REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

Services For Patients Involved In National Institutes Of Health-Supported Research: How Should They Be Classified And Who Should Pay For Them?

The National Institutes of Health incurs costs for care of patients participating in research that should be paid by patients or insurers. The Institutes often does not know whether grantees are charging it reasonable rates for patient care services because of inadequate monitoring of financial management aspects of grants involving such services.

The Institutes should undertake corrective actions, such as

--establishing a policy on patient care services it will pay for,

--establishing criteria for evaluating use of centers where research is performed on patients, and

--enforcing more vigorously the requirement that grantees promptly submit reports of operations.

The Congress should state whether patients should pay for nonresearch services received at the Institutes' Clinical Center.

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

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To the President of the Senate and the
Speaker of the House of Representatives

This report describes changes that could be made to more fairly distribute charges for patient care services between the National Institutes of Health and the health insurance companies or patients. Significant increases in patient care costs incurred by the Institutes in recent years attracted our attention.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We are sending copies of this report to the Acting Director, Office of Management and Budget, and the Secretary of Health, Education, and Welfare.

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

SERVICES FOR PATIENTS INVOLVED IN NATIONAL INSTITUTES OF HEALTH-SUPPORTED RESEARCH: HOW SHOULD THEY BE CLASSIFIED AND WHO SHOULD PAY FOR THEM?

D I G E S T

Clinical research supported by the National Institutes of Health provides knowledge and experience for developing fundamental discoveries into improved treatment and care for humanity.

The Institutes annually supports research involving thousands of patients throughout the Nation. Estimated patient care costs it incurred in 1975 totaled about $76 million, including $32 million at the Institutes' Clinical Center and about $44 million for patient care provided through grants and contracts awarded by seven of the Institutes' organizations. (See p. 3.)

Many research patients require hospitalization and other services for their medical condition; their participation in research is incidental to their hospital stay. Other patients do not necessarily require hospitalization except to participate in a research study.

There are no Institutes-wide guidelines on what patient care services can be paid with research grant and contract funds. Only two of the eight organizations paying for patient care services have written guidelines indicating when services can be charged to the Institutes. These guidelines provide that grantees separate services for patient care between research and nonresearch portions based on medical judgments, charge the Institutes for the research portion, and charge insurers or patients for the nonresearch portion. (See pp. 5 to 8.)

Organizations with guidelines providing that charges to the Institutes for patient care services be based on medical judgments do not require that grantees comply with them. Grantees often disregard the guidelines and base charges on administrative determinations. The 87 grantees of one organization having guidelines reported 28,452 patient discharges in fiscal year 1975.

GAO's review included five of these grantees. Of the 1,721 discharges they reported, GAO estimated from a random statistical sample that, in about 30 percent of the cases, either the Institutes, or patients and insurers, were inappropriately charged for routine hospital care because patients were not classified in accordance with the guidelines.

Estimated net overcharges to these five grants totaled $126,800, based on rates used for charging the Government, while net undercharges to patients or insurers totaled $121,800, based on ordinary hospital rates. (See pp. 10 to 12.)

Grantees are required to submit rate proposals each year for Department of Health, Education, and Welfare regional comptrollers to use in negotiating Government rates for patient care services.

Of 86 grants GAO reviewed, 70 were charging for patient care services at unapproved Government rates, regular hospital rates, or rates that were more than a year out of date. (See pp. 14 to 16.) In many instances, grantees do not promptly submit necessary information upon which to negotiate a rate, but in other instances, regional comptrollers fail to act promptly on rate proposals. (See p. 15.)

The Institutes does not take sufficient action to insure that grantees submit information required for grant administrators to make sound financial management decisions.

Many grantees reviewed were late in submitting required reports of operations. Those submitted often contained erroneous information or were based on improper rates for patient care. (See p. 17.) Further, Institutes officials do not have guidelines to help them determine when clinical research centers are being efficiently used. (See pp. 18 to 20.)

Current legislation neither clearly permits nor clearly prohibits charging patients for services at the Institutes' Clinical Center. (See p. 27.) Patients receive care at the Center without charge even though many of the services they receive are routine and not research related. (See pp. 23 and 24.) This situation creates an inconsistency wherein patients at the Center receive all services free, while patients at clinical research centers funded by the Institutes have to pay for nonresearch services.

RECOMMENDATIONS

The Secretary of Health, Education, and Welfare should take actions to establish an equitable basis for determining which patient care services the Institutes should pay for and to improve various financial management aspects of grants involving patient care services. Such actions should include:

--Establishing a uniform Institutes-wide policy on patient care costs, with implementing guidelines on allocation of charges for patient care between the Institutes and the patient or other parties.

--Providing for adequate enforcement of the new guidelines and, until they are implemented, requiring that grantees comply with existing guidelines.

--More vigorously enforcing the requirement that grantees submit satisfactory rate proposals and reports of operations.

--Requiring that patient care rates be negotiated within a certain time

--Establishing criteria for evaluating use of clinical research centers. (See pp. 29 and 30.)

The Congress should clarify section 301(e) of the Public Health Service Act to specifically state whether study patients at Public Health Service institutions, hospitals, and stations, including the Clinical Center, can be charged for any services they receive. (See pp. 30 and 31.)

The Department of Health, Education, and Welfare agreed with most of GAO's recommendations, although in some instances, the agreement was qualified. The Department's comments did not always fully respond to the recommendations.

The Department disagreed with GAO's recommendation that the Congress clarify legislation on whether partients admitted to the Clinical Center can be charged for services they receive. It believed the present language in section 301(e) indicates that these patients should not be charged, that establishing a workable fee-for-services system at the Center would be virtually impossible, and that to do so might hamper research.

Based on the results of this review, GAO continues to believe that the Congress should clarify its intent as to whether patients at the Clinical Center or any Public Health Service facility can be charged for services they receive.

Contents

ABBREVIATIONS

DRR	Division of Research Resources
GAO	General Accounting Office
GCRC	General Clinical Research Center
HEW	Department of Health, Education, and Welfare
NCI	National Cancer Institute
NHLBI	National Heart, Lung, and Blood Institute
NIH	National Institutes of Health
ROE	report of expenditures

CHAPTER 1

INTRODUCTION

The clinical research of the National Institutes of Health (NIH) provides knowledge and experience for developing fundamental discoveries into improved treatment and care for humanity. NIH has been increasingly emphasizing clinical research; as a result, its clinical research costs have been growing at over twice the rate of its total research budget. A part of clinical research costs goes for patient care.

Patient care costs can be incurred for services provided to inpatients or outpatients. They include routine and ancillary costs. Routine costs are for items customarily included in the hospital room rate, such as dietary and nursing services and minor medical supplies. Ancillary costs are for such items as laboratory tests, use of operating rooms, and anesthesia. Depending on several factors, including a patient's medical condition and the policies of a particular NIH organization, NIH may pay either (1) all costs for patients participating in research or (2) costs for only those patient care services directly connected with research studies, leaving the cost for non-research-related care to be paid for by patients or insurers.

We examined how patient care costs incurred by NIH are determined and how much financial and management control NIH exercises over patient care costs incurred by research centers under NIH grants. Our review was directed primarily at NIH management of patient care costs rather than clinical research programs in general.

PROJECTS INVOLVING PATIENT CARE COSTS

Patient care costs come from two areas: (1) research at the NIH Clinical Center and (2) grantees and contractors funded by any of the NIH research institutes and the Division of Research Resources (DRR), which serves the resource needs of all the institutes.

The largest amount of NIH grant awards for research patient care is for operating discrete clinical research centers, areas of hospitals with a specific number of beds set aside for research patients. A discrete center typically has from 6 to 30 beds and its own nursing, dietetic, and supporting technical staff to provide precise controls and observations, in addition to its own laboratory, diet kitchen,

patients' lounge, nurses' station, and conference room. Many also have outpatient facilities.

NIH also awards grants for operating clinical research centers, known as scatter bed centers, where research may be conducted on patients anywhere in the hospital. In addition, it allows patient care costs as part of some grant awards for regular research projects, such as when NIH-funded clinical research centers are not available to investigators that are studying patients and doing other types of research. In either instance, grant awards may restrict patient care costs to research involving either inpatients or outpatients or it may allow research involving both types of patients. An institution may receive several grant awards, including funding for both a discrete center and a scatter bed center.

Most NIH-supported clinical research centers are operated through grants awarded by DRR. They are known as General Clinical Research Centers (GCRCs). Studies under the GCRC program can deal with a wide range of human diseases. Grants to GCRCs typically fund administrative costs of operating the GCRCs as well as routine costs, ancillaries, and other services involved in clinical research. The grants do not directly provide funds for researchers' salaries or other costs associated with actual research. Support for specific projects can be obtained through non-Federal or Federal sources, including research grants from one or more of the NIH institutes, each of which does research on specific categories of diseases. NIH officials estimate that more than 1,500 of the 3,900 researchers using GCRCs in fiscal year 1975 were supported by $280 million in grants and contracts awarded by individual institutes for research projects.

The National Cancer Institute (NCI) and two other institutes also award grants for support of clinical research centers where facilities for research on specific diseases are needed or where there is no GCRC available to researchers. Unlike grants to GCRCS, these grants often help pay clinical researchers' salaries.

NIH supports over 1,300 hospital beds for research on human subjects. The GCRC program alone funds about 785 beds. Another 519 beds are located at the NIH Clinical Center, a Public Health Service research hospital located on the NIH reservation in Bethesda, Maryland. Additional beds are supported through contracts and grants awarded to institutions throughout the Nation by the individual institutes. In fiscal year 1975, the average daily inpatient

census in the GCRCs and the NIH Clinical Center was 918 patients, while outpatient visits to GCRCs and the Clinical Center totaled 127,739 visits.

PROGRAM FINANCIAL DATA

During calendar year 1975, patient care costs incurred at the Clinical Center and grant awards for patient care by DRR and six research institutes totaled an estimated $76 million. 1/

Most of the patient care costs identified by NIH were incurred at the Clinical Center and through grants awarded for support of discrete centers. Estimated patient care costs at the Center totaled $32 million during 1975. The table below shows the amount of grant awards, the number and types of grants awarded, and the NIH organizations making the awards.

NIH Grant Awards for Patient Care Costs During 1975

NIH organization	Grants to discrete centers		Grants to other facilities	
	Number	Amount	Number	Amount
DRR	85	$32,608,646	2	$ 171,387
NCI	6	1,910,958	84	6,135,009
National Heart, Lung, and Blood Institute (NHLBI)	-	-	50	1,882,579
All others (4 institutes)	3	473,047	56	629,835
Total	94	$34,992,651	192	$8,818,810

1/NIH records do not separately show patient care costs incurred through contracts. Such costs could be substantial in total, but they may make up only a small portion of individual contracts. There were 2,060 research contracts funded for $389 million in fiscal year 1975, and NIH officials could not readily determine the number of contracts involving patient care costs or the portion of total funds awarded under contracts for these costs.

PRIOR GAO REPORT

In a December 26, 1968, report to the Congress, "Need for Further Action To Determine Allowable Costs and Recover Overpayments Under General Clinical Research Center Grants" (B-164031(2)), we pointed out that five of the six grantee institutions reviewed had received cost reimbursements in excess of allowable costs, we recommended that (1) the Department of Health, Education, and Welfare (HEW) Audit Agency audit other grantees as requested by NIH and (2) based on such audits, NIH act to recover any amount improperly charged to the grants.

NIH agreed to request the audits and as of June 1972, reported a total of $1,978,872 in recoveries from grantees. NIH also expected further recoveries following settlement with grantees. In October 1976 an NIH official told us the audits had been completed and recoveries had been made in full. However, files showing recoveries after June 1972 were not available either at NIH or the HEW Audit Agency, and we were therefore unable to determine the total amount recovered.

CHAPTER 2

GRANTEES ARE INCONSISTENT IN CLASSIFYING RESEARCH PATIENT CARE SERVICES CHARGED TO NIH GRANTS

NIH does not have an overall policy indicating when it will pay the costs of patient care services. Only two of the seven NIH organizations that award research grants providing for patient care services have issued guidelines on the subject. Although these guidelines differ in some respects, they both provide (1) that medical judgments be used in determining which services should be charged to the grants and (2) that payment should usually be made only for those services related to research studies under the grants.

Most of the grantees we visited based their charges for patient care services on various financial considerations, such as the amount of unexpended grant funds or whether patients had health insurance coverage. This occurred because either there were no guidelines or the NIH organizations that had guidelines did not require that they be followed. Consequently, in 46 of 150 cases we sampled, grantees charged NIH for the cost of patient care services not related to research or charged the patients' health insurance firms for research-related services.

LACK OF UNIFORM CRITERIA FOR DETERMINING CARE COSTS

There are no NIH-wide guidelines that specifically discuss patient care services payable from research grant and contract funds. Only DRR and NCI have established guidelines for separating research from nonresearch patient care services. The two sets of instructions differ, however, in how such costs are to be determined and do not apply to contracts that may be awarded by the two organizations.

DRR guidelines

From the inception of the GCRC program in 1960 until the program policy was modified in 1968, GCRCs were operated exclusively for research patient admissions and the grant paid all costs of the hospitalization. The program policy modification allowed grantees the option of admitting patients to GCRCs primarily for care provided that such patients be financially responsible for the cost of their care.

To give grantees guidance in complying with the program policy modification, DRR prepared a service patient policy for GCRCs in 1970. Over 90 percent of the GCRCs had implemented this policy in some form as of July 1977, according to DRR officials. The policy divides patients into the following categories.

--Research patients: Persons selected by a GCRC primarily to participate in a research project. They are either healthy individuals to be used as a control group or, although they may have to be hospitalized for research purposes, they have a medical problem not requiring hospitalization for treatment. The grant should be charged for all costs relating to care of research patients.

--Research service patients: Persons who require hospitalization for diagnosis and treatment for their illnesses and whose participation in research is only incidental to their hospitalization. These patients are fiscally responsible for their routine costs and for the costs of non-research-related ancillary services.

--Patients not participating in research: Persons admissible under certain circumstances to maximize use of hospital beds. These patients are fiscally responsible for all of their costs.

GCRCs may categorize a research service patient as a research patient when necessary to enlist his cooperation in a research project. According to a DRR official, this provision was included to insure that researchers would not have to deny hospital admission to patients of research importance because they are unable or unwilling to pay for hospitalization. He added that the decision to categorize a research service patient as a research patient should be made upon the patient's admission and only after carefully considering the patient's value to the project.

Until February 1976 the service patient policy prohibited professional fees from being charged to either research or research service patients by individuals providing medical care to patients, because such individuals often receive salary support from other grants to do the research. This prohibition was to minimize the potential for patients to be charged for services also paid for through the grants. Concern that this policy could deprive a patient of the best consultative services or discourage GCRC admission

of potentially informative research cases resulted in DRR modifying the policy to allow professional fees to be charged research service patients.

Comparison of service patient policy for GCRCs and the NCI guidelines

The NCI guidelines, implemented in 1968, state that all services are to be divided between research and treatment; the grant will pay for the research portion of services, but the patient should not be relieved of all financial responsibilities merely because of that research. The guidelines do not, however, specifically prohibit the grantee from charging the grant for nonresearch costs not paid by the patient or the patient's insurer. The service patient policy for GCRCs explicitly disallows such charges because the hospital should be fiscally responsible for all billings and collections when patients require hospitalization for treatment, just as it would be if the patient were admitted to a regular hospital bed.

The NCI guidelines provide that the principal investigator, or the attending staff physician he designates, must decide for each day of care whether the patient is in a research or normal care status. If both research and normal care elements are involved in a day, the investigator must decide which of the two predominates. If it is research care, the grant should be charged for that day's routine costs; if it is normal care, the routine costs should be paid by the patient or his insurer.

The NCI guidelines also provide that a judgment be made about whether the cost of ancillary services are to be charged to the grant or to the patient or insurer. When the research requires tests or services in addition to those that would be otherwise required, the guidelines allow the grant to pay for the additional items. But the grant will not ordinarily pay for services that do not result in expenses greater than those the patient would have incurred even though no study existed.

The service patient policy for GCRCs uses different, and we believe clearer, language for determining whether the grant will pay for the cost of routine and ancillary services. But, unlike the NCI guidelines, the service patient policy for GCRCs provides that the grant will pay for all costs when patients are hospitalized primarily for research. We believe a separate decision should be made as to whether a patient requires hospitalization for a medical condition

and whether ancillary services provided are required as part of the research study or for treatment. The grant should pay for ancillary services required as part of the research study and for routine costs when the patient does not require hospitalization for his medical condition.

According to an NCI official, NCI guidelines do not allow fees for professional services to be charged to the grant because salary support for professional and other personnel is provided under other grants. The guidelines also indicate that professional fees cannot be charged to patients unless they are for services to a patient requiring hospitalization and are not related to the research project.

NIH organizations other than DRR and NCI do not have written guidelines for either grantees or contractors to use in identifying patient care services chargeable to NIH. During 1975, five organizations not having such guidelines incurred about $3 million in patient care costs through grants, most of which were incurred by the National Heart, Lung, and Blood Institute. NHLBI officials indicated that, although no guidelines exist, NHLBI grantees are asked to obtain insurance reimbursements where possible.

CHARGES FOR PATIENT CARE OFTEN NOT BASED ON MEDICAL JUDGMENTS

DRR and NCI guidelines provide that medical judgments be used to separate services for care chargeable to the grant from those for which the hospital is responsible for collecting from patients or insurers. However, most DRR grantees did not follow these guidelines; instead, they assessed charges based solely on financial considerations, such as whether grant funds were available or whether the patient had insurance. The NCI-funded grantee we visited was ignoring the NCI guidelines by submitting the patient's bill to insurers without regard to whether services related to research or treatment and charging to the NIH grant the portion of the bill not paid by insurers. The NHLBI grantee we reviewed was following a similar practice.

Grantees operating GCRCs

In fiscal year 1975, DRR made grant awards totaling $33 million to fund costs for the research portion of patient care services. During the same period, grantees received from persons categorized as research service patients, and their insurers, reimbursements estimated by DRR to total $3.2 million. We visited five GCRCs that received awards

totaling $3.7 million from NIH and reimbursements totaling $1.1 million from patients and insurers for patient care services.

Officials at only one of the GCRCs based charges on medical decisions as provided for in the policy. At the other four centers, officials often classified patients as research patients and charged the grant for all services when adequate hospitalization insurance was not readily available. Where such insurance was readily available, they often classified patients as research service patients and charged insurers for all patient care services provided, regardless of whether the services were required for their medical condition or for the research study.

At one GCRC and a unit of another, administrative personnel were classifying patients based solely on financial resources, such as the extent of their hospital insurance. In addition, the GCRC billing clerk routinely placed patients in the research category if the patient was from outside the State or if insurance information might otherwise be difficult to obtain. Conversely if, in the billing clerk's judgment, patients had enough insurance, they were routinely placed in the research service category. Costs were recovered from Medicaid for two patients, who were healthy volunteers whose records were clearly marked "well patient." The billing clerk explained that "Medicaid will pay for anything."

Officials at another GCRC did not stress implementing the service patient policy until it became apparent that grant funds could not support patient care service costs for the rest of the grant year. When they began to stress policy implementation, they also placed a $100 weekly limit per patient on services chargeable to the grant. This caused some researchers to seek other ways of financing research-related services, such as classifying research patients as research service patients and billing insurers for all patient care services provided.

One GCRC had two distinct units. One unit classified patients as research or research service patients. The other unit classified patients as research patients largely because, according to the program director, the policy for GCRCs precludes payment from grant funds of the portion of a research service patient's bill not paid by the insurance company. Thus, the hospital must either require payment from the patient or absorb the unpaid portion as a bad debt. The

director indicated some patients are admitted to that hospital, rather than another, primarily to be studied at the GCRC and that it was unreasonable to charge such patients.

Officials at another GCRC appeared to be trying hard to follow the policy for GCRCs. To aid investigators in classifying patients, they had established written policies and procedures requiring that (1) upon a patient's admission, orders be prepared prescribing research tests to be charged to the grant and (2) a patient's classification be listed for each day of his admission. We believe that this grantee had the best system for classifying patients of any grantees visited.

Extent of patient misclassification

DRR officials do not make reviews to determine if grantees are properly classifying patients. A DRR official said that personnel were not available to review all aspects of grantee operations. He stated that grantees receive assistance in interpreting and applying policies on patient classification when they request it or when instances of patient misclassification become evident during work with grantees or reviews of grantees' reports. He is considering ways to improve grantee compliance with the policy for GCRCs. One option that he is considering is for his office to review classifications of selected patients.

Because of inconsistencies in the methods grantees use to determine patient care costs chargeable to DRR grants, we reviewed patients' records at the GCRCs visited to estimate the extent of noncompliance with the policy for GCRCs when making patient classifications.

A total of 1,721 patients were discharged during fiscal year 1975 from the five centers visited. From lists of patients discharged, we took a random statistical sample of 150 patient records, and copies of related research studies, for our medical advisor to use. He determined whether patients had been properly classified--either as research service patients who require hospitalization for their medical condition or as research patients who were hospitalized primarily for the study. We asked NIH to designate a physician to corroborate these classifications, but NIH officials agreed to accept our classifications without corroboration.

After initially reviewing the cases, our medical advisor discussed them with physicians at the GCRCs where necessary

and obtained additional information on some cases. He then made his final classifications.

These final classifications differed from classifications by GCRC officials for 46 of the 150 cases reviewed, as shown below.

GCRC	Total discharges 1975	Sample	Classified by GAO as research service but by grantee as research	Classified by GAO as research but by grantee as research service	Total classification differences
A	98	15	1	8	9
B	454	30	0	4	4
C	383	31	10	1	11
D	663	56	13	5	18
E	123	18	4	0	4
	1,721	150	28	18	46

For cases that were classified as research by the grantee but as research service by us, we found no evidence that grantees used the special provision in the service patient policy that allows categorization of research service patients as research patients to enlist their cooperation. Rather, it appeared that such differences occurred primarily because grantees did not make classifications in accordance with the policy. Of the 28 cases in this category, 14 were in units that routinely classified patients as research patients, 10 were in a GCRC that did not stress policy implementation until late in fiscal year 1975, and the other 4 were in units that made classifications solely on administrative judgments.

The net financial result of classification differences for the cases reviewed is that DRR would have been charged $12,600 less using our classifications and, after adjustments for differences explained in chapter 3, ordinary rates and rates charged the Government, patients, or insurers would have been charged $12,700 more. Projecting the sample results to the total 1,721 patients discharged from the five GCRCs in fiscal year 1975, we estimate that 488 patients were classified improperly. These improper classifications are estimated to have resulted in a net overcharge to the GCRC grants of $126,800, based on rates used for charging the Government, and a net undercharge to the patients or their

insurers of $121,800, based on ordinary hospital rates. Patient discharges reported by all GCRCs totaled 28,452 in fiscal year 1975.

After our review, officials of DRR's GCRC Branch drafted a proposal that would require institutions operating GCRCs to have local review groups audit classifications of study patients admitted to GCRCs. DRR representatives visiting GCRCs would be required to review and report on the adequacy of these groups' auditing practices.

Centers funded by NCI and NHLBI grants

A cancer research center we visited received a grant award of $1.2 million from NCI and reimbursements of more than $705,000 from insurers in fiscal year 1974. The NHLBI grantee we visited received a grant award of about $600,000 and reimbursements of about $472,000 from insurers.

Officials at the cancer research center were not generally attempting to comply with NCI guidelines for identifying patient care services allowable to be paid under the grant. Instead they were billing insurance firms for their patients' entire hospitalization and then charging the grants for the portion of the bills not paid for by the insurers.

Officials at the center funded by NHLBI charged for patient services in a similar manner. As a result, both grants have been charged for routine patient care required for patients' medical conditions. Also, insurance firms are likely to be paying for research, as well as nonresearch, costs, because the insurers we contacted said they are generally unable to determine whether procedures, such as urine samples and blood tests, relate to research or treatment.

The NCI guidelines state that the nonindigent patients should not be relieved of their obligation to pay for hospitalization expenses they would have incurred if there were no research study. However, the NCI grantee we visited made not charging the patient the rule rather than the exception.

The NHLBI grantee also never charged patients studied at their center. An official of a major insurer in the area where the NCI and NHLBI centers are located said his firm was not aware that Federal grant funds were being used to relieve patients of all financial responsibility. He indicated that, had the firm known, it would have refused to pay for services provided at both the NCI and NHLBI

centers because (1) the firm was being billed for research along with nonresearch services and (2) many insurance contracts exclude payment for services indirectly paid by the Government or for which patients have not been charged directly.

Both NCI and NHLBI grant officials said they were not aware that the grantees were not separating research from treatment services as a basis for determining charges for patient care services. An NHLBI grant official believed the grantee was determining such charges based on DRR's service patient policy for GCRCs. An NCI grant official said many NCI-funded grantees were probably billing grants for the balance of patient care services not paid by insurers, but he believed grantees were separating research services before billing insurers.

The NCI official felt that grants management officials were responsible for informing the grantee of the NCI position on patient care costs chargeable to the grant and that the grantee was responsible for complying. The official agreed that neither patients nor insurers should be charged for services provided as part of the research study. The official noted, however, that NCI has not stressed to grantees the importance of separating research- from non-research-related services because grantees have reported the procedure to be difficult.

The NCI-funded grantee we visited was separating research services from treatment-related services when such separation was to its financial benefit. For example, because researchers' salaries are included in the grant awards, NCI has instructed the grantee not to charge professional fees to the grant and NCI guidelines indicate that patients or insurers can be charged professional fees only for non-research-related procedures. Therefore, the grantee had specified which procedures were research procedures and was billing insurers professional fees for services relating to other procedures.

CHAPTER 3

FINANCIAL MANAGEMENT OF GRANTS INVOLVING PATIENT CARE COSTS

HEW officials are inadequately monitoring various financial management aspects of grants involving patient care services. In some instances, regulations do not require certain actions to be taken, while in other instances, program officials do not enforce the regulations. As a result, (1) grantees are not submitting timely, adequate rate proposals for patient care costs, (2) final approved rates are not being negotiated annually, and (3) grantee reports of expenditures (ROEs) and annual reports of total activity are often late, inaccurate, and thereby not providing a reliable basis for sound management decisions.

GRANTEES USE UNSUBSTANTIATED RATES IN CHARGING FOR PATIENT CARE COSTS

Grantees' claims for reimbursement of patient care costs incurred under an HEW research grant must be supported by the timely submission of a rate proposal for each fiscal year during which such costs are claimed. Hospitals awarded grants involving over $25,000 in research patient care costs must, according to the HEW Grants Administration Manual, submit rate proposals based on recent data to the HEW comptroller in their region no later than 3 months after the effective date of the first grant year and within 6 months after the close of each succeeding fiscal year. The HEW regional comptrollers use these proposals to set rates that hospitals can charge the grants for patient care services. Also, timely negotiation of rates can be important in comparing costs per patient day incurred by the various clinical research centers and in computing future grant awards. Actual rates allowable--negotiated rates--are not normally set for some time after the close of the grant year. Therefore, HEW regional comptrollers establish provisional rates for grantees' temporary use, and adjustments to previously submitted charges are made after allowable rates are negotiated.

Charges to grants not based on currently negotiated rates

Rates for patient care services are often outdated. NIH officials have not emphasized the need for timely submission of rate proposals by grantees. Further, HEW regional comptrollers do not place a high priority on negotiating rates,

nor are they required to negotiate rates periodically or by any specific date. As of August 1976, 68 of 84 GCRCs 1/ were charging for patient care services at rates which were more than a year out of date: 36 were 1 to 2 years, 18 were 2 to 3 years, 11 were 3 to 5 years, and 3 were 5 to 6 years out of date. For the NCI-funded research center we visited, rates had not been negotiated since fiscal year 1972.

No rates have ever been negotiated for the NHLBI grantee we reviewed. This grantee was charging the grant for patient care services based on the hospital's normal billing rate. NHLBI grant awards involving patient care contain a standard statement that "institutional hospital patient rates may be used unless rate otherwise negotiated * * *." This policy is contrary to the intent of the HEW Grants Administration Manual, which provides that provisional or negotiated rates be used. It is also unnecessary because the manual already provides instructions to hospitals that do not have negotiated research patient care rates. Grantee officials said that NHLBI, by approving the grant award, has authorized them to charge at normal billing rates. This resulted in higher charges to the grant than would have been made using a negotiated rate.

The four regional comptrollers we contacted said one problem is that grantees often do not respond promptly to requests for backup data on rate proposals previously submitted. Other grantees submit rate proposals late. The comptrollers also said that they sometimes delay rate negotiations because of heavy workloads.

Because of delays by regional comptrollers in negotiating rates, DRR personnel do the negotiations for some GCRCs and recommend rates to regional comptrollers for approval. However, a DRR official said DRR does not have enough personnel to negotiate rates for all GCRCs.

The HEW Grants Administration Manual states that failure by a grantee to submit timely rate proposals may result in research patient care costs being disallowed. It indicates that the awarding organization, such as DRR in the case of grants for operating GCRCs, is responsible for insuring that grantees submit rate proposals. Grant administration officials we contacted said that the most severe action taken

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1/Since 1975, three of the GCRCs shown in the table on page 3 have been phased out of the program.

against grantees who fail to submit rate proposals is to limit payment to the amount of the grant award based on previous years' costs. Since health care costs are rising, this could result in the grantee not being fully reimbursed for current costs. One official told us that, because grantees do not fear NIH action, grants management personnel can do little to obtain compliance except threaten to withhold future funds. Another official thought that the NIH Division of Contracts and Grants, not the awarding agency, was responsible for insuring that grantees submit rate proposals. An official at the Division, however, said that its duties on insuring rate negotiations extended only to providing a list of grantees due for rate negotiations to HEW's Office of the Comptroller.

Expenses for some grantees are finalized--claims for expenses settled and files closed--based on provisional rates set by HEW regional comptrollers or approved orally by DRR officials. A DRR official explained that this is done when provisional rates do not appear unrealistic and, based on these rates, the grantee has charged the maximum allowable under the grant. For one grantee DRR had finalized expenses for each of 3 grant years from 1970 to 1972, although the claims for grant years ended in 1970 and 1971 were not in accordance with the negotiated rate, and claims for 1972 were based on provisional rates. The HEW Audit Agency reported on this grantee's activities in 1973 and again in 1976. Because of a lack of negotiated rates, they were unable to comment on the reasonableness of more than $900,000 in patient care costs claimed for the 5 grant years from 1970 to 1974. We noted that DRR had finalized expenses for at least six grantees as of August 1976 even though negotiated rates were lacking.

A DRR official said that some grantees have been significantly underpaid for patient care services because their awards were based on outdated provisional rates that were too low. By the time rates are negotiated and the amount of underpayment is finalized, several years have often elapsed, all DRR grant funds for that year have been obligated, and therefore DRR cannot compensate the grantee for charges in excess of the grant award. By the same token, the official said some grantees receive grant awards in excess of their charges for services and are allowed to retain the excesses until a rate is negotiated and grant expenses are finalized for that year. According to him, these excesses could be used to compensate underfunded grantees if they were identified in time, but because of delays in rate negotiations, excesses must sometimes be returned to the U.S. Treasury.

LATE, INCOMPLETE, OR INACCURATE REPORTS

NIH requires that grantees report annually on both financial and scientific aspects of grant operations. Reports summarizing financial data are known as reports of expenditures. More detailed financial data on specific aspects of grantee operations is contained in annual reports. Both ROEs and annual reports are used by NIH grant officials to determine the amount to reimburse grantees. These reports could also be important for handling other grant management activities, such as estimating future funding needs for individual grants and groups of grants and for desk auditing grantees' financial activities. However, the reports were generally of little use because most were either late, incomplete, or inaccurate.

Annual reports and ROEs must be submitted to NIH within 3 months after the close of the grant period. Of the 84 GCRCs, 7 were 3 months past due and another 6 were 7 months past due in submitting ROEs at August 1976. Of those past due, six also had not submitted completed annual reports. Another 20 grantees had submitted ROEs but had not submitted completed annual reports. As previously indicated, many reports submitted were inaccurate because of outdated negotiated rates. In addition, the reports often contained erroneous information or were improperly completed. Some grantees wrote that they were delaying submission of reports until rates are negotiated.

Failure by grantees to submit complete and timely reports results in more work for NIH officials. According to a DRR official, they have to follow up, often repeatedly, with telephone calls and letters to grantees requesting that reports be submitted or requesting clarification because information submitted was erroneous or incomplete. Also, desk audits and other monitoring activities are delayed and made more difficult.

NIH guidelines dated November 1971 state that:

> "A recurring problem in the administration of many NIH grant programs is the delinquency on the part of some grantees in submitting reports required as a condition of the grant award."

The same document directs NIH organizations to assure that such reports are submitted. Although guidelines allow NIH organizations to deny future funding to grantees failing to report, a DRR official said NIH does not take punitive

action against grantees failing to report or reporting improperly. The official said that, because grantees do not fear such action, they do not stress proper preparation and timely submission of reports.

NEED FOR CRITERIA FOR MONITORING USE OF CLINICAL RESEARCH CENTERS

No specific criteria exist for NIH officials to use in evaluating use of clinical research centers, but several NIH and grantee officials have said that patient occupancy rates, the number of researchers using the centers, and the existence of training programs are important factors to be considered. Two GCRCs we visited appeared to be underused based on these three factors, and patient occupancy reports showed that other GCRCs had low occupancy rates in fiscal year 1975. Guidelines indicating factors to consider when monitoring grantees' use of centers, including when grants should be considered for formal evaluation, would make it easier for NIH grant officials to identify underused GCRCs.

For many clinical research centers, NIH funds operations of an area of the hospital set aside for research patients. For these centers, as occupancy rates decrease, costs per patient tend to increase and vice versa. Information prepared for hearings by the Subcommittee on the Department of Labor and HEW, House Committee on Appropriations, showed justifications for GCRCs with occupancy rates below 50 percent. In a staff paper, a DRR official wrote that "* * * occupancy rates of less than 50% result in excessive wasted staff time, while occupancy rates of over 80% lead to undesirable delays in admission." HEW has stated that about 70 to 75 percent occupancy is considered optimal.

During fiscal year 1975, 11 of the 84 DRR-funded GCRCs reported that less than 50 percent of their beds were used by inpatients categorized as either research or research service. DRR officials explained that research tests on some outpatients require use of beds. Also, the officials explained that some beds are used for ordinary hospital admissions, and the hospital reimburses the grant for the cost. The following table shows fiscal year 1975 patient activity reported by DRR at the 11 GCRCs.

GCRC	Bed-days available	Inpatient days: Research-related	Inpatient days: Non-research related	Inpatient days: Total	Number of outpatient visits
A	3,290	1,277	370	1,647	1,115
B	2,704	1,232	562	1,794	318
C	4,080	1,943	0	1,943	0
D	5,475	2,658	729	3,387	1,476
E	3,650	1,781	235	2,016	115
F	5,110	2,236	709	2,945	0
G	3,285	1,128	0	1,128	342
H	2,190	1,028	428	1,456	0
I	1,825	818	0	818	0
J	3,285	1,436	154	1,590	159
K	2,190	882	166	1,048	289

Total use of beds for two of the five GCRCs visited averaged under 45 percent during fiscal year 1975. Neither GCRC was used for ordinary hospital admissions, but one was used to study outpatients. In the applications used as a basis for recommending the grants for approval, the grantees said they planned to use 75 percent of their beds.

NIH and grantee officials have indicated that factors other than occupancy rates to consider when evaluating use of a clinical research center include the number of researchers using the centers and the existence of training programs. The Chairman of the Subcommittee on the Department of Labor and HEW told the Director of DRR during 1976 hearings: "We don't like the idea that these centers are made captives by one or two investigators." A GCRC peer review committee member has stated that funding a research center that supports only a few researchers is a poor investment. A grantee official stated that centers used by fewer than four major researchers are not practical or cost effective. A paper prepared by DRR officials states that one important goal

of the GCRC program, inseparable from the research itself, is to educate physicians, scientists, and paramedical personnel in the complex techniques and disciplines of clinical research.

One GCRC we visited functioned primarily for two researchers who, in fiscal year 1975, accounted for over 70 percent of the total inpatient days, over 75 percent of the total outpatient visits, and an estimated 75 percent of work done in the GCRC laboratory. The fiscal year 1974 annual report from this GCRC indicated that these two researchers used about 75 percent of the total inpatient days and 90 percent of the total outpatient visits. According to the program director, it is difficult to teach clinical research techniques with only two active researchers available and, therefore, the GCRC has no formal training program aside from rotation of medical personnel. During a review of the GCRC in October 1972, a peer review group cited the small number of researchers using the GCRC as a weakness but cited the fact that several new groups of potentially good researchers were developing as a strength. It recommended approving the application because its strengths far outweighed its weaknesses.

Another GCRC functioned primarily for three researchers who, in fiscal year 1975, accounted for about 80 percent of the total inpatient days. It had no formal training program and was ignoring the service patient policy for GCRCs when making final patient classifications. After our visit to this GCRC, DRR officials reduced the grant award for patient care from $240,269 in grant year 1975 to $98,335 in 1976.

CHAPTER 4

SHOULD PATIENTS RECEIVE NONRESEARCH SERVICES FREE AT THE NIH CLINICAL CENTER?

Patients are accepted without charge at the NIH Clinical Center for study, diagnosis, and treatment. Hospitalization of some patients is required only for their participation in research studies. Many other patients, however, must be hospitalized for their illness, and their participation in research is incidental to their treatment. These patients or their insurers would have been subject to charges for services rendered had they been admitted to an ordinary hospital or an NIH-funded clinical research center.

The feasibility of collecting reimbursement for nonresearch services provided at the Clinical Center has been studied before. A 1974 NIH study was made to:

--Evaluate the impact of third-party reimbursement on each institute's intramural clinical research program.

--Discuss third-party reimbursement with insurance firms and Medicare and Medicaid officials.

--Sample the Clinical Center patient population to determine the extent of insurance coverage and nonresearch services provided.

--Analyze alternative collection mechanisms and their relationship to the existing NIH accounting structure.

The results of the feasibility study were provided to the Secretary of HEW in two memorandums. In the first, the Director of NIH said that three major concerns were repeatedly mentioned regarding the impact of third-party reimbursement. These concerns were that (1) patient recruitment would be impaired, (2) the quality of clinical investigations might be affected, and (3) problems associated with recruiting and retaining investigators would increase because they would have to perform more administrative tasks. The Director of NIH concluded the memorandum as follows:

> "We realize that it is impossible to prove, before the fact, that these strongly held beliefs and predictions would result from the institution of a third-party reimbursement policy. It is our sense that the

risks have been carefully and thoughtfully assessed, and we are convinced that if these beliefs are proven to be true, the deleterious consequences for our programs of clinical investigation will be irreversible." (Underscoring supplied.)

The second memorandum was submitted to the Secretary of HEW by the Assistant Secretary for Health. It dealt with the three remaining objectives of the study. First, it included the results of discussions with insurance carriers, which showed that services currently provided in Federal institutions were nonreimbursable and that reimbursement would not be allowed unless all patients were legally obligated to pay for services received. The discussants felt that these problems could be resolved, but only through legislative action.

A second objective discussed was the result of a sampling of Clinical Center patients as to whether they had health insurance coverage and whether they received nonresearch-related services. Based on a 50-percent sampling taken by attending physicians and social workers of the 304 patients in the Center on January 30, 1974, it was reported that (1) about one-third would not have come to the Center if they or their insurance carriers were charged for routine services and (2) 29 percent of the patient population received services that NIH officials believed to be reimbursable by insurance carriers.

Finally the memorandum included estimates by Clinical Center officials of how much it might cost to operate a system that could identify nonresearch costs. Using university medical center and independent clinical research institution models, the officials estimated that the cost of a fee-for-service system would range from $250,000 to $500,000 annually with a staff of 15 to 50. One estimate included in a memorandum from the Assistant Secretary to the Secretary and dated several months before the memorandums reporting the study results projected a $200,000 cost to collect $9 million. Isolating nonresearch costs was considered a major problem.

The Assistant Secretary for Health concluded his memorandum by referring back to the percentage of patients who reportedly said they would not have come to the Clinical Center if they or their insurance carriers were billed for routine services. He stated that, in his judgment, third-party reimbursement would jeopardize the intramural research programs, and he recommended that no charges be initiated.

We believe that this recommendation is inconsistent with the data obtained during the study, the information gathered during our review, and the requirements to charge patients in NIH-funded clinical research centers. It appears that the Federal Government could save a lot of money with little or no adverse impact on research programs if NIH were to charge for nonresearch services related to patients' illnesses. Insurers we contacted said they would pay for such services under the conditions described on pages 26 and 27.

The legality of collecting reimbursement for nonresearch services has also been addressed. NIH officials have twice asked the HEW Office of General Counsel whether patients can legally be charged for the cost of treatment provided by the Clinical Center. The Office of General Counsel gave opinions in 1952 and 1973, concluding that the Public Health Service Act and related statutes provide no sound legal basis for charging for the care of study patients. We agree that current legislation does not clearly provide for HEW to charge for any services provided to patients studied at the Clinical Center or any other Public Health Service hospital, and we believe that clarifying legislation is needed to specify whether charges can be imposed for nonresearch services.

EXTENT OF NONRESEARCH SERVICES PROVIDED AT THE CLINICAL CENTER

Patients at the Clinical Center receive a wide variety of nonresearch services, estimated by NIH officials to cost $9 million annually. Some services, such as physical and dental examinations, are routinely provided, while others are provided as needed.

The Clinical Center feasibility study indicated that 80 (or more than half) of the 152 patients sampled required hospitalization for their condition during part of their admission and that at least 55 required hospitalization during their entire admission. In 11 randomly selected cases requiring hospitalization at the time of the study, our medical advisor reviewed the patients' medical records. He found that all procedures performed on seven patients during the admission included in the study were nonresearch in nature. For the other four patients, unconventional methods were used to try to improve their medical condition and to study the effects of these methods. A Clinical Center official said that research at the Center often involves observing and collecting data on the effects of accepted medical procedures

in an effort to improve them or as a basis to compare results of untested procedures performed on other patients.

We recognize that there is often a need to accept patients requiring nonresearch services, and we are not suggesting that the Clinical Center change its method of selecting and caring for patients. However, because the Center has a policy of not charging for any services provided to its patients, it absorbs the cost of nonresearch services provided these patients. This is contrary to the DRR service patient policy for GCRCs and the NCI guidelines for cancer research centers discussed earlier, which require that patients needing hospitalization, or their insurance carriers, pay for costs of hospitalization and nonresearch service.

POTENTIAL IMPACT ON RESEARCH PROGRAMS OF CHARGING PATIENTS FOR NONRESEARCH SERVICES

During the 1974 feasibility study, various NIH officials expressed a strong belief that programs of clinical investigation would be hindered as a result of third-party reimbursement, primarily because of the fear that even partial collection of third-party reimbursement would greatly impair patient recruitment. They explained that patients having exhausted, or fearing future exhaustion of, their insurance coverage would likely seek treatment at local institutions rather than assuming transportation and other costs related to an NIH admission.

As part of the study, a questionnaire was prepared for all the patients included. Two of the questions dealt with whether the patients would still have come to the Clinical Center if they or their insurance companies were billed for routine services.

Of 80 patients who required hospitalization for their condition, 74 were available to respond to the two questions. Fifty-five patients indicated that they would still come to the Center even on a fee-for-nonresearch-services basis. The following table shows the number of patients indicating whether or not they had health insurance and the number of those stating whether or not they would have come to the Center had they or their insurers been billed for routine services.

	Would still have come		Would not have come		No response or unsure		
	No.	Percent	No.	Percent	No.	Percent	Total patients
Patients with insurance	51	80	3	5	10	16	64
Patients without insurance	4	40	3	30	3	30	10
Total	55	74	6	8	13	18	74

All six patients stating that they would not have come to the Clinical Center on a fee-for-services basis gave financial problems as the reason for their responses. A Center official stated that the absence of the six patients could have somewhat hampered research. However, he believed that such patients would agree to participate in research if the Center could selectively write off charges for routine care and nonresearch services when such patients are of major research significance.

When patients in the study explained the effect on their coming to the Center if they were billed for routine services, the responses were overwhelmingly complimentary regarding the Center's services. Of the 13 patients commenting about services provided, only one made a comment that might be considered negative. He believed that more expert consultations were needed but said that he would still come to the Center even on a fee-for-services basis. Following are questionnaire responses from some other patients.

--"It's the best in the world."

--"For further surgery would come here if had to pay because cannot get the kind of all round care as at NIH even when paying for it."

--"Would come here if it meant mortgaging the house.* * * Chose NIH over other recommended centers * * *."

We recognize that hospital care is expensive, and we are not suggesting that patients be placed in financial jeopardy by attempts to collect from them. However, we believe that patients who can pay for their routine care and nonresearch services should do so.

In response to our inquiry about the potential impact of charging patients for nonresearch services, a GCRC program official said there was no evidence to suggest that such charges hamper the GCRCs' ability to obtain patients for their projects.

CONDITIONS UNDER WHICH INSURERS WOULD PAY FOR SERVICES BY THE CLINICAL CENTER

According to the feasibility study, all major carriers maintained that services provided by Federal institutions were nonreimbursable, and commercial carriers and Blue Cross/Blue Shield expressed this position through standard exclusion clauses in their contracts. We met with officials of several major insurance companies to learn under what conditions they would pay for non-research-related services provided at the Clinical Center.

Officials of California, Massachusetts, and Washington, D.C., insurance companies we contacted--Blue Cross/Blue Shield and Prudential--said their standard exclusion clause would not preclude their paying for services provided at the Clinical Center. They explained that the standard clauses excluding payment to Federal and State institutions are used because patients in those institutions are generally entitled to free care. One official cited examples of Federal hospitals reimbursed by his insurance company for services provided to policyholders. He knew of no reason why any insurer would not pay for hospitalization costs of a patient admitted to the Center merely because it is a Federal hospital.

Insurance company officials noted, however, that insured and uninsured patients must be treated equally with regard to charges. Otherwise they would not consider themselves liable to pay for services provided to their policyholders. However, this should not affect hospitals' procedures for admitting patients and providing services to them. For example, the insurance officials would not expect a hospital to refuse admission to patients unable to pay for needed services not covered by insurance.

The feasibility study indicated that the Clinical Center could charge patients or insurers for nonresearch services only if it implemented a billing system acceptable to health insurers. The Center has no such system. The NIH study included an analysis of collection mechanisms used by university medical research centers and independent clinical research institutions. It concluded that, although the final

system design cannot be determined before third-party negotiations, the Clinical Center could probably use aspects of each of the techniques discussed in the study in creating an acceptable billing system. As stated on page 22, NIH estimates that such a system would require from 15 to 50 positions and an annual operating budget of $250,000 to $500,000. Collections could amount to as much as $9 million annually.

LEGALITY OF CHARGING PATIENTS AT THE CLINICAL CENTER

The Clinical Center operates under authority of section 301(e) of the Public Health Service Act, which states:

> "For the purposes of study, [the Secretary is authorized to] admit and treat at institutions, hospitals, and stations of the Service persons not otherwise eligible for such treatment; * * *."

The HEW Office of General Counsel pointed out in its opinions that this section makes no provision for charging study patients at Public Health Service hospitals. In contrast, sections 322(b) and 324(b) allow for treatment of certain classes of patients, such as seamen from foreign flag vessels, but expressly provide for charging them. Moreover, HEW Counsel said (1) patients admitted for study have traditionally not been charged for treatment and (2) the study patient category is the only one in which the patient is selected by the Public Health Service and which has as its primary purpose not the therapeutic treatment of the individual but the furtherance of a general service function. Therefore, HEW Counsel concluded that the Congress did not intend that research patients be charged since it did not specifically state this.

We found that section 322(d) of the Public Health Service Act providing for temporary treatment of patients in emergencies includes language similar to section 301(e) providing for treatment of study patients. Neither section makes a provision for charging the patients, but HEW has charged patients admitted under section 322(d) while treating all patients admitted under section 301(e) without charge. In addition, although sources cited by the HEW Office of General Counsel do not make a specific provision for charging study patients, they do not prohibit such charges. However, we cannot specifically conclude that the Public Health Service Act allows for charging study patients.

CHAPTER 5

CONCLUSIONS, RECOMMENDATIONS, AND HEW COMMENTS AND OUR OBSERVATIONS

CONCLUSIONS

NIH-funded clinical research programs are an important means of applying medical advances in fundamental biomedical research to humanity. A part of the cost of clinical research goes for patient care. Some services provided to patients at NIH-supported clinical research centers are required as part of research projects, but many are necessary for the patient's medical condition. In many instances, NIH has paid for all services, even those required for the patients' medical condition. In other instances, insurers or patients have been charged for services required as part of research projects.

There are no NIH-wide guidelines for determining which patient care services can be charged to NIH contracts and grants. The NIH organizations that do have guidelines for separating research from nonresearch services do not enforce them and are unaware of the extent to which grantees are being reimbursed for costs for which patients or insurers would ordinarily be responsible.

NIH needs to give more attention to various financial management aspects of grants involving patient care services. Rates that grantees use to charge for patient care services are often out of date. Reports of expenditure and annual reports submitted to NIH are often late, incomplete, or inaccurate, and little or no management action results. Further, NIH officials do not have any guidelines to help them determine when clinical research centers are being efficiently used.

At the NIH Clinical Center, study patients or insurers are not charged even though services provided many patients, including their hospitalization, are required because of their medical condition. NIH has concluded that valuable research patients may not come to the Clinical Center if they are charged and that insurers may not pay for services provided at the Center because it is a Federal institution and it lacks a billing system.

Information from patient questionnaires indicated that most patients needing hospitalization would come to the Center

even if they were charged for nonresearch services. We believe the few patients stating that they would not come if they had to pay would do so if the Center were to write off charges they could not afford to pay. Insurance officials we contacted said they would not refuse payment to a hospital just because it is a Federal institution and would not expect a hospital to refuse admission to patients unable to pay for needed services. Although no system exists for determining charges for nonresearch services provided at the Center, an NIH analysis showed that an acceptable billing system could be designed based on systems used by other organizations doing clinical research.

Current legislation neither clearly permits nor clearly prohibits charging patients at the Clinical Center for nonresearch services. Historically, NIH has not charged for any services at its Clinical Center. This creates an inconsistency inasmuch as patients at a research center funded by an NIH grant or contract can be required to pay for nonresearch type services, while patients at NIH's Clinical Center are not required to pay.

We believe that this inconsistency need not exist and that it can be eliminated with little, if any, detrimental effect to research conducted at the NIH Clinical Center if the legislation were amended to include language specifically allowing patients at the Center to be charged for nonresearch services.

RECOMMENDATIONS TO THE SECRETARY OF HEW

To improve the overall system under which patient care service rates are determined and charges for such services are made, we recommend that the Secretary of HEW require the Director of NIH to:

--Establish a uniform NIH-wide policy on patient care costs with implementing guidelines on allocation of charges for patient care between NIH and the patient or other parties.

--Require all contractors and grantees, as part of the guidelines, to submit information on how they computed patient care costs charged to NIH, such as is now required by the Division of Research Resources in annual reports from General Clinical Research Centers.

--Require that contract and grant officials enforce the new guidelines.

We further recommend that the Secretary strengthen procedures for negotiating rates and obtaining reports by:

--Determining whether the regional comptrollers are adequately negotiating patient care rates or whether NIH should develop the capability to negotiate its own rates.

--Requiring that patient care rates be negotiated within a certain time.

--Requiring the Director of NIH to more vigorously enforce the requirement for grantees to submit satisfactory rate proposals, reports of expenditures, and annual reports; strengthen the penalities for noncompliance; and impose the penality permitted in the regulations when grantees fail to cooperate.

Until the new guidelines are implemented, we recommend that the Director of NIH be instructed to:

--Require NIH organizations with guidelines for charging patient care services to their grants to require that grantees comply with these guidelines so that improper payments for nonresearch services provided by grantees will be minimized.

--Require NHLBI to discontinue placing in grant awards the provision allowing grantees to use ordinary hospital rates for computing charges to the grant for patient care.

Finally, we recommend that the Secretary require the Director of NIH to establish criteria for evaluating use of clinical research centers. The criteria should include, but not be limited to, consideration of occupancy rates, the number of researchers using the centers, and training programs provided by the centers.

RECOMMENDATION TO THE CONGRESS

The Congress should decide whether it is appropriate for patients participating in federally supported medical research projects to receive all services free at the NIH Clinical Center, while patients participating in research at an NIH-funded clinical research center can be required to pay for the non-research-related services received.

We recomend that the Congress clarify section 301(e) of the Public Health Service Act to specifically state whether study patients at Public Health Service institutions, hospitals, and stations, including the Clinical Center, can be charged for any services they receive.

HEW COMMENTS AND OUR OBSERVATIONS

HEW agreed with most of our recommendations although, in some cases, the agreement was qualified. The comments were not always fully responsive to our recommendations. HEW disagreed with our recommendation to the Congress. The following sections deal with areas in which HEW did not agree with our recommendations or qualified its agreement.

Establish uniform NIH-wide policy

HEW agreed that there should be a uniform NIH-wide policy on patient care costs, but cited the complexity of separating research from nonresearch costs. Specifically mentioned was the difficulty of categorizing laboratory examinations for research or patient care purposes. HEW also pointed out that some of the misclassifications reported on page 11 were due to one clinical center classifying patients as research patients rather than research service patients in order to obtain their cooperation in a research project.

We believe that a policy on patient care costs should include a provision that all services be categorized as either research or nonresearch. The researcher must know why he is ordering an examination, and a simple method, such as using different colored slips to record examination orders, could be used to separate research-related from non-research-related examinations. Also, a policy on patient care costs should include a provision that researchers briefly document circumstances in which an individual who would normally be classified as a research service patient is classified as a research patient.

Require enforcement of new guidelines

HEW agreed that the new guidelines should be enforced but said that NIH believes retrospective classification of patient care costs is difficult. Therefore, it concluded that NIH must rely on grantee institutions to accurately apply these guidelines.

Although grantee institutions have a key role in insuring compliance with the new guidelines, we believe that NIH cannot fully rely on them to enforce the guidelines. As discussed on page 12, DRR plans to improve compliance with its guidelines by requiring that local groups appointed by grantee institutions selectively review classifications of study patients admitted to GCRCs. We believe that a similar requirement in connection with the planned NIH-wide guidelines could facilitate their enforcement.

Determine whether regional comptrollers or NIH should negotiate patient care rates

HEW did not believe that NIH should do its own rate negotiating. It felt that negotiation of both patient care and indirect cost rates should be centralized in one office to prevent hospitals from having to negotiate with different HEW offices which might take different views of proper cost allocation.

We agree that coordination within HEW is desirable when negotiating patient care and indirect cost rates. However, HEW did not specify whether a determination would be made of the adequacy of regional comptrollers' efforts to negotiate patient care rates. Since NIH officials have been doing some rate negotiations, some formalized procedures might be initiated that would allow NIH officials to coordinate with the regional comptrollers in negotiating rates.

Enforce reporting requirements and strengthen noncompliance penalties

HEW explained that the main problem in obtaining reports of expenditures and annual reports is the delay in establishing negotiated patient care rates. Grantees are reportedly reluctant to prepare their reports based on provisional rates, which, when later finalized, are negotiated at higher amounts. HEW did say that, if regional comptrollers notified NIH of delinquent rate proposals, cooperation would be provided.

We do not believe that HEW's comments clearly express whether any new steps will be taken to enforce reporting requirements. Also, no mention is made about strengthening or imposing penalties for not complying with reporting requirements.

Require NHLBI to discontinue grant award provision allowing grantees to use ordinary hospital rates for computing patient care charges

HEW said that NHLBI does not allow grantee institutions to use ordinary hospital rates in place of HEW-negotiated rates. In the future, the grantee will be advised that, in the absence of an HEW negotiation agreement, rates used to charge patient care costs to a specific grant are subject to later HEW adjustment to actual costs.

Our point is not that NHLBI allows grantee institutions to use ordinary hospital rates in place of HEW-negotiated rates. Rather, as discussed on page 15, the grantee we reviewed had never attempted to obtain negotiated rates. The grantee indicated that a standard statement in NHLBI grant awards for patient care allowed normal billing rates to be used unless a rate had been negotiated by HEW. This statement is not included in grant awards by other NIH organizations we reviewed. We pointed out that the statement is both unnecessary and contrary to the intent of the HEW Grants Administration Manual. We therefore believe that it should be eliminiated.

Establish criteria for evaluating use of clinical research centers

HEW concurred in our recommendation to establish criteria for evaluating use of clinical research centers. However, HEW believes that it continously evaluates and assesses use of clinical research centers through the NIH peer review process and program staff review. HEW mentioned that the GCRC program does not have written criteria on inpatient occupancy rates but that GCRC evaluators are given general written guidelines to evaluate use. HEW stated that GCRCs are evaluated every 2 to 5 years by scientific review groups in accordance with DRR guidelines. Also, staff reviews of GCRC scientific and expenditure reports are made annually.

Our recommendation is to establish criteria for evaluating use of all clinical centers, not just GCRCs. The guidelines used to evaluate GCRCs could be used as a basis for establishing NIH-wide criteria to evaluate the use of all clinical research centers.

Clarify legislation regarding charging patients for services

HEW did not agree that section 301(e) of the Public Health Service Act should be clarified to specifically state

whether study patients at Public Health Service facilities, including the NIH Clinical Center, can be charged for any services they receive. To support its position, HEW cited a 1973 legal opinion of its General Counsel, which reaffirmed a 1952 opinion. The opinions state that study patients admitted to the Center should not be charged because this would make ability to pay a factor in selecting patients and that this was inconsistent with congressional intent and could shift treatment criteria to those for which the patient would be expected to pay. HEW also argues that the Congress expects patients to pay for emergency treatment under section 322(d) of the act for which no appropriation is made but does not expect patients to pay at the Clinical Center, which receives a congressional appropriation.

HEW also supports its contention that patients at the Clinical Center should not be charged by stating that:

--Every patient is admitted to the Center under a research protocol and, therefore, all services they receive are necessary to the research objective.

--Determining nonresearch services at the Center is almost impossible because certain services required for a routine hospital stay are necessary at the Center for research protocols.

--The 1973 patient survey, which showed that over 74 percent of the patients interviewed would come to the Center even on a fee-for-nonresearch-services basis, was hasty and limited and reflected misleading patient attitudes.

--In 1973 discussions with insurance carriers, they indicated that it was unlikely that a viable contract would be negotiated with them or other carriers because of the Center's program.

We believe that congressional intent regarding patients being charged for nonresearch services at the Clinical Center is not clear and that specific clarification of section 301(e) of the Public Health Service Act would eliminate the long-standing controversy over this matter. Although we recognize that the Congress appropriates money for Center operations, we are not convinced that it is aware of (1) the extent of nonresearch services provided, (2) the January 1974 NIH patient survey which indicated patients would come to the Center even on a fee-for-services basis (see pp. 24 to 26), and (3) statements by officials of major insurance companies

we contacted suggesting conditions under which they would pay for services provided by the Center (see pp. 26 and 27). We believe the Congress should once again look at this issue using the most current data available and then clarify section 301(e) as it deems appropriate.

CHAPTER 6

SCOPE OF REVIEW

This review was made during 1975 and 1976 at NIH headquarters and the Clinical Center in Bethesda, Maryland; Children's Hospital National Medical Center, Washington, D.C.; University of California Medical Center, San Francisco, California; Stanford University Hospital, Stanford, California; and Peter Bent Brigham Hospital, Boston, Massachusetts. We reviewed 5 of 85 grants for discrete General Clinical Research Centers funded by the Division of Research Resources, 1 of 6 discrete clinical research center grants funded by the National Cancer Institute, and 1 of 50 grants involving patient care costs funded by the National Heart, Lung, and Blood Institute.

We randomly selected 150 patient medical and fiscal records from 1,721 patients discharged during fiscal year 1975 from the GCRCs visited. With the help of a medical advisor and after discussions with grantee officials where appropriate, we also classified patients as research or research service in accordance with criteria in the service patient policy for GCRCs. We then compared our classifications with those of GCRC officials.

An NIH analysis of charging patients studied at the Clinical Center, including an evaluation of questionnaire responses by 152 (or half) of the patients hospitalized at January 30, 1974, was reviewed. We summarized questionnaire responses indicating whether patients had insurance and whether they would come to the Clinical Center if they were billed for routine services.

We reviewed legisation, HEW Audit Agency reports, studies, legislative hearings, grantee and NIH records, and NIH and grantee guidelines relating to patient care costs allowable under NIH grants. We also spoke with four HEW regional comptrollers and NIH, grantee, and health insurance officials.

APPENDIX I

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D C 20201

October 14, 1977

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Services for Care of Patients Participating in Research Supported by the National Institutes of Health - How Should They Be Determined and Who Should Pay Them." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Thomas D. Morris
Inspector General

Enclosure

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON THE COMPTROLLER GENERAL'S DRAFT REPORT TO THE CONGRESS OF THE UNITED STATES ENTITLED "SERVICES FOR CARE OF PATIENTS PARTICIPATING IN RESEARCH SUPPORTED BY THE NATIONAL INSTITUTES OF HEALTH--HOW SHOULD THEY BE DETERMINED AND WHO SHOULD PAY THEM"

GAO Recommendation

The Secretary of HEW should require the Director of NIH to establish a uniform NIH-wide policy on patient care costs with implementing guidelines on allocation of services for patient care between those chargeable to NIH and those for which the patient or other parties are responsible.

HEW Comments

We agree that NIH policy should be consistent and we plan to establish a uniform NIH-wide policy on patient care costs. However, separation of research costs from nonresearch costs is a complex problem involving different considerations in different settings. Any such policy would have to allow consideration for the specific programmatic requirements of the multiple awarding components.

The service patient policy of the General Clinical Research Centers Program (GCRCP) was implemented in 1970 as an optional, not mandatory, policy to permit research centers to charge patients and third party carriers for patient care rendered during the conduct of research. There was significant resistance to even this optional policy by the medical scientific community because of strongly held opinions that patients' voluntary participation in research projects was of such value that they should be relieved of all financial responsibility during the period that research was being conducted. Due to resistance by many to the idea of charging research patients and the existence of many regions where third party insurance coverage was marginal, NIH decided to make the policy optional and gradually implement it in order not to impede the progress of medical research. The implementation has been gradual, on a center by center basis, with advice or assistance from GCRCP staff and with some accommodation for the individual financial systems peculiar to each host institution. Over 90 percent of the General Clinical Research Centers (GCRC's) have now implemented the service patient policy in some form.

The three categories of patients who may be admitted to the GCRC are defined as follows:

1) Category A--Research Patients--Those patients admitted to the GCRC primarily to participate in a research protocol. The GCRC grant pays all costs of Category A patient admissions.

2) Category B--Research Service Patients--Those patients admitted to the GCRC primarily for the purposes of diagnosis or treatment according to established therapeutic regimens, and who are participating in a GCRC research protocol that may or may not be related to their illness. Category B patients are fiscally responsible for the routine service costs of their hospitalization and for the costs of non-research related ancillary services. The delineation between research costs and service costs is a professional decision made by the individual investigator and is subject to review by the GCRC advisory committee at each institution.

3) Category C--Non-research Patients--Those patients admitted to the GCRC solely for the purposes of diagnosis or treatment according to established therapeutic regimens and who are not participating in a research protocol. Category C patients are fiscally responsible for their hospitalization costs and may be admitted to the GCRC only when there are unfunded or underutilized beds in the Center.

We feel that classification of individual patients in many research projects by any one physician is an extraordinarily difficult task due to the variety of specialized medical research involved and knowledge of local circumstances which is needed. The separation of research activities from regular treatment is a complex problem. Frequently, research and routine treatment are occurring simultaneously in the same patient and differences in classification in even the same types of patient may be appropriate at different centers. The classification of research patients must take into account various factors including the requirements of the research project, the stage of the disease process, and the resources available for treatment. Because of the foregoing complexities, we do not believe that it is practical for us to attempt to retrospectively classify individual patients.

The GAO visited 5 centers and sampled 150 patient records. The report states that 28 patients were classified as research service by the GAO but as research by the grantee. In two of the centers, accounting for 14 of the 28 cases, the service patient policy had not yet been implemented. These cannot be called misclassifications since the service patient policy was not in effect. In a third center, accounting for most of the remaining 14 cases called misclassifications, the GCRCP was informed that investigators frequently have classified patients as research patients rather than research service patients in order to enlist their cooperation in the project.

The GAO classified as research patients 18 patients for which the grantee was recovering insurance funds. While such misclassifications result in a substantial savings for the Government, we do not condone such practices and plan to implement stronger guidelines for utilization review to curtail these practices.

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Finally, the report states that in four cases classifications were made solely on the basis of administrative judgment. We agree that classification of patients by administrative personnel is inappropriate even though the fiscal resources of the patient may be a legitimate consideration in classification. One center indicated that these judgments are made at a professional level and has written to clarify the possible misunderstanding. Two other center Directors contacted have indicated that judgments are made at a professional level and instructions given to administrative personnel on classification by the responsible investigators. We feel classification by administrative personnel is appropriate only with appropriate professional medical supervision.

It would be very difficult to categorize laboratory examinations on GCRC patients for research or patient care and could result in enormous expenditures of time and resources. It is possible to make this classification for research service patients where certain unusual tests are clearly being performed only for research purposes, and program guidelines already allow for this. However, to separate research and patient care tests on research patients requires a professional judgment which is very tedious and time consuming.

GAO Recommendation

The Secretary of HEW should require the Director of NIH to require all contractors and grantees, as part of the guidelines, to submit information on how they computed patient care costs charged to NIH, such as is now required by the Division of Research Resources in annual reports from General Clinical Research Centers.

HEW Comments

The NIH concurs with this recommendation.

GAO Recommendation

The Secretary of HEW should require the Director of NIH to require that contract and grant officials enforce the new guidelines.

HEW Comments

We agree that the new guidelines should be enforced. However, NIH feels that it is difficult to classify patient care costs retrospectively. The GAO stated, on page 20, that insurers "stated that they are generally unable to determine whether procedures, such as urine samples and blood tests, relate to research or treatment." We feel that the responsibility for classification is best assigned to the principal investigator and that NIH must rely on grantee institutions to accurately apply these guidelines.

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GAO Recommendation

The Secretary, HEW, should strengthen procedures for negotiating rates and obtaining reports by determining whether the regional comptrollers are doing a satisfactory job in negotiating patient care rates or whether NIH should develop sufficient capability to do its own rate negotiating.

HEW Comments

The HEW believes that NIH should not develop its own capability to negotiate patient care rates. Current Department policy mandates the use of Medicare cost reports for the development of cost data needed for both indirect costs and patient care costs incurred by hospitals performing on Departmental agreements. This procedure was adopted for several reasons. It included a desire on the part of the Department to not impose upon hospitals an additional administrative layer of reporting forms. The use of one set of reporting forms for hospitals also eliminated the possibility of costs being distributed in differing proportions to a given program merely as a consequence of cost allocation techniques required by a reporting format. Furthermore, the centralization of negotiation functions for both patient care and indirect costs into one office precluded hospitals from having to negotiate with different Departmental offices--an additional bureaucratic hinderance. Without centralization of this function, a hospital must cope with the potential problem of individual HEW offices taking different interpretive views of proper cost allocation.

GAO Recommendation

The Secretary, HEW, should require that patient care rates be negotiated within a certain time.

HEW Comments

We agree that timely rates are essential to the effective financial administration of grants. Accordingly, we will investigate the reasons for the dated rates cited by GAO and take corrective actions.

GAO Recommendation

The Director, NIH, should more vigorously enforce the requirement for grantees to submit satisfactory rate proposals, reports of expenditures, and annual reports, strengthen the penalties for noncompliance, and impose the penalty permitted in the regulations when grantees fail to cooperate.

HEW Comments

We agree that these reports should be obtained from grantees. However, the primary difficulty in obtaining reports of expenditures and annual

reports has been the delayed establishment of negotiated rates which are acceptable to NIH, the grantee, and the regional offices. Although the Grants Administration Manual Chapter 6-50-30D emphasizes the advantages of predetermined rates, more frequently the Regional Comptrollers' negotiations provide for provisional rates for forward funding purposes. These provisional rates are usually based on historical costs without consideration to inflationary factors. As a result, grantees are reluctant to use such rates on timely filed Reports of Expenditures since the awarding agency is inclined to use unexpended funds against the next year's budget. Subsequently when rates are finalized as much as two or three years later, and generally at higher amounts, there are no funds available for adjustment. If notified by the Regional Comptrollers of grantees that are delinquent in submitting required rate proposals, we will cooperate with them as fully as possible.

GAO Recommendation

Until such time as the new guidelines are implemented, the Director of NIH should be instructed to require NIH organizations, presently having guidelines for charging patient care services to their grants, to require that grantees comply with these guidelines so that improper payments for nonresearch services provided by grantees will be minimized.

HEW Comments

We concur. We will attempt, with our currently available resources, to improve grantee compliance with these guidelines.

GAO Recommendation

The Director, NIH, should require NHLBI to discontinue placing in grant awards the provision allowing grantees to use ordinary hospital rates for computing charges to the grant for patient care.

HEW Comments

The NHLBI does not allow grantee institutions to utilize ordinary hospital rates in place of rates negotiated by HEW. In the future, however, we will advise the grantee that, in the absence of an HEW negotiation agreement, rates used to charge research patient care costs to a specific grant are subject to subsequent adjustment to actual costs by the HEW.

GAO Recommendations

The Secretary, HEW, should require the Director of NIH to establish criteria for evaluating utilization of clinical research centers. The criteria should include but not be limited to consideration of occupancy rates, the number of researchers using the centers, and training programs provided by the centers. Once criteria have been established, a minimum frequency for carrying out such evaluations should be established.

HEW Comments

We concur. However, we feel that we are continuously evaluating and assessing the utilization of clinical research centers by means of the NIH peer review process and constant program staff review.

"Utilization" of a GCRC is a term used in two different contexts. In a narrow sense it means the occupancy rate for inpatients. Although the GCRCP does not have specific written criteria for the inpatient occupancy rate, site visitors have been given general written guidelines for evaluating the utilization of GCRC's. We do not feel that it is feasible, to establish strict criteria which do not allow for unusual circumstances at a particular center. About 70-75% occupancy is considered optimal. Low occupancy rates waste staff time and too-high rates create problems with scheduling the orderly completion of scientific protocols. However, a center's inpatient space and personnel resources are usually also "utilized" for the study of outpatients and sometimes for nonresearch patients. The GCRCP has a program which provides for certain "mixed centers" which allow service patients to be mixed with research patients.

A typical mixed center would include five research beds on a ten-bed center with nursing and dietary costs shared between research and service patients admitted to the center in order to prevent diversion of research resources to service. This is particularly useful in a small center where personnel costs are proportionately high on a per bed basis. We feel that it is an effective means of cost saving and allows flexibility in matching center bed size to scientific need and productivity. When nonresearch patients and outpatients are included in the occupancy calculation for the GCRC's for 1975, only 3 out of 83 centers fall below the 50% occupancy level, not 11 as stated in the report, and corrective action has been taken at each of these. In addition, a center with an apparently low occupancy rate may, in fact, have its beds occupied during daytime hours by studies being conducted on outpatients. Further, it is not meaningful to apply strict criteria or attempt to implement uniform measures for outpatient utilization since outpatient studies may vary from only a brief visit for examination and testing to many hours of timed infusions and specimen collections. It is most effective to rely on program staff and peer scientific judgment to determine the extent of resource occupancy.

The report also seems to use the term utilization in a broader sense, to include scientific accomplishments, training value, and value to the institutional research atmosphere. Evalutions of this type of utilization are made at many different points in the life cycle of a GCRC, and explicit criteria have been developed for them. Centers are evaluated by scientific peer review groups and staff every two to five years in accordance with DRR guidelines. These guidelines have been re-examined recently and are currently undergoing revision. These peer reviews are a thorough examination of the scientific productivity, occupancy, training programs, need for the center, administration of the center, medical

care coverage, staffing patterns, fiscal classification of patients, appropriateness of hospital rates and future direction of the research program. In addition, annual ranking is carried out by the GCRC Advisory Committee and the National Advisory Research Resources Council on all centers in their terminal and preterminal years.

Staff reviews of GCRC scientific and expenditure reports are also conducted annually. Funding is reduced at centers whose activity is at a lower level than anticipated. Criteria used in evaluating the centers include occupancy rates, outpatients use, scientific productivity, use of the center for training, and amount of non-DRR NIH support for research projects conducted on the center. Problems are identified during this review process, staff visits are made to the center, or center staff is invited here to assist in the negotiation of hospital rates, to discuss problems itemized in the review, to correct reporting problems, etc. Finally, to the extent possible early peer review evaluations are scheduled by scientific and grants management staff with consultants to review the entire program of a center where annual reports and other evidence suggest it is performing below the expectations of the previous review.

The DRR is aware that some centers may occasionally be utilized by only a small number of investigators and that, in general, at least four investigative groups using a center are desirable. However, this does not necessarily preclude support to centers with fewer investigators, particularly where the narrow use appears temporary and the remaining investigators are highly productive. In the center described on pages 34 and 35, a site visit was conducted in 1973 and the reviewing committees stated that the strengths of this application far outweighed the weaknesses. The Advisory Council recognized that the major usage and productivity of the unit had involved only a small number of investigative groups, but saw evidence that several new groups of potentially good investigators were developing. They unanimously recommended approval of the center at a high scientific priority. During the past three years, four major groups were using the center. In addition, a new group has recently joined the center and is now using approximately 20% of the facility.

The second center described on page 35 lost several major investigative groups during the past few years. Due to this loss, administrative action was taken to reduce the center from six to three beds, which we feel is consistent with the level of scientific activity by the remaining investigators. A site visit review was conducted this year and the reviewers recommended continued support for one year at the current reduced level to allow time for a recruitment effort to bring additional investigators to the center.

The DRR feels that such cases are exceptional and must be judged individually both as to the appropriate level of support and the potential for broader utilization.

GAO RECOMMENDATION TO THE CONGRESS

The Congress should decide whether it is appropriate for patients who participate in Federally supported medical research projects to receive all services free when they are at the NIH Clinical Center, while patients who participate in research at an NIH funded clinical research center, must pay for the services received which are nonresearch in nature.

We recommend that the Congress clarify section 301(e) of the Public Health Service Act to specifically state whether study patients at Public Health Service institutions, hospitals, and stations including the NIH Clinical Center, can be charged for any services they receive.

HEW Comments

We do not agree that section 301(e) of the Public Health Service Act should be amended. We believe that the present language indicates that patients at the NIH Clinical Center should not be charged for any services they receive.

The report indicates that many patients at extramural clinical centers require hospitalization and other services for their medical condition and their participation in research is incidental to their hospital stay. By applying the extramural experience to the NIH, the GAO concluded that many Clinical Center patients must be hospitalized by their illness and that their participation in research is incidental to the treatment they receive. This conclusion is inaccurate. While most hospitals exist to provide direct benefits to patients, the Clinical Center's only reason for existence is to increase biomedical knowledge through clinical investigations. Every Clinical Center patient is admitted exclusively for the purpose of research under a research protocol. Accordingly, all services they receive are necessary to the research objective. All research patients receive good general medical care as an adjunct to the research.

Occasionally a patient is admitted for diagnosis to determine whether the patient qualifies under a research protocol.

The determination of nonresearch services in the Clinical Center is almost impossible. For example, although a low salt diet is a therapeutic regimen in many hospitals, it is the background for investigational studies at the Clinical Center. Although certain patient services such as physical examinations and laboratory test would be required for a routine hospital stay, at the Clinical Center they are necessary to maintain the patients so that research protocols can be carried out.

In 1973, under time pressure, we performed a hasty and very limited survey and noted that patient attitudes towards payment versus nonpayment might be misleading. Of 80 patients who required hospitalization, 74 responded. Fifty-five said they would still come to the

Clinical Center even on a fee for nonresearch services basis and only six said they would not come. Thirteen were uncertain. The GAO report indicates that this favorably indicates patient acceptance of charges for patient services. We disagree. The patients were not asked whether they would permit their limited hospitalization insurance to be used for research study. This is an important consideration since the average stay at the Clinical Center is 22-23 days compared to 7-8 days in a community hospital, and the number of laboratory tests and other regular services are extended disproportionately for research patients. Many Clinical Center patients suffer from chronic diseases and we believe many of them would not come to the Clinical Center if they had to use their limited hospitalization insurance. The survey indicated that nearly one quarter of the patients surveyed might fail to participate in Clinical Center studies if charged. Due to the uniqueness of these studies, and the relatively small numbers of patients involved, this could jeopardize NIH's ability to attract suitable research subjects for certain protocols.

We found, during discussions in 1973 with Blue Cross and Blue Shield and Maryland Medicaid, that these companies did not pay for patients involved in research and that they required that all patients be charged in a like manner. The companies considered it extremely unlikely that a viable contract could be negotiated with them or other third parties because of the nature of the Clinical Center's program and patient population. The report states that GAO recently contacted officials of California, Massachusetts, and Washington, D.C., Blue Cross, Blue Shield, and Prudential and were informed that their standard exclusion clause would not preclude their paying for services provided at the Clinical Center. However, they were not asked if they would pay for any segment of the cost of a research protocol. All Clinical Center patients are entered under research protocols. It is unlikely also, that insurance carriers would allow NIH to extract the maximum available from them and waive the balance due from the research subject. On the other hand, to hold the patient responsible for the unpaid balance, particularly when his stay may well be extended for research purposes, would also be a financial burden to the patient and would tend to limit our patients to the affluent or well-insured.

In October 1973, the HEW General Counsel stated that there is no legal base for imposing a charge for the care of Clinical Center patients. The legal opinion reaffirmed that study patients admitted to the Clinical Center under Section 301(e) of the Public Health Service Act should not be charged for two reasons: "(1) it would be inconsistent with the criteria of selection of patients as intended by Congress since it would inject a factor of ability to pay as to patients who clearly are intended to be selected solely in terms of the needs of the investigation, and (2) it would tend to shift the criteria controlling treatment to those alone for which the patient would be expected to pay." These arguments are still valid.

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The report states that HEW has charged patients admitted under Section 322(d) of the Public Health Service Act while treating without charge all patients admitted under Section 301(e). The NIH Clinical Center receives a Congressional appropriation for its continuation. There is no Congressional appropriation for the temporary treatment of patients in emergencies. This would indicate that the Congress expects patients to pay for emergency treatment under Section 322(d) but not to pay for research treatment at the NIH Clinical Center.

PRINCIPAL HEW OFFICIALS

RESPONSIBLE FOR ADMINISTERING ACTIVITIES

DISCUSSED IN THIS REPORT

	Tenure of office	
	From	To
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:		
Joseph A. Califano, Jr.	Jan. 1977	Present
David Mathews	Aug. 1975	Jan. 1977
ASSISTANT SECRETARY FOR HEALTH:		
Julius Richmond	July 1977	Present
James F. Dickson III (acting)	Jan. 1977	July 1977
Theodore Cooper	May 1975	Jan. 1977
DIRECTOR, NATIONAL INSTITUTES OF HEALTH:		
Donald S. Fredrickson	July 1975	Present
DIRECTOR, NATIONAL CANCER INSTITUTE:		
Arthur C. Upton	July 1977	Present
Guy R. Newell, Jr. (acting)	Nov. 1976	July 1977
Frank J. Rauscher, Jr.	May 1972	Nov. 1976
DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE:		
Robert I. Levy	Sept. 1975	Present
DIRECTOR, DIVISION OF RESEARCH RESOURCES:		
Thomas G. Bowery	Nov. 1969	Present
DIRECTOR, NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER:		
Mortimer B. Lipsett	July 1976	Present
Griff T. Ross (acting)	Apr. 1976	July 1976
Roger L. Black (acting)	Sept. 1975	Apr. 1976

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