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Revitalization of the Warren G. Magnuson Clinical Center at the National Institutes of Health

ABSTRACT

For nearly 45 years the Warren G. Magnuson Clinical Center has been the site of the intramural clinical research of the National Institutes of Health. It has served as the largest clinical research facility for the nation and the site for training many of the clinical investigators in the nation's academic medical centers. Research at the Clinical Center has focused on study of orphan diseases and phase 1 and 2 clinical trials, and this research emphasis has made it a special national resource. Over the last decade there has been a dramatic decline in the number of patients seen at the Clinical Center, as well as a perceived decrease in the quality of research performed at the center. The decreased activity is related in part to fiscal constraints and the impact of the changing health care delivery system. The trends at the Clinical Center are particularly distributing because they parallel what is happening at academic health centers across the country. Because its success is viewed as vital to national clinical research, a major effort has been undertaken to revitalize the center. This paper reports on the plans and activities undertaken to reorganize the center's management, revitalize its infrastructure for conducting clinical research, establish vital clinical research training, and promote partnerships with extramural investigators who will benefit from access to the center. The hope is that the model established at the NIH Clinical Center will assist in the revitalization of clinical research across the nation.
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The Warren G. Magnuson Clinical Center (Clinical Center) at the National Institutes of Health (NIH) helped spawn the nation's clinical research enterprise, including the NIH-funded General Clinical Research Centers (GCRCs) in academic medical centers, through its research accomplishments and the training of clinical investigators. For years the Clinical Center was a major force in clinical research, but the growing strength of academic medical centers has challenged its status. Furthermore, its physical infrastructure is deteriorating, and a perception exists that the Clinical Center has lost its vigor. In addition, the nation's entire clinical research enterprise, including the Clinical Center, is now under stress, primarily because of changes in the health care delivery system.[1,2] In this article, we outline recent efforts to revitalize the NIH Clinical Center in order to secure the future of clinical research across the United States.

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Scope of Clinical Center Activity

As the research hospital of the NIH, the Clinical Center supports the intramural clinical research programs sponsored by 15 NIH institutes. The interdependence of the hospital and the institutes provides the framework for laboratory and clinical collaboration characteristic of the Clinical Center.

The Clinical Center services nearly 50% of the inpatient days and 25% of the outpatient visits at all NIH-supported GCRCs. It was designed with laboratories adjacent to patient care units so that clinical investigators could move rapidly between the bench and bedside. When the Clinical Center opened in 1953, it had 550 beds and was referred to as a national center for chronic disease research[3]; today, it is

a 325-bed hospital with a 13-story ambulatory care research facility (added in 1980).

Every patient admitted to the Clinical Center is enrolled in a clinical protocol. The center supports approximately 900 active clinical protocols that focus on disease pathogenesis in cohorts of patients with rare ("orphan") diseases and include a large number of phase 1 and 2 clinical trials. This emphasis has positioned the Clinical Center to represent an important section of the nation's clinical research portfolio as well as an important referral center for evaluation and management of orphan diseases. Numerous significant medical advances have occurred at the Clinical Center, including the first implantation of artificial heart valves, use of lithium for bipolar disorders, use of AZT for AIDS, and the use of multiagent chemotherapy for cancer.

Despite these medical advances, the patient census has declined in recent years. The number of inpatient days fell from 98,276 in 1990 to 58,404 in 1996, while inpatient admissions fell from 9,314 to 6,300 and outpatient visits declined from 76,268 to 68,346. (Throughout this article "year" refers to federal fiscal year: October 1–September 30.) This reduction is similar to patterns observed in many U.S. academic health centers and is a result of numerous factors, including fiscal constraints, the impact of managed care on patient referrals, and a slight decline in length of stay (from ten days in 1990 to nine days in 1996).

CLINICAL CENTER REVIEW MANDATED

The decline in patient census and the deteriorating physical facility that has outlived its projected life span have raised concern about the future of the Clinical Center.[4–6] In early 1995, the Department of Health and Human Services (DHHS) Secretary, Donna Shalala, mandated a review of the Clinical Center to identify bureaucratic obstacles to efficiency.[4–6] Because strong management of operations was deemed crucial to support clinical research, Secretary Shalala specified that the review evaluate the operations of the Clinical Center and recommend changes that would assure sustained leadership. In addition, the review team was to consider whether privatization of the Clinical Center (contracting all or some services to non-government firms) would save money and improve efficiency.

The review was conducted by a team of extramural and intramural reviewers that submitted a report to Secretary Shalala in January 1996.[7] As part of the review, 30 academic medical centers were visited in order to set benchmarks for best practices.[8] The report offered four recommendations for broad organizational changes related to governance, funding, planning, and flexibility. Secretary Shalala accepted these recommendations, and they are being implemented.

Governance

The reviewers recognized that the governance structure of the Clinical Center is ambiguous, overly complex, and not designed for streamlined decision making. This situation derives from the Clinical Center's efforts to provide service to the 15 institutes that use the facility. Each institute has a director, a scientific director, and a clinical director, who oversee the scientific and clinical activities of their institute's intramural programs. The institute directors have broad oversight of all extramural and intramural programs, the scientific directors are responsible for management of all the intramural programs, and the clinical directors oversee the intramural clinical programs. Governance of the Clinical Center has traditionally depended upon achieving consensus among these groups, a process that the review team deemed cumbersome and inefficient. For example, institute "ownership" of the Clinical Center's resources complicates the establishment of new operating efficiencies, since decisions made for hospital-wide improvement occasionally conflict with institute-specific desires.

The review team recommended that a "clear, logical governance structure should be developed . . . through a Board of Governors with extramural and intramural members." A Board of Governors has been chartered[9] and consists of 15 members appointed by the DHHS Secretary. The board will advise the NIH director and the Clinical Center director. In this way, for the first time, the extramural community will participate in the governance of the Clinical Center. Extramural representation on the board adds new expertise in hospital management and assures that intramural managers are sensitive to extramural concerns. The chair of the Board of Governors is required to be from outside the NIH, and non-government members—experts in health care governance, management, and clinical research—comprise eight of the 15 members. Intramural members are a cross-section representation of the institutes' clinical and scientific staffs. In view of the importance of nursing to clinical research, at least one registered nurse is included on the board. The Board of Governors is charged to approve the Clinical Center's strategic plan, review the annual budget, advise the NIH director about hiring, performance, and compensation of the Clinical Center director, and annually review the planning and resource use of each institute's clinical program. The Board of Governors does not oversee the scientific projects of the institutes; this function continues to be carried out by institute directors and scientific directors with advice from extramural reviewers participating on each institute's Board of Scientific Counselors. To assure continued input from intramural users of the center, a Clinical Center Advisory Council, with representatives from the institutes, has been established.

Funding

In recent years, as the NIH budget tightened and health care costs grew, some institutes reduced their levels of clinical research in favor of less costly laboratory research. Such efforts to be fiscally responsible contributed to an unstable patient census. Clinical Center clinicians are concerned that this level of use may be approaching the threshold necessary to sustain the center. To stabilize clinical activity, the review team recommended that

> The Clinical Center should have a clearly defined budget of its own. . . . [and the] budget should be no less inherently predictable than the budget of NIH as a whole. To improve continuity and stability, [the budget should] allow savings in operating expenses to be reinvested within the Clinical Center from year to year.

A new budget process is being developed that will provide future fiscal stability for the Clinical Center while assuring that all institutes have fair access to Clinical Center facilities. To provide new flexibility in planning, the Clinical Center has been given permission to reinvest savings for use in the following year.

Planning

The third recommendation by the secretary's review team was that "a strategic plan be developed for the Clinical Center with clear and measurable objectives." Although a draft plan was prepared in 1990, the Clinical Center had never implemented a formal strategic plan. The review team felt that such a plan could serve as a blueprint for creating a stronger infrastructure for supporting clinical research. A new plan has been drafted that includes long-range goals of excellence in clinical research and training, quality patient care, cost–effectiveness, and efficiencies. One of the first actions of the Board of Governors was to approve this new strategic plan (available on the World Wide Web at <http://www.cc.nih.gov/OD/strategic/index.html>).

Flexibility

The review group identified numerous bureaucratic obstacles to efficiency and recommended that "to achieve greater flexibility and operating efficiency, the Clinical Center should be designated . . . a Reinvention Laboratory." Vice President Albert Gore defined reinvention laboratories as

> places where we can immediately unshackle our workers to re-engineer their work processes, and fully accomplish their missions. These will be offices where we can fully delegate authority and responsibility, replace regulations with incentives, and measure our success by customer satisfaction.[10]

As a "reinvention laboratory," the Clinical Center would become a federal demonstration site in which reduced regulation, enhanced local autonomy, and improved federal personnel and procurement practices are tested. Such a designation would free the center to try novel ways to procure goods and services, manage personnel, and use operating savings creatively without compromising the quality of clinical research. Although the Clinical Center has not been formally designated a reinvention laboratory, new authorities granted by Secretary Shalala to the NIH and the Clinical Center and pending legislative initiatives will achieve many of the objectives of reinvention status even without the formal designation.

The review team concluded that implementation of these recommendations would be more beneficial than privatization because removing bureaucratic obstacles would result in major savings that would have been largely lost as overhead for a private contractor. In addition, the review concluded that privatization would impinge on the delicate relationship between the institutes and the Clinical Center and thereby endanger the clinical research mission of the NIH.

RECOVERY OF FUNDS FROM THIRD-PARTY PAYERS

Ever since the Clinical Center opened, incidental care has been free to the patients participating in its research protocols. For more than 20 years the NIH opposed collection of third-party payments for care associated with research at the center. Reluctance to pursue recovery of funds from third-party payers was based on the difficulty of distinguishing standard care from clinical research, the impact that third-party collection would be likely to have on patient recruitment to protocols, the expense attached to traditional billing, and the potential disruption to clinical research associated with the bureaucracy needed for third-party collection.

President Bill Clinton's NIH budget request for 1997 called for the Clinical Center to collect $18 million from third-party payers, and the Congress granted the NIH permission to collect third-party payments at the Clinical Center. In response, the center began discussions with third-party payers about how funds might be recovered, considered ways to identify and track costs for care provided, and collected insurance information from patients. Our dialogue with business representatives revealed their concern that selective acceptance of patients to NIH protocols would create a perception of unfair access of certain patients to the Clinical Center. Third-party payers were concerned that payment for care associated with research at the Clinical Center would establish a precedent for third-party payment for all care associated with clinical research nationally. A six-month survey of patients revealed that the Clinical Center could not collect insurance from about 60% of them because they had no insurance or had federal insurance. (By policy, federal health insurance can not be collected by the Clinical

Center.) The survey also revealed that more than 1,000 third-party payers represented the insured patients, creating bureaucratic difficulties for collection. The Board of Governors concluded that the risk to the mission of the Clinical Center did not justify the high cost of developing a collection process, and the board recommended against recovery of third-party payment. A final decision on third-party collection will be made after review by the administration.

ENHANCING INFRASTRUCTURE TO SUPPORT CLINICAL INVESTIGATORS AT THE NIH

Many activities and facilities are essential to a strong clinical research environment. These include training programs, administrative support, and scientific infrastructure. All of these areas, which are of interest to all medical centers conducting clinical research, are targeted for improvement in the Clinical Center's strategic plan.

Training Programs

Despite general acceptance of Flexner's 1925 dictum that training, research, and care are intertwined,[11] formal training in clinical research has not been emphasized at most academic medical centers or the NIH.[12] The Clinical Center, with its large number of studies and physicians from many specialty areas, is in a strong position to help correct this lack of training in clinical investigation. Last year, the Clinical Center introduced a new curriculum in clinical research for physicians, physician assistants, nurses, and PhD scientists, open to both intramural and extramural investigators. The centerpiece of the curriculum is the Clinical Center's introductory core course, with additional courses on biostatistics and epidemiology offered by the NIH Foundation for the Advancement of Education in the Sciences. The core course on clinical research includes lectures and practical experiences with protocol reviews through mock institutional review boards. The course has four modules that address epidemiologic methods, ethical and regulatory issues, oversight of patient-oriented research, and strategies for organizing and funding a clinical research study (List 1). The syllabus for the course has been placed on the World Wide Web at <http://www.cc.nih.gov/OD/core/index2.html>, and a textbook is under development. In addition, the Clinical Center is pursuing collaboration with other medical schools that offer advanced master's and PhD degrees (one has already been initiated with Johns Hopkins University and another is under development with Duke University). In addition, the Clinical Center will be experimenting with collaborative teaching at remote medical centers using state-of-the-art telecommunications.

The need to train medical students to conduct clinical research has been highlighted recently by the NIH Director's Clinical Research Panel under the leadership of Dr. David Nathan from the Dana–Farber Cancer Institute. At the suggestion of this panel, a program to bring medical students to the NIH for intensive training in clinical research at the Clinical Center has begun with nine students, enrolled from nearly 80 applicants in 1997. The plan is for this program to grow to 30 students per year. If successful, the program will be replicated at medical schools throughout the country.

List 1

Introductory Course on Clinical Research, National Institutes of Health

Module	Content
Epidemiologic methods	Study design and development; clinical trials design; measurement; analyzing and presenting data; biostatistics in clinical trials; meta-analysis, survival analysis, and quality-of-life analysis
Ethical and regulatory issues	Ethical principles; legal issues; regulation of human subjects research; the institutional review board (IRB); gender and race diversity in study populations; and scientific conduct
Oversight of patient-oriented research	Data management in clinical trials; monitoring clinical trials; quality assurance in the hospital setting; relations with the Food and Drug Administration; alternative and complementary therapies; data- and safety-monitoring boards; dissemination of information; and technology transfer
Preparing and funding a clinical research study	Infrastructure for clinical research; analysis of resources required for clinical research; how to succeed in the NIH peer-review process for grants; and writing a clinical research protocol

Administrative Support

Specific areas of administrative support are targeted for improvement in the strategic plan—patient recruitment, protocol services, and information systems.

Patient recruitment. The growing managed care industry has made attracting patients a competitive business for many health care providers. At the same time the source of patient referrals to research protocols has shifted from primary care physicians to managed care organizations. This has presented a unique challenge to the Clinical Center. To maintain a steady stream of participants to protocols, a patient re-

cruitment service center has been established to help identify patients for specific protocols and to coordinate the interaction of NIH investigators with referring physicians and with managed care organizations.

Educating the public about clinical research is also important. The Clinical Center is developing materials for the public about its role, the importance of clinical research, and what it means to be a patient volunteer in clinical research.

Patients and referring physicians may have difficulty identifying active protocols for their specific clinical problems. To address this issue, NIH intramural clinical protocols have been placed on the World Wide Web at <http://www.cc.nih.gov//>. The protocol database can be searched easily by symptoms or diagnosis and is designed for both lay and professional communities. An abstract of each protocol is provided, along with a guide to e-mail correspondence with the Clinical Center. The Clinical Center is also trying to combine all NIH–sponsored intramural and extramural protocols into a common database available through the World Wide Web. The national protocol database will guide patients and referring physicians to all active protocols and will assist all NIH–sponsored intramural and extramural investigators with patient recruitment.

Protocol services. Local coordination of all clinical protocol activities has become an increasingly important service to provide to clinical investigators. Over the past few years, ever-increasing numbers of committees have been established to approve protocols, adding time and complexity to the protocol-approval process. Therefore, a protocol coordination service center has been established at the Clinical Center to assist principal investigators with all aspects of protocol development, review, implementation, and monitoring. A new feature is the use of protocol maps for individual protocols. These protocol maps provide details of all tests and procedures for each admission, enable accurate projections and monitoring of protocol costs, address the expectations of patients and referring physicians, and establish a database for coordination of all aspects of protocol implementation.

Information systems. Clinical research requires the best information systems for coordination of clinical research and fiscal data. Over the last two years, the commitment of resources to information systems at the Clinical Center has increased from about 2% to over 4% of the budget. Recent additions include an improved medical information system containing all clinical information and a new, very popular "standard clinical desktop" available at all computer stations in patient care areas. This standard clinical desktop includes electronic searching of leading textbooks of medicine and pharmacology, expanded access to the World Wide Web, literature searches using the National Library of Medicine's Pub Med, a graphics package to design, organize, and present data for papers or presentations, a powerful word processor, a spreadsheet, summaries of all NIH intramural protocols, and protocol consent forms for all intramural protocols. In addition, an executive information package to help institute executives manage Clinical Center resources should be completed this year. This new package will provide managers with current information about personnel use and budget status and will help them monitor their use of Clinical Center resources and project their future requirements.

Scientific Infrastructure

Service centers. The Clinical Center's strategic plan calls for strengthening several scientific services to support clinical investigation. Clinical epidemiology and biostatistics and stem-cell harvesting will receive special emphasis.

Although some of the largest institutes at NIH have strong clinical epidemiology and biostatistics facilities, many of the smaller ones have little or no access to these services. A new clinical epidemiology and biostatistics service center will assist investigators in the smaller institutes in protocol design and in establishing data and safety monitoring boards. A new stem-cell facility within the Clinical Center's Department of Transfusion Medicine has been opened. It will coordinate the harvesting and processing of stem cells to be used as targets for gene therapy and for bone marrow transplants.

Protocol review. There are over 900 active protocols at the Clinical Center, with approximately a 25% turnover each year. To assure top-quality clinical research within the intramural programs, protocols are reviewed prospectively by sponsoring institutes for cost and scientific potential, and annually by the Clinical Center for patient accrual (including meeting demographic objectives) and cost. In addition, all intramural clinical research programs are reviewed retrospectively every four years by a team of extramural reviewers called Boards of Scientific Counselors. The boards review all intramural clinical investigators for the quality and cost of their clinical research. In addition, the network of institute-based intramural institutional review boards (IRBs) is under evaluation by the NIH Deputy Director for Intramural Research to be certain that the IRBs function efficiently and are of uniformly high quality.

EXTRAMURAL OUTREACH

To help alleviate the national crisis of increasingly scarce resources for clinical research, the Clinical Center has created a number of outreach activities to extend its services to extramural investigators. The new stem-cell facility (described above) is exploring ways to assist extramural colleagues with their cellular and gene-transfer protocols. The Clinical Cen-

ter will encourage extramural investigators to collaborate with intramural investigators in projects that use its high-technology resources, such as the positron emission tomography (PET) scanner, and to study the unique cohorts of patients with orphan diseases. New sabbatical programs for extramural investigators to come to the Clinical Center have been developed to allow extramural investigators to spend time with a Clinical Center investigator and then continue projects long term with regular visits to the center.

An additional objective is stronger relationships with the NIH–funded GCRCs. One academic medical center has suggested that the Clinical Center assist in coordinating multicenter clinical trials carried out at GCRCs and at the center. Telecommunications and telemedicine technology are being put in place at the Clinical Center to support such interactive projects.

To improve intellectual exchange among medical centers, selected NIH Clinical Center Grand Rounds and a new Clinical Center Roundtable are now televised live to more than 1,000 medical centers nationwide through GE Tip-TV Healthcare Network and CenterNet. Remote participants may phone in during the question-and-answer sessions. In addition, the Clinical Center has begun using telemedicine for patient recruitment, patient follow-up, and new collaborations with primary-care investigators in remote locations. Telemedicine technology is expected to enable primary-care physicians and physician assistants to participate in clinical research protocols. Two telemedicine suites are being developed at the center.

The Clinical Center is not a full-purpose hospital; there is no emergency room, and certain specialties, such as orthopedic surgery, are not available. This limits the scope of clinical research that can be pursued and is an obstacle for ideal training of young clinical investigators. To broaden the available programs, the Clinical Center has pursued venues to broaden the scope of clinical research. For example, a partnership was recently formed between the NIH Clinical Center, Suburban Hospital in Bethesda, Maryland, and The Johns Hopkins University in Baltimore. This alliance will broaden the clinical training of young investigators and support new studies of emergency conditions, such as trauma, acute stroke, and myocardial infarction. Partnerships with other hospitals in the Washington, D.C., area and throughout the country are under development and will be made possible with telemedicine technology.

NEW NIH CLINICAL RESEARCH CENTER

The 43-year-old Clinical Center is now functionally obsolete, inefficient to operate, and expensive to maintain, a conclusion supported by an in-house study done in 1988, a separate review by the U.S. Army Corps of Engineers in 1991, a review of the NIH intramural programs mandated by Congress in 1994, and the 1996 review of the Clinical Center by Secretary Shalala's committee.[7] Each of these reviews concluded that failure to act soon would result in hundreds of millions of dollars in repairs, operating-cost increases, unacceptable risks of systems failure, disruption of services and research programs, and, most important, threats to the safety of patients and employees.

In 1997 Congress approved construction of a new clinical research center, in recognition that it was a necessary part of NIH's responsibility to improve the quality of clinical research. Congress named the new facility the Mark O. Hatfield Clinical Research Center. The initial plans describe a building with 850,000 square feet, including 250,000 square feet of contiguous laboratory space.[13] A design competition selected the Zimmer, Gunsul and Frasca Partnership, located in Portland, Oregon, to serve as architects. The firm was selected on the basis of its experience, assembled team of consultants, and proposed highly flexible design, which was deemed least obtrusive to the existing campus and surrounding community.

The new clinical research center will be smaller than the existing one, with 250 inpatient beds, compared with 325 open beds in the existing facility. In addition, the new clinical research center will have expanded day-hospital resources for patients who require longer observation times than are possible in traditional outpatient clinics. The day-hospital resources will increase from the current 60-"chair" capacity to 100-hospital "chairs." Routine clinic space, the clinical pathology and radiology departments, and the surgery suites will remain in the current facility but will be connected to the new building. The long-range plan is to convert the present inpatient units and old laboratories to modern laboratories.

To make a smaller, more efficient clinical research center possible, a major change must occur in the assignment of clinical resources to user institutes. Agreement about this new process highlights the spirit of collaboration and cooperation that the research institutes and the Clinical Center have formed. Currently, specific wards are assigned to participating institutes, but the new center will have generic space shared by the institutes. Shared space and better management will save money. Major advances in information transfer are anticipated. Telemedicine rooms will connect electronically to extramural sites, and television monitors throughout patient-care areas will facilitate the transfer of radiologic, anatomic, and pathologic images to patient-care providers. The new clinical research center, which is expected to be completed in 2002, will provide an inviting environment for extramural investigators and, most important, a healing environment in which to provide the best care to patients participating in clinical studies.

CONCLUSION

The foregoing efforts to revitalize the NIH Clinical Center will provide a strong foundation to help invigorate the nation's clinical research enterprise. Among other things, the renewed Clinical Center will encourage new collaborations with extramural investigators through study of the rich variety of patient populations, unique technology, and special services available at the NIH. In this way, the new clinical research center will become a truly national facility for bettering the nation's health.

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