model.
- Use of multifunctional workers for nonclinical tasks.
- Establishment of staff training for customer interactions.

Themes and advice:

- Develop sound measurement systems and strategies to show progress.

Barnes Hospital — St. Louis, Missouri

Meeting date: 18 August 1995

Participants: John J. Finan, President; Vice President of Ancillary Services, Director of Information Systems, Director of Organizational Development, Director of Medical Records, Director of Clinical Laboratories, Directory of Surgery, Director of Radiology, Director of Nursing.

Subcommittees: Governance and Information and Reporting

Major objectives:

Establish integrated health delivery system with partners, consolidate and integrate services with partners.

Develop low-cost position to compete effectively in managed-care environment.

Reduce operating costs by 30 percent (10 percent across-the-board cut ordered in August).

Reduce staff by 15 to 20 percent (500 positions cut, mainly by attrition in 1995).

Develop fully integrated clinical, financial, research, and administrative information system.

Activities undertaken:

Defined 16 clinical service lines, each responsible for identifying business by market share, financial and cost position, competitiveness, and options.

Clinical service directors held accountable to meet planning objectives.

Financial incentives given for meeting goals.

Shifting all RN staff to skill mix using patient care technicians.

Belong to Voluntary Hospital Association consortium for procurement and use their clinical financial information system to benchmark with other hospitals, especially as concern top 25 DRGs.

Institute physician profiles to ascertain low-cost and high-cost providers and use M.D. headed teams to bring them into a high-profit position consistent quality.

Reduce warehouses and inventories, deal with Baxter for supply distribution.

Increase outsourcing; in-house departments compete to provide services.

Use teams to look at ways to cut costs and improve productivity and quality.

Developing care paths to improve processes; piloting patient-focused care.

Twenty two information system projects, e.g., electronic patient records, master patient index, executive and manager computer workstations, and outcomes review.

Project with three corporations to develop multihospital information system.

Developing new reporting pathways, department/organizational relationships.

Themes and advice:

Important to engage in sophisticated strategic planning to develop organizational mission and goals.

Managers plan for their departments how to implement change to meet the organizations strategic goals and are held accountable for doing so.

Must focus on cutting operational costs and measuring efficiency and effectiveness – even nickel-and-dime savings are important.

Boston Children's Hospital — Massachusetts

Meeting date: 28 July 1995

Participants: Michael Epstein, M.D., Executive Vice President; Chief Operating Officer
Hospital Epidemiologist, Program Director of General Clinical Research Center,
Representatives in Medicine, Cardiology, Pediatrics, Pediatric Oncology, Pediatric
Nephrology, Laboratory Medicine, and Research Affairs

Subcommittee: Benchmarking

Major objectives:

Reduce operating costs by \$22 million; increase net revenues.

Monitor financial, program, and operational performance.

Inventory management and product safety standardization.

Quality improvement – optimal measured outcomes, maximum customer satisfaction, and efficient use of resources.

Evaluate outsourcing opportunities – compare in-house with contracted service provision on the basis of true variable costs.

Improve information system.

Activities undertaken:

Contracting with prime vendor for just-in-time stockless inventory system.

Develop clinical clusters with bottomline – manage own operating and capital budget with authority to hire and contract.

Incentivizing cost saving by keeping saved money to be retained by a department.

Interdisciplinary program based on the Patient Care Assessment (PCA) model.

Committee to measure quality, think strategically, prioritize goals, and cycle improvement of outcomes rapidly.

Benchmark by tracking own internal operations over time, rather than try to compare with other hospitals.

Assessing whether to contract food services – contract for linen service (saved \$100,000) and security (saved 15 percent).

Looking at computerized order entry and lab system upgrades.

Survey customers biannually to measure satisfaction and identify problems.

Themes and advice:

Use interdisciplinary committee structure to deal with thorny issues and with planning and prioritization of goals.

Objectives clearly spelled out and department goals are aligned with those of the organization.

Incentive system used to financially reward cost-efficiency.

Quality must not be compromised by cost effectiveness actions.

Prospectively price research protocols.

Develop measurement systems with employee input.

Corporation for National and Community Service — Washington, D.C.

Meeting date: 3 August 1995

Participants: P. Kalwolczyk, Chief Financial Officer Corporate Attorney

Subcommittee: Vision

Type of organization:

Wholly owned government corporation.

Involves Americans in community-based service (focus on education, public safety, and human and environmental needs).

Governance:

Fifteen member Board of Directors; appointed by the U.S. President, with the consent of the Senate.

Ex-officio members include Cabinet Secretaries and other administrators.

Chief Executive Officer, two managing directors, and a Chief Financial Officer are appointed by the President, with the consent of the Senate.

Budget and Finance:

Financed 100 percent by appropriated funds.

Subject to all Federal financial accountability regulations and audits.

National Service Trust established to reinvest funds and use interest for capital and other expenditures.

Authority to solicit and accept public donations.

Personnel:

CEO appoints employees and determines their compensation in accordance with Title 5.

Has authority to devise an alternative to the personnel system and to issue regulations for selecting and compensating employees.

Procurement:

Adhere to all provisions of the Federal Property and Administrative Services Act of 1949 and its amendments.

Advantages:

The corporate structure permits flexibility and ease of function.

Corporate regulations made quickly.

Public/private partnerships have been facilitated.

Disadvantages:

Enabling legislation defines power and change is difficult.

No relief from Federal acquisition regulations because not given in charter.

Getting sufficient appropriated funds is difficult.

Dana-Farber Cancer Institute — Boston, Massachusetts

Meeting date: 28 July 1995

Participants: Dorothy Puhly, Chief Financial Officer; Chief of Clinical Services; Director of Budget and Reimbursement; and the Database Administrator

Subcommittee: Budget

Major objectives:

Cost reduction to effectively compete in a changing marketplace, with managed care making major inroads.

Maintain patient referrals for research protocols.

Maintain quality of patient care.

Activities undertaken:

Analyzing costs and comparing these in specific treatment areas (e.g., bone marrow transplants) with neighboring hospitals.

Moving increasingly to day hospital and outpatient services.

Using commercial software (TSI) to merge patient information with financial data on a protocol by protocol basis.

Tracking protocol mix of costs and DRG-related costs.

Informing department managers of their costs to encourage them to seek reductions or to provide justifications for their budgets.

Ascertaining that cost reductions do not adversely affect quality.

Themes and advice:

Need to recognize change and uncertainty.

Referral sources were more reluctant to send patients, would rather keep funding "at home."

Research hospitals face an unfriendly future with pressure from service hospitals to become more cost-efficient.

Quality of care needs to be of concern as pressure for efficiency mounts.

Dana-Farber receives about 50 percent of its income from reimbursements from third-party payers, even for patients on research protocols. It only recoups service costs and encounters difficulties separating research costs from routine care costs.

Duke University Medical Center and Health System — Durham, North Carolina

Meeting date: 2 August 1995

Participants: Dr. Mark Rogers, Vice Chancellor and Chief Executive Officer; Assistant Vice Chancellor for Health Affairs; Chief Operating Officer; Vice Chancellor for Medical Center Administration; Chief Financial Officer; Vice Chancellor for Academic Affairs; Director of Clinical Research Unit; and Director of Information Systems

Subcommittees: Governance and Information and Reporting

Major objectives:

- Hospital generates enough income to support education and research.
- Reduce staff-to-bed ratio by 25 to 30 percent, approximately 800 positions.
- Reduce residency positions by one-third; also reduce number of fellowships.
- Save \$59 million per year, half from personnel and supplies.
- Develop an open architecture information system integrating the point of care clinical system with data repositories.

Activities undertaken:

- Develop success criteria on numerically based goals-evaluation measures for each department and every function to compare actual against expected.
- Transform performance and productivity units into individual performance criteria.
- Activity-based costing for cost per patient-day based on service delivery units.
- Stockless inventory system with just-in-time delivery; negotiating volume discounts and switching to comparable less costly supplies.
- Develop revenue and cost per protocol measures.
- Patient unit consolidation and space-allocation decisions with Chief Operating Officer negotiating with departmental chairman.
- Reengineering functions not processes, increasing skill mix of staff.
- Computer Advisory Committee advising CEO on what is needed, priorities, blueprints for new systems, and schedules.
- Develop common data repositories for clinical, administrative, and outcome data-query system and data to support clinical decisions.

Themes and advice:

- Organizational goals and missions are derived at the top. Evaluate each function to determine how it can efficiently support goals; eliminate functions that do not.
- Need a rigorous evaluation of resources; no room for “entitlement mentality.”
- Must ascertain how much more costly a Clinical Center bed should be than a community hospital bed given the complexity of the science.
- Use fear as instrument for change – incremental change will not work.
- Have each department manage its own budget and be responsible for spending within projected budget; if under budget, can keep what is saved.

Emory University Hospital System — Atlanta, Georgia

Meeting date: 7 September 1995

Participants: James T. Hatcher, Chief Financial Officer Director, Utilization Review

Subcommittee: Budgeting

Major objectives:

Compete effectively in a managed-care environment.

Increase efficiency in patient care delivery.

Activities undertaken:

Utilization review process that reports resource utilization of all patients.

Benchmark physicians against one another for use of specific resources by service and diagnostic related groups (DRGs).

Develop standards for efficient care delivery based on man-hours worked per unit of service or patient-day.

Contract firm providing evaluation of efficiency and helping develop internal standards on time and personnel per procedure.

Internal standards used to benchmark against 50th percentile for national external standards.

Billing system used to measure personnel hours, patient service output, and report monthly trends to department heads for personnel adjustments.

Constantly update strategic plan and assure annual business plan conforms.

Preparation and collection of clinical pathways and outcome data.

Themes and advice:

Difficulty billing nationally based patients who have different private insurance plans.

Importance of an integrated information system with real-time data capability for management purposes.

Department heads are responsible for the number of FTEs and job classification mix.

Personnel costs are handled by controlling FTEs; overtime and compensatory time count as an FTE.

Departments are not held accountable for supply costs, since controlled by doctors and addressed by utilization review.

Investment in a system for billing is better spent on tracking efficiency and seeking improvements.

Fairfax Hospital — Falls Church, Virginia

Meeting date: 22 August 1995

Participants: Holly Horn, Director, Decision Support and Outcomes Analysis; Associate Administrator for Women's and Children's Center; Chair of the Radiology Department; Director of Pharmacy; Director of Clinical Information Systems; and Director and Administrator for Orthopedic, Neurology, and Critical Care Patient Care

Subcommittee: Information and Reporting

Major objectives:

- Reduce costs; be competitive in the marketplace.
- Develop an integrated, multidisciplinary customer-focused information system.
- Maintain and increase quality of patient care.
- To be profitable, while maintaining mission to the community.

Activities undertaken:

- Five service line teams addressing quality, cost, and data collection to improve quality and assess how to lower the cost of services.
- Collecting workload and financial data.
- Developing outcome measures for patient satisfaction, quality, and cost of care.
- Replacing computer system to include a regional communication network – total budget approximately \$60 million.
- Installing data repository software to integrate data from multiple systems to bridge the clinical and financial systems, allowing end users to better manage.
- Currently reengineering – Total Quality Management began 7 years ago, followed by process management.
- Using financial data extensively for reviewing and holding managers responsible for costs, revenues, and profits.
- Developing and implementing critical pathways.
- Measuring productivity using Medicus and hours per workload index.
- Pharmacy using prime vendor with automated ordering.
- Radiology tracking films with a bar code system permitting identification of the location of previous studies, lowering loss rates, and optimizing availability to clinicians.
- Increasing number of affiliate facilities and redesigning specific care sites with specific product lines.
- Changing skill mix of staff.

Themes and advice:

- Strategic planning process answers three basic questions: Where are we now? Where do we need to be in the future? How do we get there?
- Objectives and responsibilities are tied to strategic plan.
- Centralized decisions concerning information systems – all purchase requests reviewed and approved centrally for consistency with overall strategic plan and compatibility with existing systems, technical soundness, and cost effectiveness.
- Untimely or absent data on cost/reimbursement of procedures delays identification of inefficiencies/unprofitable areas and precludes basing decisions on sound financial arguments.

Federal Home Loan Mortgage Corporation (FREDDIE MAC) — Washington, D.C.

Meeting date: 29 August 1995

Participants: John Gibbons, Vice President of Marketing

Subcommittee: Visions

Type of organization:

Established in 1970 as a government sponsored enterprise (GSE).

Became a publicly owned private corporation in 1989 with issue of common stock.

Provides a secondary market for conventional home mortgages.

Governance:

Eighteen member Board of Directors; 5 appointed by the President and 13 elected by shareholders.

Budget and finance:

Major source of earnings are fees and interest.

HUD is charged with assuring no unreasonable risks to the government.

GAO has authority to audit.

Personnel:

Has its own personnel system.

This has been a problematic area – it is difficult to bring about personnel policy change without threat of insolvency.

Procurement:

Department managers control the system.

Acquisition process is long and tedious.

Not encumbered by government procurement policies and regulations.

Very problematic area.

Advantages:

Ability to fail and generate urgency to bring about change.

Organized functionally and geared to customer-oriented business units.

Managers may take actions needed to achieve results and are held accountable for results.

Disadvantages:

As a business, risk of failure is present.

Change is difficult without urgency of crises or threat of insolvency.

Frederick Cancer Research and Development Center — Maryland

Meeting date: 29 August 1995

Participants: Jerry Rice, National Cancer Institute

Subcommittee: Visions

Type of organization:

Federally Funded Research and Development Center (FFRDC).

It engages in a diversity of biomedical research functions.

Governance:

This interview did not include governance as a topic.

Budget and finance:

National Cancer Institute is its primary sponsor; National Institute for Allergy and Infectious Diseases is its secondary.

Personnel:

2,000 employees; 350 are civil service and the remainder are contracted.

Contracted employees are assured work and portability of benefits under the contracts.

There has been friction over compensation. The government's salary structure is flatter than that of the contractor's, especially at the upper end.

Contract employees are supervised by the contractor, under the direction of government employees.

Procurement:

The Frederick Cancer Research and Development Center (FCRDC) employs five prime contracts to assure competition. Most contract funds go to operations and technical support.

The Department of Labor has held the FCRDC to service contract rules.

One contract, with Frederick Memorial Hospital, is seen as being "much cheaper than the cost in the Clinical Center."

Advantages:

Flexibility.

Government and contractors work closely.

May establish long-term relationships with agencies and has opportunities to perform interesting, important, and mission-sensitive work.

Does not have to compete for work.

Disadvantages:

Uncertainty of funding.

May not be assigned work or may be decertified.

Works under Federal government constraints and must be accountable to governmental sponsors.

Henry M. Jackson Foundation for the Advancement of Military Medicine — Rockville, Maryland

Meeting date: 5 September 1995

Participants: John W. Lowe, President and CEO; Vice President for Scientific Affairs; Director for Sponsored Programs; Associate Director for Special Programs; General Counsel

Subcommittee: Vision

Type of organization:

An independent, not-for-profit corporation.

It carries out medical research and educational projects under cooperative arrangement with the Uniformed Services University of the Health Sciences (USUHS).

It focuses on the interchange between military and civilian medical personnel.

Governance:

Corporate oversight is exercised by a Council of Directors.

Ex officio members are the Chairs and ranking minority members of the Armed Services Committees in Congress, and the Dean of the USUHS.

The council selects an Executive Director and sets his/her compensation.

Budget and finance:

Foundation receives no appropriated funds.

A significant proportion of its revenue is derived from federally sponsored programs.

It is subject to financial and compliance audits by an independent auditor.

The Defense Contract Audit Agency performs audits of activities and reviews indirect cost rate proposals.

It may “accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made” to it.

Personnel:

The personnel system is free of Federal regulations, except for contract prescriptions.

Compensation levels are market driven.

Employees may not be employees of the Federal government.

Procurement:

The Purchasing and Contracting Office supports the requisitioning and purchasing process, as well as grant and contract activity.

There is flexibility in the process and efficiency and timeliness of the procurement cycle.

Contract awards are in compliance with applicable Federal regulations.

Advantages:

A legislative charter provides for wide areas of independent action.

Personnel system has broad rules and the acquisition process is flexible.

It can manage endowments, unlike most donations to government agencies.

Disadvantages:

It operates as a business corporation and is concerned about the “bottom line.”

John Dempsey Hospital, University of Connecticut

Meeting date: 8 August 1995

Participants: Andria Martin, Vice President of Operations and Hospital Director; Associate Hospital Director and Director of Nursing; Director of Laboratory Medicine; Director of Network and Systems Services; Administrative Director; and Associate Directors of Purchasing

Subcommittees: Information and Reporting, Options as a Federal Entity

Major objectives:

Reduce costs to be competitive in managed-care environment.

Attract physicians to admit patients.

Centralize and improve information systems to enhance operational efficiency, profitability, and meet the needs of end users.

Activities undertaken:

Total reengineering, looking at all operational and service areas and prioritizing improvements according to need.

Streamlining processes and cutting delays.

Courting doctors; hired an ombudsman who works on behalf of doctors.

Measuring productivity by number of admissions, number of lab tests and x-ray procedures, average daily census and occupancy rate, etc.

Benchmarking costs and productivity data to that of other hospitals.

Contractor conducting surveys to measure quality of service, barriers to change, and employee work-imaging.

Using cost data to plan \$6 million in savings.

FTEs decreased by 60 positions; layoffs in management to flatten organization.

Redesigning material management and consolidating warehouses; and considering real-time purchasing; participating in group purchasing with University Consortium.

Meetings reduced by 30 percent.

Implementing centralized patient registration and scheduling.

Phasing out admitting office – patients will be registered prior to admission and unscheduled patients will be registered on nursing unit.

Standardizing patient care documentation.

Project redesign teams looking at how care is provided and who does it considering use of nurse extenders.

Phasing in an electronic medical record, creating data depository, making lab and x-ray results available online.

Centralizing information system investment, plans, and purchases.

Using the separately (from the state) created Finance Corporation to simplify and expedite purchasing and take advantage of discounts.

Contract to assess major purchases and to advise on equipment maintenance agreements.

Themes and advice:

Greatest barrier to change is difficulty integrating the governance of faculty practice and hospital departments.

Information system improvements are supported by user charges.

Use of in-house clinical engineers for equipment repairs reduces costs.

An extensive competency assessment system ensures high performance standards.

Use of a nongovernmental corporation for large procurements provides relief from onerous government regulations.

Johns Hopkins Hospital — Baltimore, Maryland

Meeting dates: 3 and 17 August 1995

Participants: Vice President of Finance, Chief Financial Officer, Vice President for Human Resources and Organizational Development, Director of Organizational Effectiveness, and Human Resources Administrator

Subcommittees: Budgeting and Options as a Federal Entity

Major objectives:

Develop and support an integrated delivery system.

Improve patient care processes and outcomes.

Maintain market share

Developing, demonstrating, and communicating value and affordability.

Activities undertaken:

Implement performance measurement and assessment in all departments.

Build a system-wide marketing organization and infrastructure.

Track measures of numbers of cases, length of stay, total charges and ancillary costs.

Implement a computerized relational database for cost accounting.

Benchmark against hospitals included in the Maryland Rate Commission cost reports, with case mix adjustments.

Monitor workload measures – market share, outpatient visits, covered lives, operating margin, net days in accounts receivable, inpatient admissions, length of stays, and lab/x-ray utilization.

Engage in reengineering effort with flattening hierarchical structure.

Restructure 500 job classifications and collapsed 40 pay grades into 8 bands; increase the number of multiskilled workers.

Themes and advice:

Strategic planning process to address mission, vision, and goals based on external and internal environmental assessment.

Annual operating plan based on the strategic plan framework.

Cost accounting requires a significant investment in organizational energy and capital, but the benefits make it worthwhile.

Managers competing in a managed-care/capitated reimbursement environment need cost information that is readily available and flexible.

Logistics Management Institute (LMI) — McLean, Virginia

Meeting date: 28 August 1995

Participants: John Ciucci, Corporation Counsel

Subcommittee: Visions

Type of organization: Federally Funded Research and Development Center (FFRDC).

It operates under guidelines established by the Office of Federal Procurement Policy.

It is a private, not-for-profit membership corporation.

It is charged with conducting research studies and analyses for defense departments and agencies

Governance:

A 15 member Board of Trustees.

The Board elects its members.

A CEO and six other corporate officers are responsible for day-to-day operations.

Budget and finance:

Revenue was derived from the FFRDC cost-reimbursable, level-of-effort, task order contract.

LMI is held to the same standards and regulations as other contracting organizations.

It is sponsored by the Office of the Secretary of Defense.

It is audited by the Defense Contract Audit Agency.

Personnel:

LMI has its own personnel policies and does not follow Federal personnel regulations. Comparative compensation studies are used to guide decisions about compensation and benefits.

Must follow various personnel practice provisions of Federal contracts.

Salary adjustments must be approved by the primary sponsor and the reasonableness of employee and executive compensation must be reviewed by the Defense Finance and Accounting Service.

Procurement:

LMI has developed its own procurement policies that are less stringent and cumbersome than the Federal Acquisition Regulations (FAR).

Must follow FAR guidelines for prime contractors.

Advantages:

Flexibility in operations and increased ability to respond quickly to problems.

Personnel practices are unencumbered and permit attracting and retaining employees.

Has long-term relations with agencies and flexibility in its work.

It does not have to compete for work.

Disadvantages:

Uncertainty of funding.

It may be decertified as an FFRDC.

It works under government constraints and is accountable to governmental sponsors.

Massachusetts General Hospital — Boston

Meeting date: 10 August 1995

Participant: Samuel O. Thier, M.D., President

Subcommittee: Governance

Major objectives:

Complete mergers of the integrated regional network that includes Brigham and Women's Hospital, physician practices, and rehabilitation hospitals.

Reduce MGH and BWH operating budgets by \$300 million over three years from the current \$1.1 billion.

Reduce excess beds (as much as 50 percent) in the two hospitals.

Integrate clinical and financial information systems.

Reduce fellowships 20 percent, residencies between 5 and 25 percent, and subspecialty positions 25 to 30 percent.

Activities undertaken:

Reengineering processes.

Working on measuring health outcomes.

Developing measurable goals.

Using prime vendor for supplies (Owens and Minor) to save \$20 million over three years.

Spending approximately \$10 million to acquire information systems.

Themes and advice:

Need to obtain valid and reliable data that are trusted.

Formalize processes and decision-making, noting who is responsible.

Establish principles up front with measurable objective criteria, then enforce them.

Someone must be in charge to make tough decisions.

Engage in strategic planning.

Develop performance measures.

Mayo Clinic — Rochester, Minnesota

Meeting date: 27 July, 1995

Participants: Dr. B.L. Riggs, Director, General Clinical Research Center (GCRC); Chair of GCRC; Research Administrator; Hospital Administrator; Division of Systems and Procedures; Director for Research; Chair of Research Administration Subcommittee – Benchmarking

Major objectives:

Develop a strategic plan from the departmental to institutional level.

Reduce costs.

Quality improvement.

Activities undertaken:

Engaged for 5 years in a best practices analysis department by department.

Space and equipment subcommittee allocates resources; decisions based on rate of return and ability to put Mayo in the forefront of medical science.

Two year effort to improve processes; looking at largest cost areas.

Twenty-one teams involved in cost reduction, service improvement, and cycle time reductions.

Implemented a patient lifting team (saves \$1 million/year in workmen's compensation expense for nurses with back injuries).

An 800 telephone number for referring physicians to inquire about protocols.

Benchmark with Eastman Chemical research and development for some operational procedures.

Using a structured annual plan for each department to develop a strategic plan for the institution.

Use a computerized admissions scheduling program with data on 120 active protocols, including tests to be done and acuity of patients.

Designate Hospital Medical Services organization to provide medical services to research patients, includes 24-hour emergency coverage, admission exams, and daily rounds.

Prospectively cost each protocol in detail – e.g., supplies, drugs, labs, and exams.

Examine the efficiency of each protocol in terms of number of tests, length of stay and quality of protocol.

Develop incentives to give savings to the departments with cost efficiencies.

Themes and advice:

See greater merit in improving care processes than in detailed cost accounting systems and productivity comparisons.

The institution, not clinical services, control beds.

Reengineering processes important to maintain viability; enhance quality, not reduce FTEs.

Managers at the local level must have access to information to make decisions.

Incentive system is important for all levels of the organization to create savings.

If staffed to run big and deliver little, you are set up to be inefficient.

Mount Sinai Hospital — New York

Meeting date: 13 July 1995

Participant: John W. Rowe, M.D., President

Subcommittee: Governance

Major objectives:

Reduce operating costs.

Ensure bed occupancy and excellent case-mix ratio.

Create a permeable membrane whereby department chairs cooperate to meet organizational goals.

Structure organization to meet patient needs.

Information system development.

Activities undertaken:

Changes to nursing – fewer nurses, flexible time schedules, discontinued performing nonnursing functions.

Every job in the hospital is multiskilled.

Reengineered care processes.

Developed interdisciplinary care centers, e.g., cardiology, cancer, gastrointestinal, and restorative medicine.

Information system development with user-based initiatives.

Eliminated unnecessary offices and services, e.g., transport, admissions, and intravenous team (saved \$31 million).

No ownership of beds; all beds are institutional, not department beds.

Themes and advice:

Need governance structure with clear lines of authority to make and implement difficult decisions.

Reduce turf issues and reduce influence of branch chiefs.

Need to streamline and be efficient.

Reengineer resource allocation process.

Information system development with user orientation.

Undertake formative evaluations – ask how are we doing financially and qualitatively.

Institutionalize efficiency – penalize overspending and financially reward underspending.

Warren Grant Magnuson Clinical Center needs to address three issues: nursing, information systems, and reengineering.

National Institute of Standards and Technology (NIST) — Gaithersburg, Maryland

Meeting date: 12 September 1995

Participants: Allen Cassady, Chief, Personnel Demonstration Project Office

Subcommittee: Options as a Federal Entity

Major objectives as a personnel demonstration project:

Improve hiring, classifying, compensating, and retaining employees.

Attract high-quality candidates and make hiring more efficient.

Obtain permanent status for the project.

Strengthen manager's role.

Increase efficiency of personnel system.

Activities undertaken:

Create career paths and broad pay bands within a simplified classification system.

Develop a performance appraisal system and pay principals.

Regularly inform and meet with employees about project's progress.

Transform staffing process from the Office of Personnel Management to NIST management.

Direct hire.

Collect and utilize salary surveys.

Increase manager's decision-making power.

Automate position classification surveys.

Themes and advice:

Secure your own legislation for a demonstration project.

Construct your project relative to your organizational climate and leadership.

Consider the project as a continuing experiment.

Survey employees before beginning project to develop a comparative baseline data.

Get consensus on the requirement for smaller, briefer evaluations.

Develop a logical rationale for direct hire of a few occupations.

Ability to hire capable people means there is a need for fewer people.

National Library of Medicine (NLM) — Bethesda, Maryland

Meeting date: 8 September 1995 (via telephone)

Participants: Dennis Black, Chief, Office of Acquisition Management

Subcommittee: Options as a Federal Entity

Major objectives:

Achieve efficiency in procurement processing.

Activities undertaken:

Eliminate the requirements for pre-solicitation and pre-award reviews.

Obtain small business review authority.

Obtain Federal Information Processing (FIP) approval authority.

Eliminate requirement to obtain Public Health Service review for Information Resource Management.

Increase authority to approve JOFOCs to \$100,000.

Increase the small purchases dollar threshold to \$100,000.

Eliminate the requirement to obtain approval for acquiring “administrative ADP.”

Seek authority to procure “common use items.”

Themes and advice:

Request more changes initially.

OP Demonstration Projects — Washington, D.C.

Meeting date: 25 July 1995

Participants: Paul Thompson, Chief of the Demonstration Project Development Staff,
Office of Merit Systems Oversight and Effectiveness

Subcommittee: Options as a Federal Entity

Major objectives:

Create, sponsor, and evaluate demonstration projects for personnel systems.

Activities being undertaken:

Seven demonstration projects were implemented: Navy (China Lake), NIST, Pacer
Share (Air Force/DLA), USDA, FAA, and FBI.

Working with VA, FAA, IRS, Hoover Dam, and OSHA on possible projects.

Exploring more demonstration projects.

Themes and advice:

Time frames for development and approval are long.

Must obtain union approval, agency approval, and public comments.

Major obstacles are:

Gaining approval by employees, management, unions and agency; length of time for
implementation; and evaluation costs.

Phoenix Native Medical Center — Arizona

Meeting date: 3 October 1995

Participants: Anna Albert, Medical Center Director; Procurement Officer; Nursing representative; Personnel Officer; Financial Officer

Subcommittee: Reinvention

Major objectives as a Reinvention Laboratory:

Reduce costs and operate efficiently.

Improve client services.

Increase use and functionality of information system.

Activities undertaken:

Revising and improving nursing documentation system.

Obtaining relief from a variety of procurement and personnel regulations through delegations of authority or waiver of Department of Health and Human Services (DHHS) and Public Health Service (PHS) regulations.

Implementing a new cost accounting system.

Themes and advice:

Identifying a “reinvention lab champion” at the PHS or DHHS level is crucial to the success of the laboratory.

Maintaining enthusiasm for the project is challenging, but critical to success.

University Hospital — SUNY Health Science Center at Syracuse – Syracuse, New York

Meeting date: 6 September 1995

Participants: Greg L. Eastwood M.D., President of University Hospital – SUNY Health Science Center; Hospital Administrator; Chief Financial Officer; Director of Planning

Subcommittee: Vision

Major objectives:

Attain independence from the state university system.

Gain system flexibility to gain access to capital and contracts with other organizations.

Ensure future survival in an increasingly competitive market.

Increase market share.

Activities undertaken:

Introducing and lobbying for legislation to free itself from the state university system.

Restructuring and reengineering jobs.

Piloting two projects that implement patient-focused care models.

Attracting and increasing the number of private physicians to practice at hospital.

Developing incentives for private physicians, such as purchasing agreements, access to hospital information systems, and billing.

Themes and advice:

When striving for independence, know the political climate and anticipate opposition from other institutions from the same system (State University of New York) and from the system's bureaucracy.

Work outside the system when looking for radical change.

Expect problems from unions when attempting to restructure jobs.

Efforts to restructure work units will be resisted by various hospital departments.

University of California — San Francisco

Meeting date: 21 July 1995

Participants: William Kerr, CEO; Director of Clinical Research; Associate Director of Clinical Resource Management; Chief Information Officer; Director of Nursing; Director of Operations; Budget Director

Subcommittee: Benchmark

Major objectives:

- Reduce FTEs by 550.
- Reduce costs for clinical services.
- Reduce length of stay by one-third.
- Integrate data systems.
- Reduce number of departments and specialization.

Activities undertaken:

- Benchmark value – combination of cost and quality.
- Standardize variable cost elements.
- Organizational structural changes.
- Service line reengineering focusing on outcomes.
- Benchmark on quantitative areas with University Hospital Consortium.
- In-depth medical record review for length of stay.
- Master plan for information services.

Themes and advice:

- Track benchmarks internally over time, bottom-up approach.
- Couple responsibility with authority.
- Dramatic emphasis on the need for change.
- Without facing danger, it is difficult to motivate change.
- Increase emphasis on cost; standardize variable cost elements.
- Restructure the delivery system on both a vertical and horizontal axis.
- Organizational structural changes are critical.
- Look to Centers of Excellence for best practice models.
- Variable staffing is essential to efficiency improvements.

University of Chicago Hospitals — Illinois

Meeting date: 29 August 1995

Participants: JoAnn Shaw, Vice President of Human Resources and Support Director and Manager of Human Resources

Subcommittee: Options as a Federal Entity

Major Objectives:

- Improve the quality of services.
- Remain financially strong.
- Decrease the cost of delivering patient services.
- Restructure the care process.

Activities undertaken:

- Introduced patient-focused care to 31 percent of the hospital's units.
- Cross-trained employees and decentralized services.
- Flattened managerial structure, reduced functional specialization, and removed barriers between work units.
- Undertook benchmarking; measured and evaluated patient care indicators, customer satisfaction, and patient outcomes.
- Introduced new recruitment and hiring process.
- Implemented a new 32 hour orientation process for all new employees.
- Created the University of Chicago Hospitals Academy to provide education and training for employees to develop continuous learning perspectives.
- Redesigned employee evaluation review process that uses a five point rating scale to measure performance in job-specific and general responsibilities.
- Developed merit payment scheme related to performance and financial incentives for achieving results against defined objectives.
- Financial recognition through grants to engage in projects in the community and a scholarship to develop skills for organizational transformation.
- Top management began a cultural change to create uniformity and consistency between the values of the organization and bureaucratic processes.

Themes and advice:

- Important to establish and reinforce values as the organizational focal point.
- Employee recognition and investment in education and training are important to organizational transformation efforts.
- Financial incentives are difficult to develop and use with employees covered by collective bargaining agreements.

University of Maryland Medical Center — Baltimore

Meeting date: 1 August 1995

Participants: Stephen C. Schimpff, M.D., Executive Vice President; Corporate Vice President; Vice President of Finance; Vice President of Human Resources; Director of Operations; Director of Purchasing

Subcommittees: Governance, Budgeting, Options as a Federal Entity

Major objectives:

- Achieve regional and national distinction as a quality health care system.
- Maintain financial viability and stability.
- Retain a competitive advantage with payors on the basis of price and quality.
- Develop and implement resource allocation, data-driven methodology.
- Maintain flexibility by consensus-based, data-defined strategic plan.

Activities undertaken:

- Retraining managers to look at how things are done and how things could improve.
- Establishing outcomes in financial terms – number of patient-days needed to meet financial goals.
- Translating patient-days into workload measures for each department.
- Developing key performance outcomes to measure organizational success – customer satisfaction, clinical outcomes, price competitiveness, market share, and financial performance.
- Benchmarking with other Maryland hospitals using data from state cost review commission.
- Quality Indicator Committee looking at high-visibility, high-use procedures.
- Identified six multidisciplinary tertiary clinical services for development.
- Identify patient care units as cost centers and assign managers resource control and accountability.
- Each department establishing standards to match workload with work force.
- Looking to break costs apart and to use of improved cost accounting system.
- Reducing warehouse costs by use of prime vendor and just-in-time deliveries.
- Improving information system for cost accounting, inventories, and clinical management.

Themes and advice:

- Need strategic planning to ensure fiscal viability, establish goals, and identify measurable objectives.
- Define success and collect data to measure whether successful.
- Board of Directors essential for challenging and holding hospital management accountable, as well as acting as champions with legislature.
- Clinical Center needs to expand world view, turn mission around, and establish who is in charge.
- Focus on fundamentals and eliminate duplication of efforts.
- Managers must be responsible and accountable.

University of Michigan Hospital — Ann Arbor

Meeting date: 20 July 1995

Participants: Host, Dr. Paul Watkins, Director of the GCRC; Chief Executive Officer; Assistant Director of Finance; Administrative Manager, GCRC; Associate Hospital Director; Director of Management Engineering; Associate Dean, School of Medicine

Subcommittee: Benchmarking

Major objectives:

Reduce operational costs by 25 percent over four years – goal of saving \$30 million per year.

Downsize inpatient service.

Monitor performance and productivity.

Improve information system integration.

Activities undertaken:

Individual departments set workload and cost standards.

Use Mecon system to assess productivity and cost-effectiveness.

Benchmark against the University Hospital Consortium (UHC) database of 41 hospitals.

Information systems used to allocate costs, analyze costs, and return on investment.

Challenge departments to meet median costs by set dates.

Seven cross-functional teams looking at length of stay and use of operating and recovery rooms.

Conduct telephone surveys for patient satisfaction.

Using the Transition Systems Incorporated (TSI) cost accounting system to determine costs for five levels of clinic patient-type complexity.

Program where half of hospital operating profits are shared by employees (\$2,500 per employee).

Suggestion program with cash awards.

Implement TSI patient care information system.

Themes and advice:

Goals must be aligned between organization and departments.

Incentive system program based on seeing measurable success.

Define ingredients of a culture that will allow change.

Leadership assessment by peers and subordinates.

The University Hospital Consortium is a good source of external benchmarking information.

Use quality improvement teams to meet cuts in resources.

Managers must be held to bottom-line accountability.

U.S. Army Medical Research and Materiel Command (MRMC) — Fort Detrick, Maryland

Meeting date: 19 July 1995

Participants: Colonel Douglas Lake, Comptroller and Director of Financial and Manpower Resources; and Human Resources subject matter specialists

Subcommittee: Options as a Federal Entity.

Major objectives as a personnel demonstration project (start date April 1996):

Improve hiring.

Compete for personnel, through direct hiring and higher entry salaries.

Motivate and retain staff.

Strengthen manager's role in personnel management.

Simplify the classification system through pay banding and reduction of guidelines, steps, and paperwork.

Reshape and respond to changes in mission and new technology.

Revitalize creative research intellect.

Support the "open laboratory concept."

Not increase the budget.

Activities undertaken:

Modifying Navy demonstration project classification system.

Delegating classification authority to line managers.

Proposing solutions for accessions and internal placement, sustainment, and separation.

Themes and advice:

Obtain dedicated staff to develop a project.

Obtain project team that can work together.

Be aware that resistance may come from higher levels within your agency.

Utilize Office of Personnel Management resources, experience, and people.

Be attuned to change opportunity windows.

Leadership enthusiasm is imperative.

Communication with employees and unions is critical.

Keep good records of public hearings and address all questions.

Delayed time frames must be expected.

Walter Reed Army Medical Center — Washington, D.C.

Meeting date: 19 July 1995

Participants: MG Ronald Blanck, Commanding General; Chief of Staff; Director of Patient Administration; Deputy Director of Patient Administration; Director of the Third Party Collection Program

Options Team participants:

Dr. Helen Smits and NIH representatives.

Objectives of Walter Reed's Third Party Collection Program (TPCP):

Meet the legal requirements of the Consolidated Omnibus Budget Reconciliation Act of 1986, which established the TPCP.

Maximize the net revenue from the TPCP.

Do not compromise patient care aspects in order to implement the program.

Make the process virtually transparent to the medical staff of the hospital.

Activities undertaken:

Attempting to simplify the program, eliminate as much paper as possible.

Make decisions about the billing process on a business basis, e.g., deciding whether to outsource claims processing, paying a claim processor 20 percent of the net receipts versus 6 percent in-house processing.

Themes and advice:

Clearly communicate the logic of the program with patients and staff.

Do not hassle patients. Define those circumstances – i.e., type of patients or diseases — that will be excluded from billing.

Operate the billing system as a business organization.

Clement J. Zablocki Veterans' Affairs Medical Center — Milwaukee, Wisconsin

Meeting date: 17 August 1995

Participants: R.E. Struble, Medical Center Director and Reinvention Liaison

Subcommittee: Reinvention

Major objectives as a Reinvention Laboratory:

- Improve customer service.
- Reduce costs, increase efficiency.
- Improve quality and timeliness of services.

Activities undertaken:

- Budget flexibility, permitting transfers between accounts and scheduling of purchases.
- Reducing procurement time.
- Redesigning nursing units model of care delivery.
- Developing and enhancing clinical programs.
- Offering performance-based rewards.
- Evaluating workers' shift schedules.

Themes and advice:

- Develop measurement systems and strategies to show success.

APPENDIX C

Institute Leadership Interview Survey Findings

Institute Leadership Interview Survey Findings

From August through October 1995, members of the Warren Grant Magnuson Clinical Center Options Team subcommittees conducted interviews with the leadership at the National Institutes of Health (NIH). Sixteen people from eight Institutes and the Director's office generously gave their time to discuss the Clinical Center. The respondents included five directors, three deputy directors, three clinical directors, three scientific directors, and two branch chiefs.

There was unanimity among the leadership that the Clinical Center is essential and the major feature of NIH. The Clinical Center is seen as the primary focal point for clinical research and for collaboration among Institutes. It is the place that gives a human face to biomedical research; it permits research physicians to attend to patients; it provides researchers the hands-on experience to lead extramural research efforts.

The following statements indicate the overwhelming belief that the Clinical Center, as the home for NIH's intramural clinical research program, must be retained as a viable institution.

"We need a politically strong and visible Clinical Center."

"The Clinical Center is fantastic, exciting, and sets the tone of the way to do science."

"We must preserve and invigorate the Clinical Center."

"The Clinical Center is the best place in the world to conduct clinical research."

"It is essential for the Clinical Center to exist for the health of the Nation."

CLINICAL CENTER USE

The majority of clinical research at all the Institutes is undertaken at the Clinical Center. Three-quarters of the interviewed Institutes admit research patients to other hospitals. For the most part, however, the number of outside patients is limited, as are the purposes for such admissions. Outside facilities were used because the Clinical Center did not provide needed services such as cardiac surgery and care for acute stroke patients. One director noted that he is negotiating with a university hospital for space to conduct clinical research. While he would rather work at the Clinical Center, the lack of space and the limit on the number of employees are major deterrents.

The support given researchers by the Clinical Center was seen as excellent. When compared to other hospitals, the Clinical Center was seen as providing a much better environment for conducting research. The Center's proximity to labs and contiguity with basic science were seen as beneficial by 40 percent of the respondents. The availability of specialized diagnostic laboratories was seen as beneficial by 40 percent, and 25 percent enjoyed the ability to collaborate with teams of experts. The totality of services provided by the Clinical Center was seen as beneficial by 25 percent of the Institute leaders.

When asked about managing the use of the Clinical Center and its low bed occupancy rates, about half of the respondents noted that this is a national problem of decreasing inpatient utilization of hospitals and diminishing referrals due to managed care. Fifty percent of respondents also mentioned that the amount of clinical research was down nationally, as well as interest in pursuing careers in clinical research. One respondent said, "Scientific research is tilted toward the bench; basic research is less expensive and awarded more prizes than is clinical research."

Only two Institutes appear to have established ways to closely monitor the use of the Clinical Center. These Institutes are fairly accurate in their predictions of inpatient and outpatient utilization and hold researchers accountable for meeting related projections. Other Institutes estimate utilization from their budgets or from past patterns.

Although most respondents acknowledged that costs per occupied bed was high because of low utilization, few appeared willing to allow the Clinical Center to make independent decisions about space allocation. One director made it clear that he would not give up his research space, while several felt that the Clinical Center Director could work on gaining agreement with the Institutes for space reallocation. It was suggested that perhaps protocols that demanded similar types of work could share space at the Clinical Center.

GOVERNANCE

When asked how the governance structure of the Clinical Center could be improved, few suggestions were made. For the most part, the Institute leadership did not think that change was necessary. While things may look askew, a consensual and collegial decision-making system is in place. All believed that the Institutes must have a voice in governing the Clinical Center, although respondents' views about the degree to which every voice must be followed varied.

One-quarter of the respondents did not believe that the Clinical Center should be separated from Institute influence or control. As one director noted, "The Clinical Center is to provide service to the Institutes, not the other way around. The Institutes must stay dominant."

Almost two-thirds of the respondent Institutes believed that the Medical Board was the appropriate governing body for the Clinical Center. The major reason given was that the Board represented the Institutes. Forty percent felt that the Medical Board was not acting in a governance capacity, but should be reminded of its responsibility to do so.

Forty percent of the Institutes felt that the Medical Board was too large and unwieldy. These respondents believed that a smaller advisory body would expedite decision-making. Another 25 percent suggested that the Clinical Center Advisory Board be reactivated to act as a governance advisory body. While one person suggested an external group act in this capacity, another leader disagreed with this idea.

Half of the respondents felt that the Director of the Clinical Center was in a powerful position. They believe he serves on bodies that provide forums for him to influence and persuade Institute leaders of his point of view. It was noted that the Director of the Clinical Center has a direct line to the Director of NIH, "who could make things happen." Several respondents mentioned that the management fund also enhanced the Director of the Clinical Center's decision-making power.

BUDGET

The Clinical Center budget and how costs are allocated elicited a good deal of discussion. Forty percent of the Institute leaders noted that the Clinical Center needs financial stability. One director favored multiyear funding, as long as there was budget oversight. Another 40 percent noted that a rational method of charging must be developed. The present system was said to be difficult to understand, too complicated and lacking transparency, in that it did not show how money was spent.

One-quarter of the Institutes favored the Clinical Center having a line-item budget derived at the NIH Director's level. The Director should tell Institutes how much they should contribute, thus minimizing Institute discretion in payment. It would also make the Clinical Center less dependent on National Cancer Institute (NCI) for its finances. One dissenter believed that it would be a mistake to disconnect service from payment. Another 25 percent believed that the Clinical Center budget should be separated from the other items in the management fund.

Fifty percent of the Institutes disliked the idea of receiving an appropriation from Congress for the Clinical Center. One reason given was that congressional staffers would scrutinize the budget and see that costs per patient-day were higher at the Clinical Center than they were at other hospitals. One director saw an appropriation as a direct assault on his budget: "Every dollar given to the Clinical Center would mean less money for my Institute." An underlying belief was that an appropriated budget would lessen the Institutes' influence over the Clinical Center.

In contrast, 25 percent of the Institutes saw merit to an appropriation from Congress. One thought that partial funding by this mechanism had merit. The reasons given for this viewpoint were contradictory to the views of those opposing such funding. For example, one respondent did not feel that the Clinical Center had a constituency to lobby for a generous budget, while another claimed that the Clinical Center's constituency would provide assistance. In addition, one expressed the belief that an appropriation would decrease costs to the Institutes and that a stable budget would result.

Thirty percent of the Institutes favored a fee-for-service system of charging the Institutes. One thought that a cost per protocol had merit. The fixed cost percentage was decried as too high and the ever-increasing costs for the Clinical Center were depicted as unfair to the Institutes with research budget caps. The need for incentives to stimulate Institute efficiency was discussed by 30 percent of the respondents.

Although not asked, two respondents expressed opposition to third-party reimbursement for Clinical Center services. The reasons given were that too little money would be derived from a great deal of effort, especially since Medicare and Medicaid patients could not be charged. In addition, collection times would be lengthy because insurers would need to be convinced that they were not being charged for experimental treatments.

SUGGESTIONS FOR NEEDED IMPROVEMENTS

Three-quarters of the Institutes agreed that the Clinical Center was responsive in its approach to clinical research. In contrast, 40 percent felt that there was a need to be more flexible in its ability to respond quickly to changes in science. Although several respondents cited the quick response to AIDS research, an equal number claimed that a change in direction would take a minimum of one year.

Half of the respondents claimed that the medical information system needed improvement. Several thought that clinical help was required in the form of image projection and drug interactions. Forty percent mentioned the need for financial data, and several respondents stressed the need for a cost accounting system.

Half of the Institutes criticized the personnel system. Forty percent believed that there was an excess of workers and that the personnel system was unresponsive to work demands. An equal number felt that there was an excess of nurses. With the exception of personnel resources, there were no complaints about the efficient use of resources at the Clinical Center. One respondent felt that benchmarking may be appropriate.

Two respondents mentioned problems with the procurement system. It was felt that purchasing items took too long and demanded too much justification. A

complaint was directed at the late payments for purchases, thereby denying Institutes the discounts promised for prompt payment of bills.

Two respondents were disturbed by the lack of high quality medical and surgical consultant support. If consultants were not available through the Institutes, then the Clinical Center should assume responsibility. An equal number complained that patient responsiveness could use improvement, especially the cumbersome admission process.

Several respondents believed that the Clinical Center should become the locus for prospective studies of factors that might negatively impact clinical research. Some suggested looking at the decrease in clinical researchers and the decrease in patient referrals. For example, one respondent suggested that the Clinical Center should conduct a study with third-party insurers to ascertain their policies about patient referrals for clinical research protocols. It was thought that referral assistance could be enlisted and that possible funding for the routine aspects of patient care provided at the Clinical Center could be explored.

Respondents from 40 percent of the Institutes believed that the Clinical Center needed to improve its communications department. They stressed that it was necessary to increase public awareness of what is done at the Clinical Center. In addition, some respondents suggested that researchers acknowledge the work done at the Clinical Center in the papers that they deliver and the articles that they publish.

Although not asked, a majority of Institutes offered their opinions on contracting. In each instance, contracting out the Clinical Center was opposed. It was believed that contracting would be a terrible mistake. One respondent commented, "It would ignore and destroy what we do." If specifications could not be carefully drawn, this respondent believed that problems would occur and that excellent working relationships would be destroyed: "Contracting would disrupt the cohesiveness and morale of clinical researchers."

Opposition was also expressed for any ideas about corporative structures that would separate the Clinical Center from NIH. "The Clinical Center is NIH — what is medical research if it does not benefit humans; those benefits can only be evaluated properly at the Clinical Center." Becoming a corporation was viewed as a radical idea, one that would make the Clinical Center independent of its Institute customers.

APPENDIX D

Alternative Organizational Forms
for the Warren Grant Magnuson
Clinical Center Flexibility

Alternative Organizational Forms for the Warren Grant Magnuson Clinical Center Flexibility

This appendix summarizes the work done by the Vision Subcommittee of the internal Options Team. The subcommittee evaluated a spectrum of broad structural options — ranging from the status quo to complete outsourcing or complete privatization — to assess which of those options might allow the Clinical Center to operate most effectively and efficiently.

After making a considerable effort to identify and evaluate feasible alternative organizational forms, the subcommittee recommended that the Options Team adopt the Reinvention/Demonstration Project (i.e., Reinvention Laboratory) as the primary approach to improving the efficiency of Clinical Center operations. It further recommended that the Team consider three other options as reasonable organizational alternatives: the wholly owned government corporation, the Federally Funded Research and Development Center (FFRDC), and partial contracting. Before adopting one of those options, however, the subcommittee recommended that the Clinical Center and the National Institutes of Health (NIH) conduct a more rigorous evaluation of each.

The Options Team accepted the subcommittee's recommendation to adopt Reinvention Laboratory status for the Clinical Center, and it accepted the subcommittee's conclusion that a fully contracted out operation was not a feasible alternative.

The following sections address the options for the Clinical Center's broad organizational form. The first two sections address policy and analytical methodology.

THE ADMINISTRATION'S REINVENTION INITIATIVE

The Administration's Reinventing Government (REGO) initiative provides an important part of the context for this evaluation. The REGO initiative challenges Federal agencies to put customers first, cut bureaucratic red tape, empower employees to be innovative, and cut back to basics. Phase I of the National Performance Review's work focused on the first three elements of the REGO initiative. In December 1994, the Clinton Administration announced that the Reinventing Government II (REGO II) initiative would focus on cutting back to basics by scrutinizing the work of government programs and functions to determine what, if any, changes could be made to enhance those programs and functions. That task involves thoroughly assessing services, determining the most appropriate and effective provider for those services, and devising

incentives to achieve the ideal outcome for service provision. The ultimate goal of REGO II is to refocus and downsize government activities.

The National Performance Review outlines five basic methods for downsizing the government:

- ◆ *Service termination.* This approach reflects a government review of a service, program, or function and a decision that the service, program, or function no longer needs to be provided by the Federal government.
- ◆ *Full privatization.* In this approach, the service is provided by the Federal government, but the government no longer needs to be in direct control of the service. Privatization of services assumes that the service is important and will be provided by private-sector contractors.
- ◆ *Partial privatization: creation of quasi-government corporations.* This approach assumes that the service is necessary and readily managed by the private sector, but the commercial market is unwilling or unable to bear the sole responsibility for service provision. A corporation and market is created by the government to provide the service. The government controls the service through a combination of limited operational, management, and regulatory controls.
- ◆ *Creation of public/private partnerships.* This strategy involves a joint public and private investment relationship. The government shares in the ownership of assets and operational responsibilities.
- ◆ *Competition.* Contracting out or “contracting” (i.e., competition) reflects a decision by the government to remain fully responsible for providing all the services and management decisions, but chooses to have the services provided through or by private contractors.

METHODOLOGY FOR EVALUATING FORMS OF ORGANIZATION

The Options Team identified and analyzed several broad organizational structures for the Clinical Center to achieve flexibility. These alternatives are

- ◆ maintaining the status quo that is keeping the Clinical Center as a Federal organization;
- ◆ maintaining the Center’s status as a Federal organization, but operating it as a “Reinvention Laboratory”;

- ◆ contracting for Clinical Center operations (partially or completely); and
- ◆ Privatizing under one of the partial privatization models described immediately.

Guided by the National Performance Review's definitions of privatization, a continuum of private-based organizational structures to be considered for the Clinical Center was developed. A detailed description and discussion of each of the organizational structures is beyond the scope of this discussion. Only the most pertinent findings are presented in this appendix. The partial privatization options considered include

- ◆ government-sponsored enterprises,
- ◆ wholly owned government corporations,
- ◆ employee stock ownership programs,
- ◆ franchising, and
- ◆ Federally Funded Research and Development Centers.

The advantages and disadvantages of each of those five privatization options was considered in terms of each option's definition, purpose, characteristics, the reasons for their organizational function, legal structure, budget and financial operations, personnel procedures, and procurement procedures.

Six criteria were used in comparing each organizational structure. Relative weights were applied to the criteria. These criteria, are listed in priority order — from most critical to least critical to the mission and operation of the Clinical Center:

1. *Quality of research support* reflects the quality of service support provided to NIH's clinical research programs.
2. *Quality of healthcare rendered* reflects the quality of care provided to the clinical research subjects.
3. *Responsiveness* reflects the ability to meet or exceed the needs of the Center's customers.
4. *Flexibility* encourages freedom from bureaucratic obstacles related to budget, personnel, and procurement.
5. *Efficiency* reflects the ability to reduce costs below current levels.
6. *Accountability* means answerability to the Clinical Center, the Institutes, centers, divisions, and NIH.

Expert Choice software was used to consider the privatization structure that might be most appropriate for the Clinical Center. The software is a decision support tool that uses an analytical hierarchy process to weight priorities of decision alternatives. Based on experience gained during the subcommittees site visits to, and interviews with leaders from, several quasi-governmental corporations, each privatization structure was compared with all other structures using the criteria outlined above. The Expert Choice software was then used to produce a clearly prioritized set of alternatives based on the input of the subcommittee members.

All organizational structures that the subcommittee considered, including maintaining the current structure (i.e., the “status quo”) with improvements, are addressed in the following sections. The alternative structures are discussed in the following terms:

- ◆ *Definition* is a definition of the form of the organizational alternative.
- ◆ *Purpose* is the reason for considering the alternative.
- ◆ *Characteristics* is the key characteristics of the organizational form, traits, and functions.
- ◆ *Budget and finance* explains the nature and type of budget for the organization.
- ◆ *Personnel* describes the legal mechanism and policies for control of personnel resources.
- ◆ *Procurement* describes the legal requirements governing the organization’s acquisition operations and methods.
- ◆ *Advantages* of the alternative.
- ◆ *Disadvantages* of the alternative.

ALTERNATIVE 1: MAINTAIN THE CLINICAL CENTER’S FEDERAL STATUS, WITH EFFICIENCY IMPROVEMENTS

- ◆ *Definition.* The status quo is maintaining the Clinical Center as a direct part of a Federal agency, NIH.
- ◆ *Purpose.* Avoid upheaval. Continue to achieve the Clinical Center’s primary objectives.
- ◆ *Characteristics.* The organizational structure of the Clinical Center would remain unchanged, and it would still be subject to the existing legal structures.

- ◆ *Budget and finance.* Unchanged from current operating systems or modified at the direction of the Clinical Center’s Director in collaboration with the Director of the NIH and the Institutes Centers or Divisions (ICD) directors.
- ◆ *Personnel.* Continued reliance on Title 5 and Title 38 of the U.S. Code, *Federal Pay Schedules*; adherence to existing Federal personnel rules, regulations, and policies.
- ◆ *Procurement.* Adherence to existing Federal procurement rules, regulations, and policies.
- ◆ *Advantages.* The culture of the intramural programs would unquestionably be preserved. This option is the least disruptive and would result in the least turmoil and the least investment in change management. However, even if the status quo is preserved, some changes in operating and measurement systems would be required.
- ◆ *Disadvantages.* The Clinical Center will continue to be encumbered by the Federal rules and regulations that are viewed by most internal and external customers as the major obstacles to operating efficiency. Because of these Federal rules, regulations, and polices, the organization will likely find change management more difficult; will find adjusting to new program demands or new program directions more problematic; and will continue to struggle with funding, cost accounting, personnel, and procurement activities.

ALTERNATIVE 2: MAINTAIN THE CLINICAL CENTER’S FEDERAL STATUS BUT OPERATE THE CENTER AS A REINVENTION LABORATORY

The Vision Subcommittee evaluated the Reinvention Laboratory concept to determine if the Reinvention Laboratory designation might provide an effective, flexible option for improving the organizational efficiency of the Clinical Center. The subcommittee assessed the components of the Reinvention Laboratory process, the successes and failures of other Federal healthcare institutions that have attempted such reinvention, the impediments to successful reinvention at those sites, the advantages and disadvantages of selecting the Reinvention Laboratory status as a structural option for increasing Clinical Center efficiency, and the obstacles to efficiency perceived by major internal Clinical Center stakeholders.

- ◆ *Purpose.* The purpose of a Reinvention Laboratory is to provide an opportunity to redesign systems and work processes for operational efficiency and increased customer satisfaction. Reinvention Laboratories
 - ▶ demonstrate what can be achieved by more fully delegating authority and responsibility to employees,
 - ▶ test the implications of replacing regulatory controls with incentives,
 - ▶ measure success by adherence to customer standards, and
 - ▶ encourage models for reinvention of government that go beyond the officially designated programs.

- ◆ *Characteristics.* Successful Federal healthcare Reinvention Laboratories share several common traits: (1) The organizations were faced with a requirement for dramatic institutional change. (2) Organizational leadership was committed to innovation and creative management prior to the REGO initiative. (3) Organizational leadership was knowledgeable about the principles of quality management and quality improvement and invested in these processes before the REGO initiatives. (4) The organizations had identified an advocate at the agency level to help facilitate reinvention requests.

Most successful reinvention initiatives also share some characteristics in common:

- ▶ Impediments to success that existed at the local level were identified and eliminated. Often, local rules or even myths had acquired the aura of Federal law.
- ▶ Most successful initiatives have resulted from delegations of authority.
- ▶ The “next higher level” in the bureaucracy was often noted to be the most problematic. Obtaining waivers and/or delegations of authority to provide relief from the next higher level often was viewed as the most successful outcome of the Reinvention Laboratory.

Those initiatives have put in place measurement systems and strategies for two major reasons: Careful measurement permits the charting of organizational progress and Measurement of success allows the institution to “market and sell” the reinvention concept. Measurement systems are critical success factors for successful reinvention initiatives.

- ◆ *Advantages.* Advantages are as follows:
 - ▶ Reinvention represents the best of the Federal and nonfederal work worlds, providing many of the advantages of the Federal workplace without the burdens of the bureaucracy.

- ▶ Reinvention would preserve the critical, complex, unique, integrated clinical research culture of the Clinical Center.
 - ▶ With new leadership in place, and facing the REGO II requirement for dramatic institutional change, the Clinical Center is ideally situated for successful reinvention.
 - ▶ The science and measurement skills and experience present in the Clinical Center work force give the Clinical Center a substantial advantage over other reinvention loci when it comes to the analysis of performance data.
 - ▶ The Clinical Center's commitment to, and investment in, education of its work force in the principles and applications of total quality management provide an ideal substrate for reinvention activities.
 - ▶ Reinvention successes for the Clinical Center would undoubtedly serve as a template for implementing reinvention activities for all of NIH.
- ◆ *Disadvantages.* Disadvantages are as follows:
- ▶ Approval as a Reinvention Laboratory does not guarantee approval and implementation of the reinvention proposal.
 - ▶ Obtaining legislative support for this kind of reinvention may be difficult (and, in fact, has been unattainable for some other Reinvention Laboratories).
 - ▶ Reinvention status may make the Clinical Center "politically" vulnerable. Since the reinventing government process is not grounded in statute, the program may lack permanence.
 - ▶ Having the Clinical Center designated as a Reinvention Laboratory and granting the Clinical Center the legislative relief and delegations of authority could foster animosity, jealousy, and resentment at NIH, Public Health Service (PHS), or Department of Health and Human Services (DHHS).
- ◆ *Impediments.* Despite the encouraging results obtained at a few centers, Federal healthcare reinvention activities have achieved only limited success. Several impediments to successful reinvention are as follows:
- ▶ Obtaining total institutional alignment with, or endorsement of, "reinvention" activities has been difficult.
 - ▶ Reinvention requests that would require legislative changes to activate them have been unsuccessful or difficult to start.

- ▶ Granting one unit within an agency special status and privilege, can, and has been seen to, engender resentment and resistance from other units.
- ▶ Important institutional stakeholders are concerned about the permanence of reinvention activities.
- ▶ In the Department of Veterans Affairs, resources [both dollars and full-time equivalent (FTE) personnel] were taken from sites not actively involved as Reinvention Laboratories and were given to the reinvention sites. This produced hostility and tension among sites that previously had collegial interactions.

ALTERNATIVE 3: CONTRACT FOR CLINICAL CENTER OPERATIONS

General issues related to contracting are discussed below. The specific options of partial contracting and complete contracting of the Clinical Center are addressed afterwards. Contracting is also discussed in Chapter 3 in the report's body.

Most hospitals contract for one or more departmental services. The major reasons for doing so include specialized expertise and cost savings. For the most part, hospital executives are happy with the contracts that have been negotiated. However, contracting can also lead to problems. Before contracts are negotiated, careful thought must be given to what activities should be contracted and what should be included in contract provisions. Public institutions are told that they must be especially diligent in their evaluation of whether contracting out services is appropriate.

General Contracting Advantages

In a study issued in May 1995 to the NIH Director, Mr. Mike Goldrich, the Deputy Director of the National Institute of Allergy and Infectious Diseases, offered a summary of the advantages usually pointed to by proponents of contracting. These proponents argue that contracting offers the following:

- ◆ *Flexibility of staffing levels and schedules.* Contracted operations may offer increased freedom to managers as they attempt to adjust schedules or staffing levels in response to fluctuating workload. For example, the ability to more easily use temporary or part-time workers can help a nursing unit manager easily make short-term staffing adjustments. While such techniques are available within the civil service system as well, they are generally more complex and governed by more rules than a typical private-sector organization.

- ◆ *Freedom from government regulations and bureaucracies.* Contracting is widely perceived as a means around government regulations concerning personnel, procurement, and other functions. For example, purchasing managers in private-sector organizations routinely sign long-term, volume-committed contracts for supplies and services to obtain significant discounts; such contracts are extremely complex in the government and require completion of extraordinarily detailed documentation and administrative procedures.
- ◆ *Financial benefits in the form of reduced overhead and increased efficiency.* The perception that government organizations are inherently inefficient and more costly than their private-sector counterparts is shared by virtually all proponents of contracting. Because of the lack of competition and insulation from the pressures of the marketplace, government organizations lack the creativity and dynamism of a market-driven organization. Because of the lack of accountability to the customers they serve, the government is not driven to respond to the day-to-day needs of its clients. Furthermore, because of the astonishing web of laws, regulations, directives, and guidelines within which agencies operate, they are largely unable to try new approaches or experiment with potential improvements. Private firms are willing to incur the risks and costs of a certain measure of failure. Other financial benefits may accrue to the government when private-sector organizations are able to leverage existing capacity to perform a governmental function for marginal costs alone. The Federal government's Medical Prime Vendor programs are an excellent example of this type of benefit, because they use the existing commercial distribution infrastructure to provide substantial improvements in service at marginal cost.

General Contracting Disadvantages

Contracting is a highly politicized question with ideological overtones and a multitude of adherents and opponents. It is not surprising, then, that opponents of contracting have identified many of the same, supposedly advantageous, factors cited above as disadvantageous. In fact, opponents of contracting frequently argue that all of the supposed advantages are only fiction and that true benefits rarely appear, except in cases in which services are restricted or reduced.

More fundamental criticisms of contracting focus on the discussion of what is legitimately a government versus a private-sector function. As summarized in Donald F. Kettl's article, "Building Lasting Reform," some of the fundamental criticisms of contracting and privatization are as follows:¹

- ◆ Government exists to take on those jobs that citizens view as important and that the private market cannot or will not assume. Clearly, the public views clinical research as important. Just as clearly, no institution comparable to the NIH Clinical Center exists anywhere in the world, proving de facto the point that the private market has not assumed the Clinical Center's function.

¹Donald F. Kettl and John J. DiIulio, Jr., *Inside the Reinvention Machine: Appraising Governmental Reform*, Brookings Institution, Washington, D.C., 1995.

Therefore, any supposed economies of scale or leveraging of existing expertise that might be gained through contracting is a moot point in the case of the Clinical Center. The only exception to this would be in those areas in which specific functions, such as the supply distribution function mentioned earlier, could be accomplished by vendors.

- ◆ Democratic government requires that law, not competition, drive bureaucracy. A more applicable corollary to this statement is that scientific validity, not competition, should drive clinical research. Contracting clinical research would require the development of financial incentives that could be fundamentally incompatible with scientific and human interests. While the two domains are not necessarily irreconcilable, the potential for financial incentives that have a negative impact on NIH's scientific activity does exist and makes contracting of the Clinical Center a much more complex undertaking than, say, the privatization of a campus police force.
- ◆ Dramatic reductions in the government's ability to support basic clinical research could reduce the overall ability of the Nation's healthcare system to progress in the future. According to this line of reasoning, contracting out the Clinical Center would effectively gut the NIH's core research capabilities and would impair the NIH's ability to manage its research effort effectively. To follow this reasoning to its conclusion, contracting would result in the government's contracting out the very technical expertise it needs to effectively manage the contracted operation. This is the same reasoning used by Paul Strassmann in a recent article. According to Strassmann, organizations that contract core functions are essentially cannibalizing themselves.²
- ◆ Privatization merely postpones recognition that the real failure of government is political, not administrative. According to this reasoning, if the Clinical Center's personnel system is truly bureaucratic and unresponsive, this is a reflection of the fact that the government's democratic institutions have not reconciled their own fundamental views about fairness and equity in human relations. Contracting out the function may replace a cumbersome government system with a leaner contractor's system. However, that system will also be less fair and more arbitrary than the civil service system — unless the government specifies that the contractor follow civil service procedures, in which case, the contracted process will be neither more nor less efficient than the one it replaces.

The Extent of Contracted Services in Hospitals

Hospitals and Health Networks, Inc. conducted a survey in 1994 of 962 hospitals and found that the popularity of contract services continues to rise.³

²Paul Strassmann, "Contracting: A Game for Losers," *Computerworld*, August 21, 1995.

³K.S. Taylor, "Hired Hands," *Hospitals and Health Networks*, May 20, 1994, pp. 58 – 63.

Nearly two-thirds of hospital Chief Executive Officers (CEOs) report having at least one department run by a contract management firm, up from 55 percent in the 1993 survey. Eleven percent of responding hospitals are fully managed by contract firms.

The following were the most frequently contracted services:

- ◆ Hotel/hospitality
 - ▶ Housekeeping: 42 percent
 - ▶ Laundry: 42 percent
 - ▶ Dietary: 42 percent
- ◆ Business office
 - ▶ Collection: 74 percent
 - ▶ Data processing: 20 percent
 - ▶ Revenue recovery: 13 percent
- ◆ Clinical
 - ▶ Physical therapy: 37 percent
 - ▶ Emergency: 36 percent
 - ▶ Speech/speech pathology: 21 percent.

The following were reasons given for using contract services:

- ◆ Hospitality
 - ▶ Specialized expertise: 55 percent
 - ▶ Cost savings: 55 percent
 - ▶ Take advantage of volume buying power: 33 percent
 - ▶ Avoid cost of owning equipment: 24 percent
 - ▶ Lower the number of FTEs per bed: 17 percent
 - ▶ Enhance hospital's image: 15 percent
 - ▶ Staff hard-to-fill jobs: 15 percent

- ▶ Increase profitability: 8 percent
- ◆ Business Office
 - ▶ Specialized expertise: 65 percent
 - ▶ Cost savings: 40 percent
 - ▶ Increase profitability: 25 percent
 - ▶ Staff hard-to-fill jobs: 15 percent
- ◆ Clinical
 - ▶ Specialized expertise: 64 percent
 - ▶ Staff hard-to-fill jobs: 56 percent
 - ▶ Cost savings: 28 percent
 - ▶ Establish a new service: 18 percent
 - ▶ Recruit/retain physicians: 18 percent
 - ▶ Provide continuum of care: 18 percent
 - ▶ Avoid cost of owning equipment: 16 percent
 - ▶ Increase profitability: 12 percent

The following were reasons given for not using contracts:

- ◆ Can run department well by ourselves: 84 percent
- ◆ Adds another layer of cost: 64 percent
- ◆ Bad previous experience: 23 percent
- ◆ Once committed to contract services it is difficult to return to in house: 20 percent
- ◆ Fear of alienating employees: 10 percent.

The majority of hospital chief executives are happy with their contracts. Almost half claimed that they would sign another contract with the same company. Contracts had to be specifically tailored to ensure that desired results were achieved. The most common clauses found in the contracts include insurance/liability, automatic renewal unless notice to terminate is given, no-fault termination, fee increase protection, assumption of risk by contractor,

fixed-fee payment, cost-effectiveness specification, and quality improvement specifications. Staff credential specifications were found in 62 percent of clinical contracts.

The structural elements of partial and complete contracting are described in the following subsections.

Partial Contracting

- ◆ *Definition.* Using focused contracting to replace certain services supplied by Clinical Center employees that could be provided more efficiently, at lower cost, without sacrificing (or perhaps even improving) the quality of those services.
- ◆ *Purpose.* Self-explanatory.
- ◆ *Characteristics.* The organizational structure of the Clinical Center would remain essentially unchanged and would be subject to the existing legal structure. The leadership of the Clinical Center would decide which services to contract based on (1) the impact of contracting the service on the organization's ability to achieve its mission and (2) data suggesting that the service can be provided via contract at lower cost with increased flexibility, and/or with equivalent or improved quality.
- ◆ *Legal structure.* Unchanged from the Center's current structure baseline, or modified at the direction of the Director of the Clinical Center in collaboration with the Director of NIH and the ICD directors.
- ◆ *CEO.* Director of the Clinical Center.
- ◆ *Budget and finance.* Unchanged from current operating systems or modified at the direction of the Director of the Clinical Center in collaboration with the Director of NIH and the ICD directors. Contracted services would be bound by the terms of the contract.
- ◆ *Personnel.* Contracted services would not be subject to the same personnel regulations as in the Federal personnel system; however, many personnel requirements similar to the Federal personnel system must be met by Federal contractors.
- ◆ *Procurement.* Adherence to existing Federal procurement rules, regulations, and policies; the contractor would not be quite as limited by these rules as the government would be.
- ◆ *Advantages.* The culture of the Center's intramural programs would likely be preserved, though some prior experiences with limited contracting have not been favorable; some increase in quality could be anticipated for certain services.

- ◆ *Disadvantages.* The overall organization, will continue to be encumbered by the Federal rules and regulations that are viewed by most internal and external customers as the major obstacles to operating efficiency. The basic problems encumbering the organization, personnel, procurement, and funding mechanisms, will be unchanged.

Complete Contracting

- ◆ *Definition.* Using a single contractor to replace all Clinical Center services.
- ◆ *Purpose.* Self-explanatory.
- ◆ *Characteristics.* The contractor would determine the design of the structure of the Clinical Center in the context of the requirements established in the request for proposal documents. The contractor would be required to meet the obligations spelled out in the contract at the time the contract is let. Any changes in program direction would have to be negotiated as contract modifications.
- ◆ *Legal structure.* The operations of the Clinical Center would be governed by the contractor, with the Clinical Center contracting officer providing operational oversight.
- ◆ *CEO.* Appointed by the contractor.
- ◆ *Budget and finance.* Contracted services would be bound by the terms of the contract.
- ◆ *Personnel.* The contractor would not be subject to the same personnel regulations as in the Federal personnel system; however, many personnel requirements similar to the Federal personnel system must be met by Federal contractors.
- ◆ *Procurement.* Adherence to existing Federal procurement rules, regulations, and policies; the contractor would not be limited by these rules to the same extent.
- ◆ *Advantages.* Complete contracting might result in a staff that would be more flexible to changing demands of the various ICD clinical research programs. As long as these changes were called for within the scope of the contract, the contractor would have the flexibility of adjusting staff to meet ICD program demands.
- ◆ *Disadvantages.* Complete contracting would likely have a substantial effect on the culture of the intramural programs. Contractors would clearly be “in the business” to make a profit. This motivation would almost unquestionably change the character of the services provided. Furthermore, many of the existing staff members are in the U.S. Public Health Service’s

Commissioned Corps; they would be unlikely to leave the Commissioned Corps to work for a contractor.

ALTERNATIVE 4: PARTIAL PRIVATIZATION

Overview

For purposes of evaluation, various quasi-government corporations were considered under the broad category “privatization.” Under privatization, clinical services would be provided by the Federal government, but the government no longer needs to be in direct control of the service. Privatization of services assumes that the service is important and will be provided by the private sector. This approach assumes that a service is necessary and readily managed by the private sector, but the commercial market is unwilling or unable to bear the sole responsibility for service provision. A corporation and market is created by the government to provide the service. The government controls the service through a combination of limited operational, management, and regulatory controls.

Under the various forms of privatization considered, the Clinical Center might assume a variety of different characteristics. For evaluation and comparison, the subcommittee considered the advantages and disadvantages of five privatization options, including government-sponsored enterprises, wholly owned government corporations, employee stock ownership programs, franchising, and Federally-Funded Research and Development Centers. Findings concerning each of these options are presented in some detail below.

Government-Sponsored Enterprises

Although government-sponsored enterprises (GSEs) were researched and included in the analysis, their narrow focus, the management of investment funds, eliminated them as a viable alternative. An abbreviated description of GSEs follows.

- ◆ *Definition.* GSEs are Federally chartered financial institutions that facilitate the flow of investment funds on favorable terms into designated programs considered by Congress to accomplish a public good, such as in agriculture, housing, and higher education. An example is FREDDIE MAC, the Federal Home Loan Mortgage Corporation.
- ◆ *Purpose.* GSEs were established to serve markets that previously had little opportunity to obtain loans or obtain them at reasonable rates (e.g., farmers, certain home buyers, and students). Their nationwide mandate was to overcome regional differences of traditional institutions’ abilities and efforts to make loans to those markets. The primary purpose is to provide selected borrowers access to credit for specific purposes.

- ◆ *Characteristics.* The legal powers, organizational structures, and operating styles vary, but they share four common characteristics: They are privately owned, operate nationwide, have specialized lending powers, and benefit from an implicit Federal guarantee that enhances their ability to borrow. These attributes set them apart from other Federally chartered corporations.
- ◆ *Reasons for functions.* GSEs were created to spread the availability of funds evenly throughout the Nation; to interest large-scale investors; to lessen investment risks; to open markets for loans (e.g., to students); and to create large fund amounts for specified programs.
- ◆ *Legal structure.* GSEs are governed by boards. All have a majority of members elected by the stockholders; most have a minority of members appointed by either the President of the United States or the sponsoring Federal agency. For example, the Federal National Mortgage Association and the FREDDIE MAC each has its own 18-member board; each is composed of 13 members elected by private stockholders and 5 appointed by the President.

Wholly Owned Government Corporations

- ◆ *Definition.* A wholly owned government corporation is a corporate entity established by Congress in which the government holds all equity. Most of these entities are listed in the Government Corporation Control Act (1945). The Act does not serve as a general incorporation law; each of these corporations have their own enabling legislation that stipulates its powers. Fourteen wholly owned government corporations are listed in the Government Corporation Control Act. They are as follows:
 - ▶ Commodity Credit Corporation
 - ▶ Corporation for National and Community Service
 - ▶ Export—Import Bank of the United States
 - ▶ Federal Crop Insurance Corporation
 - ▶ Federal Housing Administration Fund
 - ▶ Federal Prison Industries, Inc.
 - ▶ Government National Mortgage Association Overseas
 - ▶ Private Investment Corporation Pennsylvania Avenue
 - ▶ Development Corporation
 - ▶ Pension Benefit Guaranty Corporation

- ▶ Rural Telephone Bank
 - ▶ St. Lawrence Seaway Development Corporation
 - ▶ Tennessee Valley Authority
 - ▶ U.S. (Uranium) Enrichment Corporation.
- ◆ *Purpose.* For the most part, wholly owned government corporations serve a public function for a public purpose. Since they conduct industrial or commercial activities and derive their revenue from the sale of goods or services, these corporations need flexibility and freedom from government controls, restraints, and the pressures of the annual appropriation process.

The Government Corporation Control Act notes that revenue-producing government entities can effectively function when subject to market demands. It acknowledges that the corporations need flexibility to carry out the functions specified in their enabling legislation. The Act emphasizes the need for a businesslike budget not burdened by annual limitations on the use of the corporation's funds.

- ◆ *Characteristics.* While there are differences in the corporations' purposes, legal structure, and powers, there are similarities. Wholly owned government corporations are legal entities separate from the United States that can sue and be sued, acquire property, and borrow money in their own name. Most have businesslike functions, have products and/or services sold for a fee to the public, and are revenue-producing and self-sustaining.
- ◆ *Legal structure.* Congress established a variety of legal structures for wholly owned government corporations. Some have boards, of directors, serving full- or part-time, who may be appointed by the President with or without advice of the Senate. They may include specific secretaries of governmental departments. Others may have an independent CEO appointed by the President with Senate approval. Some may have a CEO and a board of directors.

Whether a wholly owned government corporation should be integrated with a governmental department or be independent of it has been debated. Some wholly owned government corporations reside within a governmental department with a CEO appointed by the President with Senate approval. In addition, others report to, and are under the direction of, the Secretary of a specified department.

- ◆ *Budget and finance.* The National Academy of Public Administration lists the following attributes of wholly owned government corporations as they pertain to finance, revenue, budget, and accounting:
- ▶ *Financing.* The corporations can retain and use revenues for any of the purposes of the corporation without congressional appropriations.

Corporations also may be authorized to borrow from the U.S. Treasury, the Federal Financing Bank, or the public for purposes specified by law. Congress can direct that a service be provided at less than cost with requisite congressional appropriations to reimburse the corporation for revenues lost or foregone.

- ▶ *Rates and prices.* The corporations can fix rates and prices for goods and services in accordance with statutory authorization to do so. (This rate-setting process may include policy guidance from a Cabinet Secretary.)
- ▶ *Budget.* The corporations can prepare annual business-type budgets that provide for corporate programs but do not constitute limitations on corporate expenditures with the possible exception of administrative expenses.
- ▶ *Accounts and audits.* The corporations can maintain commercial accounts that are audited by the Comptroller General or by independent auditors in accordance with principles and procedures applicable to commercial corporate transactions. The 1990 Chief Financial Officers Act amended the Government Corporation Control Act to require government corporations to submit an annual management report to Congress. That report must include statements of financial position, operations, and cash flows; reconciliation to the budget report of the corporation (if applicable); and internal accounting and administrative control systems.
- ◆ *Personnel.* The personnel of most wholly owned government corporations are government employees subject to civil service laws, classifications, and pay schedules. Congress may specify in the corporation's enabling legislation that an alternative personnel system can be established. In addition, Congress can grant special authorities for hiring and paying employees. When permitting flexibility, Congress may include certain restrictions (e.g., merit system or limits on the salary scale).
- ◆ *Procurement.* For the most part, wholly owned government corporations may determine the purchases needed to run the organization. Their accounts are not settled by the comptroller general. Most are able to retain and utilize revenues without fiscal year constraints. Unless specified in the corporation's charter, they are subject to the Federal Property and Administrative Services Act and other procurement laws.
- ◆ *Advantages.* The advantages of being a wholly owned government corporation vary with the congressional charter granted. Corporations that are revenue-producing are free from the annual appropriation process. Most are also free of fiscal year limitations. In addition, revenues can be spent to meet corporation needs.

Those which have charters that permit freedom from civil service and procurement regulations (many do not) have considerable flexibility in shaping their work force and carrying out their contract functions.

- ◆ *Disadvantages.* As noted, most are not free from government regulations. They cannot operate with the flexibility desired. In addition, they are subject to changes in, or even dissolution of, their charter by Congress.

As with any business, there are risks that market share will diminish and revenue will not meet expectations.

Employee Stock Ownership Programs

- ◆ *Definition.* An employee stock ownership program (ESOP) is an employee-owned, private, for-profit business. The business is both owned and operated, in whole or in part, by the employees.
- ◆ *Purpose.* An ESOP may be established to offer a service that the government assumes is necessary and must be provided. The government, however, no longer sees the need to directly control, or be involved in, the provision, operation, or maintenance of the service.
- ◆ *Characteristics.* The stock is owned by the employees, who are entitled to exert some control over the business through their shares and receive some financial rewards by way of profits or dividends. Shares are allocated to employees by a formula, which may include salary, seniority, and other vesting considerations. When an employee leaves the firm, the company buys back the shares at an appraised value if not otherwise publicly available.
- ◆ *Budget and finance.* The budget is an internal business matter; funds are raised by customers' payments and loans.
- ◆ *Personnel.* The corporation is free to maintain its own personnel system regarding employee hires, dismissals, salaries, seniority, and other fringe benefits, including pensions.
- ◆ *Procurement.* Corporation-controlled.
- ◆ *Advantages.* At least initially, the ESOP has existing employees and property and equipment, which have been transferred to it. Thus, the employees, are familiar and experienced with the activity of the government agency function.

Employees have a work inducement by participating in dividends or profits and the stock appreciation.

Similar to other private businesses, planning, budgeting, and similar functions are controlled by management.

The ESOP might have an advantage in bidding for contracts from the government. Indeed, the charter may guarantee the new corporation sole-source contracts for a specified period of time to ensure that the service will not be disrupted. The ESOP may be advantaged in a competitive situation because of its experience and track record in the service area.

- ◆ *Disadvantages.* Similar to any for-profit corporation, market forces are factors in maintaining operations. The Federal government continues to exert control through regulations or sale covenants.

Expenses to set up and run an ESOP include legal, accounting, actuarial, and appraisal fees, and administrative costs of maintaining trust accounts to obtain and transfer shares to employees.

- ◆ *Notes.* In mid-1995, the Office of Management and Budget and the General Accounting Office (GAO) reviewed the potential for creating ESOPs. None currently exist in the public sector, although more than 10,000 plans have been created in the private sector, such as in the airline, construction, and car rental industries. Because of the annual expenses of operating an ESOP plan, OMB and the National Performance Review suggest that ESOPs are recommended only for agencies with a minimum annual payroll of over \$500,000 and with a strong potential for earning a reasonable profit. Moreover, by law, an ESOP may cover the lesser of 50 employees or 40 percent of all employees of the corporation (in which case, if the number is fewer than 50, certain management personnel must become collective bargaining unit employees).

The Office of Personnel Management is studying the possibility of transforming its Investigation Services into an ESOP. The function of the Investigation Services is to conduct background investigations for employment and security clearance of applicants and contractors for its own agency and for those of many customer Federal agencies. The investigations are conducted in-house. Presently, a business plan is being prepared. However, it is not clear that a sufficient number of employees support the conversion or would be willing to participate in the endeavor. Moreover, when studying the proposal, GAO noted that it is uncertain whether the ESOP will achieve greater financial stability and cost savings for the government than Office of Personnel Management's current method of providing investigative services.

Franchising

As with GSEs, franchises have extremely limited applicability for the Clinical Center. Franchising is designed for administrative and general support

functions, not medical research; therefore, very limited discussion is devoted to this alternative.

- ◆ *Definition.* Franchising is an entrepreneurial activity within a government organization that offers common administrative support services to other Federal agencies or other components within the same agency.
- ◆ *Purpose.* The principal purpose of franchising is to provide necessary administrative services or products at a competitive cost to government agencies.
- ◆ *Characteristics.* An agency that provides a service will establish a fee for such services. Other agencies, or parts of their own departments, that require the service will use it (or seek a more economical service from another governmental source provider). Examples of services provided are purchasing, warehousing, transportation, construction, management, financing, education, and a variety of products.
- ◆ *Budget and finance.* Initially, a franchise fund is established for a franchise agency. The fund is reimbursed from fees received for services.
- ◆ *Personnel.* A franchise agency either maintains its in-house government-employed staff or hires contractors to supply personnel services.
- ◆ *Advantages.* Managers have flexibility in how services will be provided.
- ◆ *Disadvantages.* There is no captive market. Focus must be on marketing for consumers and set a competitive fee schedule for services and products. There are no operating models or pilot programs now. The concept of franchising has been proposed only recently under the establishment of a Franchise Find Pilot Program authorized by the Government Management Reform Act of 1994. Program selection for pilot programs were scheduled for mid-1995.

Federally Funded Research and Development Centers

- ◆ *Definition.* Federally Funded Research and Development Centers (FFRDCs) are private nonprofit enterprises that enter into contracts with government departments and agencies. FFRDCs are created by distinct arrangements initiated by the government to accomplish specialized research and development needs. They are usually independent private corporations, industrial firms, or units within universities.
- ◆ *Purpose.* FFRDCs are established to accomplish specialized research and development needs of government agencies, to analyze problems, design special equipment, or engineer weapon or space systems — without being subject to the negative aspects of a competitive marketplace.

- ◆ *Characteristics.* There are nearly 40 FFRDCs. Examples of FFRDCs are the RAND Corporation, the Aerospace Corporation, the MITRE Corporation, the Institute for Defense Analysis, the Logistics Management Institute, the Center for Naval Analysis, the Lincoln Laboratory (operated by the Massachusetts Institute of Technology), and the Software Engineering Institute (operated by Carnegie Mellon University).

FFRDCs are sponsored by departments such as the Department of Defense, Department of Energy, Department of Health and Human Services, Department of Transportation, and NASA.

FFRDCs may be classified as studies and analyses centers, systems engineering and integration centers, and research and development laboratories.

They receive noncompetitive assignments of work from the sponsoring departments or agencies. They operate under cost-type contracts that are awarded for several years. Specific projects are assigned through administrative procedures.

- ◆ *Reasons for functions.* FFRDCs are intended to bridge gaps between the government and industry when there were difficulties and limitations in recruiting technical talent to the government. Government salary and personnel ceilings had prevented certain agencies from hiring enough scientists and technicians to satisfy demands; thus, nongovernment employees were needed. FFRDCs are deemed to have the unique expertise or knowledge needed to perform projects and are considered independent and objective in their assessments. They can supplement in-house government staff and offer quick responses to needs. They also are used to support government needs when production contractors cannot perform because of potential conflicts of interest.
- ◆ *Legal structure.* There are diverse corporate arrangements, depending on the ownership (e.g., private corporation or university-operated).
- ◆ *CEO.* Executive officials are selected within the corporation.
- ◆ *Budget and finance.* FFRDCs have authority to determine the size of their budgets and have a variety of additional financial characteristics:
 - ▶ Funds are earned by contracted payments.
 - ▶ Budgets and costs are subject to government rules. The centers must develop overhead rates (management fees) in accord with government criteria and standards and justify those fees. They are subject to governmental cost accounting standards and to government audits.
- ◆ *Personnel.* FFRDCs directly hire their personnel. Restraints on personnel policies are contractual between the managers and the sponsoring agencies. Personnel are subject to conflict of interest regulations. Compensation and

benefits are subject to review and to the upper limits of government salary rates. Position descriptions may be required by the sponsor.

- ◆ *Procurement.* Procurement is controlled by the corporation.
- ◆ *Advantages.* FFRDCs obtain contracts without competition due to a history of experienced staff and maintenance of specialized information.
- ◆ *Disadvantages.* FFRDCs are prohibited from competing for work needed by their sponsoring agencies, although they may initiate projects for funding or submit proposals responding to broad agency announcements.

The sponsoring agency must periodically review the center to ascertain its usefulness before renewing its (usually five-year contracts) or agreements. An agency may decertify a corporation as an FFRDC after reevaluating the agency's program needs. They are subject to agencies' contract officers' assessments of performance and operations.

At various times, Congress has placed ceilings on department budgets for FFRDCs to control their growth. Congress can reduce funding for each center.

Although contracts include the costs of providing service, overhead fees are developed in accord with government standards. Management fees (e.g., salaries) are subject to periodic review and renegotiation.

The scope of a center's work may be limited by its sponsor's purpose and mission. Work for nonsponsoring agencies must be consistent with that described in its sponsoring agreement and is subject to specified approval procedures.

CONCLUSIONS

Based on its site visits to hospitals and the analysis briefly summarized in this appendix and in Chapter 3, the Vision Subcommittee concludes that contracting for Clinical Center management is not appropriate at this time. Within that context, the remaining alternatives are to continue to operate the Clinical Center as a Federal organization, to operate it as a Federal organization but also as a Reinvention Laboratory, or to choose one of the partial privatization alternatives.

The subcommittee evaluated each of the remaining alternatives using the evaluation criteria described earlier. It employed the Expert Choice decision software to prioritize and numerically score the alternatives. The result of that effort was the very clear conclusion that the Clinical Center would operate most effectively and efficiently — while carrying out its mission and moving toward its vision — as a Federal organization operating as a Reinvention Laboratory. The remaining options scored much lower in the Expert Choice comparison. Of

those, the wholly owned government corporation, Federally Funded Research and Development Center, and partial contracting models had the highest evaluation scores.

APPENDIX E

**Charging for Clinical Care:
Report from Michael McGarvey, M.D.**

TRIP REPORT
VISIT TO THE NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER
Friday, August 4, 1995
by
Michael R. McGarvey, M.D.
Senior Vice President - Health Industry Services
Blue Cross and Blue Shield of New Jersey, Inc.

As part of the Federal Administration's "Reinventing Government" initiative, I was invited to participate as an outside advisor to a group from within the Department of Health and Human Services to examine various options concerning improved efficiencies in the operation of the NIH Clinical Center. Of particular interest has been the issue of reimbursement to the Clinical Center by health insurance organizations for patient care services rendered.

In order better to inform myself on the issues, I visited the NIH Clinical Center on Friday, August 4 1995. During that visit, I had the opportunity to interview the following individuals:

- ▶ Dr. David Henderson, Deputy Director for Clinical Care
- ▶ Mr. Gerald Macks, Management Analysis
- ▶ Dr. Philip Gorden, Director, NIDDK
- ▶ Mr. John Slovikosky, Financial Management Officer
- ▶ Dr. John I. Gallin, Director, Clinical Center; and
- ▶ Dr. Helen L. Smits, Deputy Administrator, HCFA (by speaker phone)

Prior to the site visit, I had the opportunity to review materials previously provided by Drs. Smits and Gallin as follows:

- ▶ Meeting records of the REGO II Options Team on the NIH Clinical Center for April 26, May 10, and May 24, 1995.
- ▶ Materials entitled “Clinical Center: Past Trends and Future Projections”.
- ▶ A draft report dated January 1995 produced by the Office of the Inspector General (OIG), Department of Health and Human Services, entitled, “Reimbursable Patient Care Cost at the National Institutes of Health’s Clinical Center”.
- ▶ A document dated May 7, 1995, entitled, “NIH Response to the Office of the Inspector General’s Draft Report: Reimbursable Patient Care Cost at the National Institutes of Health’s Clinical Center”.

Collateral reading materials included a white paper entitled, “Medical Necessity, Experimental Treatment and Coverage Determinations: Lessons from National Health Care Reform” prepared by the National Institute of Health Care Management; and papers on the topic “When and How Should Investigational Treatments be a Covered Benefit?” presented at a conference sponsored by the National Institute of Health Care Management.

Following the visit, and at the request of Dr. Smits, I provided the names of the following insurance and managed care executives who could be contacted for their views on reimbursability of Clinical Center services:

- Alan Schaeffer, M.D. Senior Vice President, Managed Care Operations,
CIGNA
- David Lawrence, M.D. President and Chief Executive Officer, Kaiser
- Sheila Leatherman, Ph.D. President, Center for Health Care Policy and Evaluation,
United Health Care
- Susan Gleeson Vice President, Technology Evaluation and Specialty
Network Services, Blue Cross And Blue Shield
Association
- William Roper, M.D. Senior Vice President and Chief Medical Officer,
Prudential

OBSERVATIONS FROM THE VISIT

A number of salient points came out of the visit to the Clinical Center. These include the following:

- Administrative staff of the Clinical Center are approaching the work of the Options Team with a sense of openness and a measure of optimistic enthusiasm.
- There are undoubtedly significant opportunities for improved efficiency. Clinical Center staff cite some such opportunities.
- Application of the principles of Total Quality Management (TQM) and Continuous Quality Improvement (CQI) hold considerable promise for improving

the efficiency and performance of the Clinical Center. The Clinical Center leadership has made accomplishments in this regard and is eager to do more.

- The Clinical Center serves a considerably different mission from other federal/governmental hospitals. The Clinical Center was created specifically to serve the research interests of the National Institutes of Health. Other federal institutions, e.g. the Veterans Administration, Military hospitals, and Indian Health Service facilities, were developed to provide health care services for defined populations.
- The possibility of “outsourcing” basic hotel services of the Clinical Center could be complicated by the existing unionization of housekeeping and nutrition services.
- The possibility of establishing the Clinical Center under some sort of public/private hybrid corporate structure (e.g., public benefit corporation) holds some appeal and warrants examination.
- The current mechanism through which the individual Institutes estimate the services to be required and fund the Management Fund does not appear to link very closely with actual needs and services. In the words of one interviewee, “We set a banquet and they (the Institutes) don’t eat very much.”
- A number of the issues raised in the OIG’s draft report have apparently been addressed and substantially corrected. Case reviews conducted by the OIG were performed on 1993 cases and, presumably, a number of the criticized practices no longer exist. These points are made as well in the NIH response to the OIG’s

draft report. For example, all “omnibus protocols” have been terminated. And, “Many NIH patients already use third party recovery to offset costs related to their care when they are away from NIH (i.e. incidental care and, where needed, “home” care).” Presumably, however, some “standard” care continues to be rendered and/or paid for by the Clinical Center and the Institutes which is not directly related to the condition under study. It is unclear whether or not all patients receiving medical services at NIH are actually enrolled in protocols or under active assessment for such enrollment.

- The OIG and other observers have raised the possibility of billing for services rendered to patients enrolled in the control arm of double-blind research studies. However, even patients in the control arm participate in data gathering and protocol compliance activities which exceed standard care. Where there is an acceptable form of treatment for a condition, control arm patients receive the accepted treatment, which could be considered “billable.” However, a move to bill for such care could impair the double blind integrity of the study.

COMMENTS

The January 1995 OIG’s report represents at least the third study in the past two decades to examine the potential for third party reimbursement for services rendered by the Clinical Center. Findings have been generally consistent:

- Potentially reimbursable patient care services are rendered by the Clinical Center.
- Such potentially reimbursable services represent a relatively small percentage of the operating costs of the Clinical Center (ranging from approximately 1.4% to approximately 4%).
- Federal legislation would probably be required to overcome the practices and contractual constraints against such reimbursement on the part of third party payors.
- Administrative effort and investment would be required in order to pursue third party reimbursement.
- Pursuit of reimbursement runs some risk of compromising patient/subject identification and referral.

It is my opinion that some of the services rendered by the Clinical Center are, undoubtedly, potentially reimbursable by third party payors. Development of a per diem approach as suggested in the NIH response to the OIG's report would probably be simplest. It could be based as much on local market practice as on the Clinical Center's actual cost structure. The administrative burden could be minimized by contracting with an outside billing organization on a contingency basis. While legislation would probably be desirable and the cleanest way to approach the issue, discussions and negotiations with insurance and managed care organizations might yield some positive results even in the absence of legislation.

However, I would raise a threshold question:

“Is it really appropriate for the Clinical Center to bill for any of its services?”

The Clinical Center is essentially funded 100% by public tax dollars. Individual citizens -- some of whom become patients/subjects in NIH/Clinical Center research -- pay taxes. Insurers and managed care organizations generally pay corporate business taxes. Although health care institutions nationwide strive mightily to maximize revenues, the Clinical Center receives fund allocations from general tax revenues in accordance with the actions of the executive and legislative branches of the federal government. The funds are awarded in pursuit of the Clinical Center’s research mission. Would reimbursement by third party payors essentially represent “double dipping” for services rendered by the Clinical Center and paid for by tax dollars? The answer would appear to be, “yes”.

Given the mission of the NIH and the Clinical Center, and the tax funded nature of the organizations, the leaders of those organizations bear a heavy fiduciary responsibility to assure that no costs extraneous to the research mission are incurred. Recent steps to discontinue omnibus protocols and to encourage patients to pursue standard insurance reimbursement for services rendered away from the Clinical Center and unrelated to their condition under study are admirable, probably long over due, and much be encouraged. Periodic audit of the amount of incidental and extraneous services should probably be conducted.

Throughout the NIH response to the OIG’s report, and during interviews on site, concerns were expressed regarding the increasing difficulty maintaining suitable patient/subject referral sources. The advent and growth of managed care is identified as a potential problem for the research

enterprise. To the extent that this is an issue, I would recommend that managed care organizations be affirmatively approached as potentially efficient sources of patient identification and referral. Entry of managed care organizations into managed Medicare and managed Medicaid programs further broadens the potential populations from which patients/subjects might be identified and recruited. If the issue of reimbursement is removed from the equation, managed care organizations should have no reservations about identifying potentially qualified patients/subjects to the NIH if they are aware of the general acceptance criteria for such individuals. Even if the issue of reimbursement is pursued, assuming charge levels generally comparable to community-based institutions, managed care organizations should be considered approachable in this regard.