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Report to the Chairman, Subcommittee on Human Resources and Intergovernmental Relations, Committee on Government Operations, House of Representatives

June 1988

HCFA RESEARCH

Agency Practices and Other Factors Threaten Quality of Mandated Studies

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Program Evaluation and
Methodology Division

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June 3, 1988

The Honorable Ted Weiss
Chairman, Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Operations
House of Representatives

Dear Mr. Chairman:

This report assesses the quality of research and evaluation at the Health Care Financing Administration (HCFA), within the Department of Health and Human Services. As you requested and as agreed in subsequent discussions with your office, we have examined three major elements of quality: the relevance of HCFA research to congressional requests, the timeliness of products, and the technical adequacy of the work. Our assessment was directed toward specifying the stage of the research management process where quality problems have occurred; that is, during planning, project execution, or report review. Some information on HCFA's efforts to disseminate its research findings is also provided.

At your request, comments were not obtained from the Department of Health and Human Services. As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of the report. At that time, we will send copies to the Department of Health and Human Services and the Office of Management and Budget. We will also make copies available to others upon request. Please call me (202-275-1854) or Lois-ellin Datta (202-275-1370) if you need further information.

Sincerely yours,

Eleanor Chelimsky
Director

Executive Summary

Purpose

More than 45 million Americans receive Medicare or Medicaid benefits. The nation spends more than $120 billion per year for these programs, which are administered by the Department of Health and Human Services (HHS). In fiscal year 1987, the Congress appropriated $28 million for research, demonstrations, and evaluation to assess whether these programs are having the intended effects and to help identify emerging problems, alternative procedures, and solutions. Since the late 1970s, the Office of Research and Demonstrations of the Health Care Financing Administration (HCFA) has had the major responsibility for these efforts. The Chairman of the House Subcommittee on Human Resources and Intergovernmental Relations asked GAO to (1) examine the quality of congressionally mandated HCFA research and evaluations since 1980, and (2) identify key factors influencing quality, including factors internal and external to HCFA's Office of Research and Demonstrations.

Background

Concern about the quality of HCFA's research and evaluation has been expressed since 1980 by the Congress, congressional agencies, HHS, and other reviewers. This report addresses quality in terms of three major elements: (1) the relevance of HCFA's research and evaluation studies to congressional requests, (2) the timeliness of these studies, and (3) their technical adequacy. GAO examined these elements at each of the three stages of the research and evaluation process—planning, project execution, and report review—from the perspective of the Congress and its committees. In addition, HCFA's dissemination of research and evaluation reports was examined. The four major strategies GAO used to gather its data are (1) literature review, including assessments by GAO and others of HCFA's research quality; (2) analyses of archival data sources, including sets of documents that cover the universe of the office's mandated and nonmandated projects or reports; (3) interviews with agency staff and others; and (4) retrospective case studies of 10 recently completed, congressionally mandated projects. GAO's analysts and expert consultants assigned technical adequacy ratings to the reports stemming from the case studies. Combining all four strategies, GAO's assessment covered 1980-1987.

Results in Brief

Mandated reports from the Office of Research and Demonstrations to the Congress were often not fully responsive to congressional needs, were frequently late, and were variable in their technical adequacy. Not a single stage of the research management process—planning, project execution, or report review—was without problems. Overall, the relevance, timeliness, and technical adequacy of the office's research and evaluation activities have improved little since the early 1980s.

Several factors affected the quality of research and evaluation studies. Within the office, relevance was hampered by lack of communication to better understand congressional intent in some generally worded mandates. Timeliness was improved by shortcuts in procurement, but technical adequacy was weakened by planning that did not include congressional interests. This meant "retrofitting" the procurement process to start jobs in a timely manner. Technical adequacy was weakened further by a lack of consistent monitoring and technical consultation. Outside the office, relevance was affected by, in some instances, after-the-fact report reviews for policy compliance. Timeliness notably decreased because of a report review and revision process that involved HCFA, HHS, and the Office of Management and Budget (OMB). Technical adequacy in some cases was affected by policy influences during the external review and revision process.

GAO's Analysis

Relevance of Mandated Studies

The relevance of mandated studies to congressional interests was a problem in at least 5 of the 10 case studies. For three of these five, relevance was hampered by the nonspecificity of the congressional mandate combined with the lack of agency communication with congressional staff. Agency staff noted that what communication occurred was primarily informal. No trend toward more systematic communication was observed. In other instances, changes made during report review affected relevance. For example, during the review of the Medigap State Regulations report, information was deleted on insurance companies' loss ratios—although this point was of significant congressional interest.

Timeliness

Late delivery of reports was a continuing problem. Of 28 reports due before the summer of 1986, 26 were delivered late or were still overdue—some by more than 2 years. Recent office strategies to initiate mandated projects more quickly than in the early 1980s have been successful, cutting the median start-up time from 2.5 to 1.3 years, but projects still lag. The major source of delay for mandated studies was the extensive review-revision cycles of reports to the Congress undertaken by officials within HCFA, HHS, and OMB, which often have lasted for months or even years.

Technical Adequacy

Technical adequacy varied considerably across reports of mandated studies rated by GAO and outside experts. Earlier reviews found similar variability. Over time, technical adequacy and procedures to ensure technical adequacy did not improve substantially. HCFA did not always follow procedures designed to ensure that the technically best projects would be selected for grant awards or cooperative agreements. In one year, more than one-third of the projects awarded by the HCFA administrator had been disapproved by the review panels on the basis of technical adequacy. In other instances, site selection was flawed by some avoidable problems during initial decision-making. Quality assurance practices of the Office of Research and Demonstrations improved technical adequacy for some projects, but not all. Finally, a technical perspective did not always dominate reviews by HCFA, HHS, and OMB, and changes made in some cases affected technical adequacy.

Internal Factors Associated With Mandated Study Quality

Variation in specificity of mandates, together with a lack of agency-congressional communication, sometimes lessened relevance. Problems of technical adequacy in mandated studies were plausibly linked to a planning process that did not take into account congressional interests (some of which could have been anticipated) and led to shortcuts in the procurement process. The shortcuts improved timeliness, but led to some technical problems. Some studies were improved, even salvaged, by indepth monitoring and technical consultant assistance, but intensive monitoring was not targeted to all studies needing help.

External Factors Associated With Mandated Study Quality

Relevance was limited in some instances by decisions made during the report review and revision cycles involving HCFA, HHS, and OMB. That is, material in the original research that was relevant to, and originally included in, the reports to Congress was deleted during these reviews on policy, rather than technical, grounds. Gains associated with prompt initiation of studies were lost in delays associated with extended review and revision. Technical adequacy was influenced by external factors in the planning and proposal cycles and, in some instances, by decisions made during the review and revision cycles.

Contextual Factors

HCFA's difficulties in achieving quality research and evaluation studies occurred at a time of reductions in funding and staff. That is, some of the planning decisions were plausibly linked to tensions between congressional and administration priorities when the number of mandated

studies increased while funds decreased. Some of the problems in technical monitoring appeared to be influenced by staff shortages that forced a choice between overloading technically appropriate staff and distributing assignments to less prepared staff.

Recommendations to the Secretary of Health and Human Services

To deal with internal factors associated with study quality, GAO recommends that the secretary of HHS direct the HCFA administrator to develop management procedures that will address the issues raised in this report. These would include, for example, procedures to ensure that agency-congressional communication is adequate during all stages of mandated studies and that the Office of Research and Demonstrations considers areas of congressional concern as it develops research and evaluation plans.

With regard to factors external to the Office of Research and Demonstrations, GAO recommends that the secretary (1) implement formal review procedures designed to ensure that HHS review of reports to the Congress will be timely, and (2) work with other executive branch agencies to develop similar procedures for reviewing HCFA's reports.

Finally, in order to deal with contextual factors, GAO recommends that the secretary direct the HCFA administrator to assess whether the Office of Research and Demonstrations has sufficient staff and resources to plan, monitor, and review studies mandated by the Congress as well as those supported by discretionary funds.

Matter for Congressional Consideration

To facilitate the quality of mandated studies when it is impossible to be ideally specific about requests, congressional committees may wish to consider establishing either procedures for clarifying the nature and scope of studies or timelines for reporting or both. In mandating new HCFA studies, it may be useful to specify scope and time by considering the resources available to HCFA in light of ongoing studies, prior requests, and planned work.

Agency Comments

At the request of the House Subcommittee on Human Resources and Intergovernmental Relations, GAO did not seek agency comments on this report.

Contents

Bibliography

Tables

Figures

Abbreviations

DRG	Diagnosis-related group
GAO	General Accounting Office
HCFA	Health Care Financing Admnistration
HHS	Department of Health and Human Services
HMO	Health Maintenance Organization
NTIS	National Technical Information Service
OMB	Office of Management and Budget
ORD	Office of Research and Demonstrations
PPS	Prospective payment system
TAP	Technical advisory panel

Introduction

Federal expenditures for health care are a large part of the nondefense budget of the U.S. government. In fiscal year 1987, estimated Medicare and Medicaid expenditures exceeded $120 billion.[1] This represents a 109-percent increase (in current dollars) since 1980. Through the 1980s, escalating health care costs have concerned policymakers and the general public. The issue is how to best control rising health care costs without negatively affecting either the quality of health services or patient access to them.

The Medicare and Medicaid programs are administered by the Health Care Financing Administration (HCFA), which is an agency of the Department of Health and Human Services (HHS). To help assess whether the money appropriated for Medicare and Medicaid has the desired effects, to identify emerging problems in health care, and to study potential solutions, the Congress has provided funds to support research, demonstration, and evaluation projects. The activities supported by these funds are administered by HCFA's Office of Research and Demonstrations (ORD).

How wisely these research, demonstration, and evaluation funds have been managed is a matter of continuing congressional concern. At one level, this is a question of whether the public is getting reasonable value for its research, demonstration, and evaluation investment. At another level—the one we address in this report—it is a set of questions about research management, identification of important policy issues, and the design and execution of studies to answer policymakers' questions in a relevant, timely, and technically adequate manner.

At the request of the Subcommittee on Human Resources and Intergovernmental Relations of the House Committee on Government Operations, we have (1) examined the quality of congressionally mandated HCFA studies since 1980, and (2) identified factors within and outside HCFA/ORD that influence the quality of these studies—including their relevance, timeliness, and technical adequacy.

The Health Care Financing Administration

HCFA was established in March 1977 to better coordinate the expanding federal role in health care financing and delivery. The agency is responsible for administering Medicare and Medicaid. Previously, Medicare had been administered by the Social Security Administration and Medicaid by the former Social and Rehabilitation Service.

[1] Includes state share of Medicaid costs.

Office of Research and Demonstrations

The Office of Research and Demonstrations supports intramural and extramural studies designed to examine alternative procedures for reimbursement, coverage, eligibility, and management of Medicare and Medicaid. Management responsibility for ORD has been assigned to HCFA's associate administrator for program development.

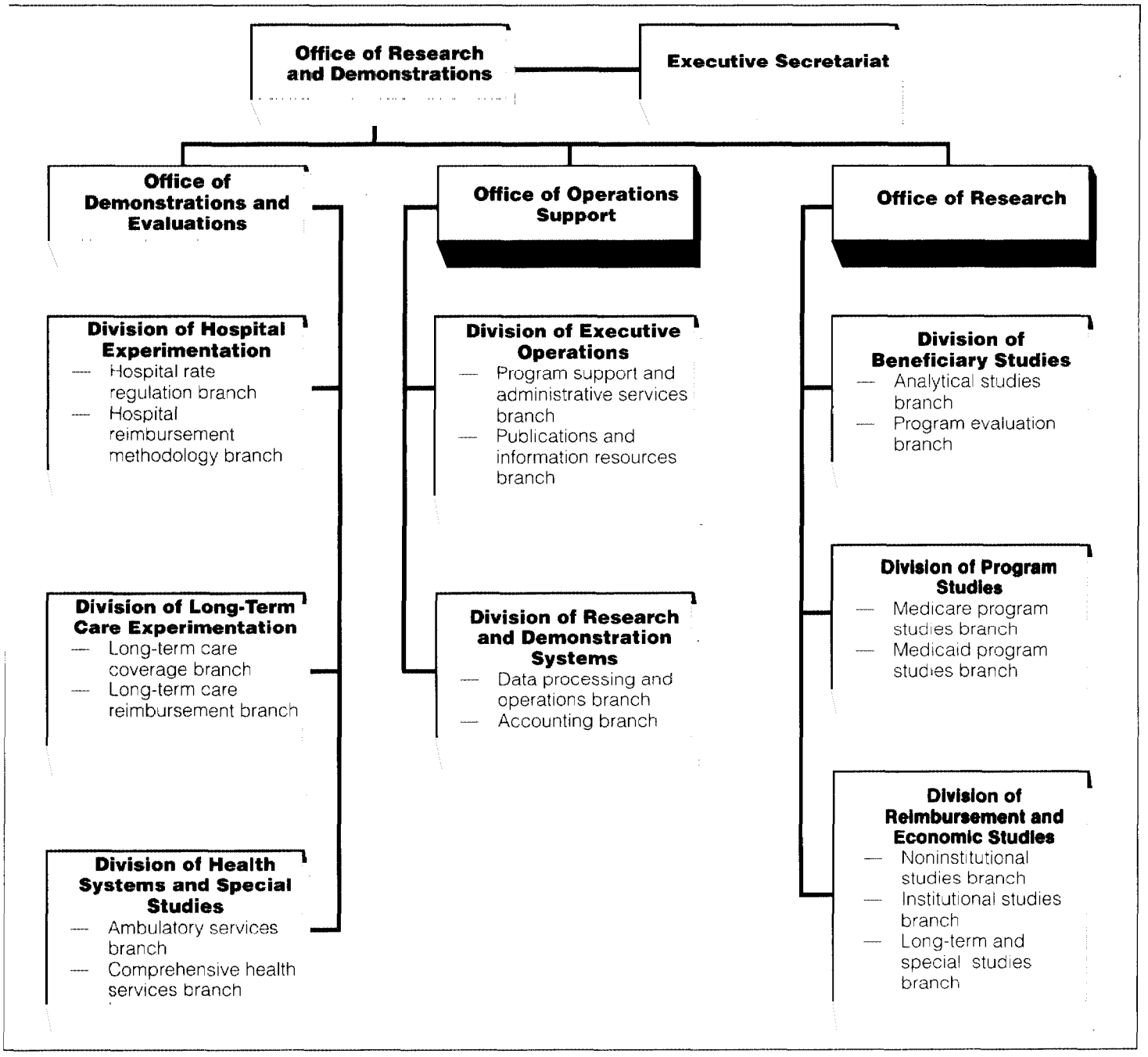
ORD Organization

As figure 1.1 shows, ORD is currently composed of three distinct units, two of which are directly responsible for intramural and extramural research and evaluation. They are

- the Office of Demonstrations and Evaluations, which includes three divisions and is responsible for developing, implementing, and evaluating demonstrations.
- the Office of Research, which also includes three divisions and is responsible for studying and assessing existing programs.

A third unit—the Office of Operations Support—has a number of management and administrative functions, including the development of the annual budget submission and the dissemination of ORD's publications.

Figure 1.1: The Organization of HCFA's Office of Research and Demonstrations



The ORD Research, Evaluation, and Demonstration Process

Each spring, ORD prepares a budget describing studies that are to be supported in the coming fiscal year and beyond, including ongoing projects and planned new starts. This plan is reviewed and approved by HCFA, HHS, and OMB. The process usually takes about nine months.[2] The approved plan forms the basis of the President's budget for ORD's extramural work, which is submitted to the Congress. (Adjustments in the planned research agenda occur for a variety of reasons, including response to congressional mandates.)

An annual announcement soliciting proposals for grants and cooperative agreements is then drafted and issued in the spring, with proposals due in late fall.[3] Review panels rate proposals on technical adequacy and other factors. The HCFA administrator makes the final decision on which projects to fund, based on the relevance of projects to policy information needs. This past year, the administrator was scheduled to decide on projects in the summer of 1987. Recipients would then be notified. The solicitation and award process, according to a HCFA document, takes about 15 months.[4] More specific solicitations, including requests for contracts, are also issued. ORD estimates that under ideal circumstances, special solicitations require 9 months from conception to award.

Execution of extramural studies is monitored by an ORD project officer through routine status reports, telephone calls, meetings at HCFA, and site visits. Draft reports for extramural projects are reviewed at ORD prior to acceptance by the project officer. Each final report is then archived at the National Technical Information Service.

Intramural studies within ORD may be the result of special analyses, reviews, or syntheses conducted by ORD staff or may be based on one or more extramural reports. A special instance of the latter is the mandated report to the Congress. Many congressional mandates in the health financing area have not only called for a research or evaluation study to be conducted by ORD, but have also specified that a report will be made to the Congress by the Secretary of HHS. In these cases, the secretary's report to the Congress is prepared by ORD staff as an intramural project. This report is typically based on one or more final reports

[2]For example, the plan for fiscal year 1989, which was drafted in the spring of 1987, was scheduled to be reviewed by December 1987.

[3]A cooperative agreement differs from a grant in that the federal government sponsor has greater control. See the subsequent section of this chapter on funding mechanisms.

[4]Thus, from the agency draft of the plan used in the budget to the project awards, about 24 months would have elapsed.

from ORD extramural studies that were conducted because of the mandate. Once a draft report to the Congress has been prepared at ORD, it is reviewed by HCFA and HHS officials as well as by OMB, then revised at ORD, and finally signed by the secretary and transmitted to the Congress.

ORD Budget, Staff, and Studies

As part of its legislative authority and work on congressional requests, ORD supports projects on a wide variety of health care issues. Its fiscal year 1987 budget for extramural research and evaluation was $28 million. In addition to those direct appropriated funds, ORD demonstrations incur program costs which have been estimated in the "waiver budget".[5] The combined funds spent on extramural research, demonstrations, and evaluations have amounted to no more than one-half of 1 percent of all program costs.

As of July 1987, there were 141 professional staff at ORD: 52 for the Office of Research, 41 for the Office of Demonstrations and Evaluations, 41 for the Office of Operations Support, and 7 for the Office of the Director and the Executive Secretariat. In fiscal year 1987, ORD supported 225 projects (demonstrations, evaluations, and research projects). Extramural projects accounted for in excess of three-quarters of ORD's work.

Funding Mechanisms

A majority of projects funded since 1982 have been grants or cooperative agreements; the rest have been contracts. As explained in HCFA's general announcement of its grants and cooperative agreements program, HCFA's involvement in grantee work is limited, whereas its involvement in work conducted under cooperative agreements is considerably more substantial.[6] Since 1984, cooperative agreements have become more numerous and important than grants, and they allow greater agency discretion.

[5]The "waiver budget" consists of estimated additional Medicare and Medicaid program expenditures resulting from demonstrations that provide exemption from various parts of the usual program rules.

[6]HCFA's role in projects funded by cooperative agreements includes, but is not limited to, "involvement in the selection of key personnel...[setting] stringent pre-award requirements limiting recipient discretion with respect to scope of work and services offered;...operational involvement during performance over and above the normal exercise of Federal stewardship responsibilities to ensure compliance with the regulations in 45 CFR Part 74" (from 50 Federal Register, No. 20, p. 4481, Wednesday, January 30, 1985).

Our Approach: Objectives, Scope, and Methodology

Objectives

The objectives of our study were (1) to assess the quality of congressionally mandated HCFA/ORD research and evaluation activities and changes in quality over time, and (2) to identify key factors, internal and external to HCFA/ORD, that influenced agency performance at all stages of the research management process, from planning through report review. Dissemination practices were also reviewed.

Scope

As agreed with the Subcommittee, we addressed its concerns about the quality of ORD research and evaluation by first assessing three major elements related to quality. They are

- relevance,
- timeliness, and
- technical adequacy.

We defined relevance in terms of a match between expressed policy information needs and corresponding projects at ORD. Consistent with the Subcommittee's request, we focused on information needs expressed or implied in congressional mandates. We defined timeliness as a correspondence between elapsed study time and either (1) the initially requested timeframe (for mandated studies), or (2) the timeframe planned by ORD.[7] Technical adequacy was defined as the appropriateness of the study's methodology and its execution relative to initial policy questions expressed or implied in mandates.

We examined these three major elements of quality—relevance, timeliness, and technical adequacy—for each of the following stages of the research management process

- planning,
- project execution, and
- report review.

[7]Another approach is to examine timeliness in terms of policy impact. Clearly, agency failure to produce a report in time for policy discussions represents a lost opportunity to use the research and evaluation results. We do not examine this indicator formally in this report.

The planning stage includes such ORD activities as selecting research or evaluation designs, coordinating related projects, and soliciting and awarding extramural work. Execution includes conducting the work and preparing a report draft for extramural projects; the primary ORD activity during execution is project monitoring. The report review stage includes agency review and the finalization of results to be reported publicly and to the Congress.

We also looked at dissemination—a necessary precondition for effective impact of project results. We examined dissemination in terms of the number and type of mechanisms for publication of ORD reports and the extent of public and congressional access to these published reports.

Within ORD, planning, execution, and the initial phases of report review are primarily the responsibility of the Office of Research and Office of Demonstrations and Evaluations staff. Responsibility for dissemination of reports is assigned to the Office of Operations Support.

With respect to the Subcommittee's interest in factors that potentially can affect each element of quality and ORD's research-management performance during each stage, we examined

- policies, staffing, and organization within ORD, and
- external factors that affect ORD's performance, including fiscal resources, nature and volume of mandates, and policies and practices within HCFA, HHS, and OMB.

Study Methods

We employed four methods to answer the Subcommittee's questions: (1) review of the literature, (2) standardized analyses of archival documents, (3) case studies of recently completed mandated projects, and (4) interviews with ORD managers and staff and with others in HCFA and OMB.

Review of the Literature

HCFA/ORD performance has been assessed five times since 1980. The results of these assessments, covering the period 1980-1986, were systematically reviewed and served as a rough benchmark for examining changes, over time, in the quality of ORD products as well as changes in ORD practices. These prior assessments are listed in our bibliography.

Analyses of Archival Material

Five archival data sources were employed in our review. First, we examined information from four recent volumes of ORD's Status Report series, thus covering virtually all studies initiated by the agency from 1982 through 1985. Content analysis of these documents allowed us to compare the topics of mandated and nonmandated studies, to trace trends in the volume of mandated studies, and to perform longitudinal analyses of timeliness and of project officer turnover. Second, we analyzed ORD's detailed budget plan for fiscal years 1987-1989, which provides an assessment of current and future plans. Third, HCFA's Executive Secretariat's tracking forms for review of reports to the Congress (from 1982 through July 1987) and other, similar ORD tracking forms provided additional data on timeliness and sources of delays. Fourth, ORD summary sheets on ratings received by all proposals and those that were approved (from 1982 to 1985) allowed us to address one aspect of the quality of ORD studies. Finally, to establish a context for HCFA/ORD practices, we reviewed the legislative histories, authorities, and responsibilities.

Case Studies

To gain a better understanding of how ORD plans, executes, and reports its studies, we conducted 10 retrospective case studies of recently completed ORD mandated projects. These studies, shown in table 1.1, were selected from a pool of 25 eligible projects listed in ORD's 1986 edition of the Status Report (see appendix I).

These 10 projects were chosen to ensure coverage of

- various types of studies, including surveys, literature reviews, and data development and analysis projects,
- extramural work as well as intramural preparation of reports to the Congress,
- projects of different sizes (large as well as small funding levels), and

Table 1.1: Ten Case Studies of Mandated HCFA/ORD Research and Evaluation Projects

Public law	Case study	Approach	Location	Funding for extramural projects[a]	Funding mechanism	Date of mandate
95-210	Urban Clinics—Evaluation of Demonstration	Evaluation of physician-directed clinics demonstration	Extramural	$827,000	Contract	12/77
97-248	Hospice—Evaluation of Demonstration	Evaluation of 26-site demonstration of home services	Extramural	$3,500,000	Grant	9/82
98-369	Social HMOs—Planning of Demonstration	Planning of demonstration integrating health and social services	Extramural	$1,553,000	Cooperative agreement	6/84
92-603	Fixed-Price Contracting—Evaluation[b]	Evaluation of experiment	Extramural	$204,000	Contract	10/72
97-414	Medicaid Home and Community Services—Evaluation	Evaluation of waiver program (prepare report)	Intramural	[c]	[d]	1/83
96-265	Medigap State Regulations—Synthesis	Synthesis of survey and other extramural work (prepare report)	Intramural	[c e]	[d]	6/80
98-21	PPS Impact—1984 Report	Synthesis of literature review, data analysis (prepare report)	Intramural	[c]	[d]	4/83
98-21	Physician DRGs—Data Development	Data development/ exploratory	Extramural	$164,000	Sole-source contract	4/83
98-21	DRGs and Nursing—Pilot Study	Pilot study/ exploratory	Extramural	$369,000	Cooperative agreement	4/83
98-21	Cost of Care Information—Literature Review	Literature review	Extramural	$30,000	Cooperative agreement (task order to policy center)	4/83

[a]Rounded to the nearest thousand.

[b]Technically, legislative language authorized HCFA/ORD to conduct the fixed-price contracting experiments; however, it was listed in the Status Report as a mandated study.

[c]Each of these intramural projects was devoted to preparation of a report to the Congress.

[d]Intramural projects assisted by extramural grants and contracts.

[e]This intramural work relied heavily on an extramural survey for which the contract was $1,259,000.

- different funding mechanisms (contracts, grants, and cooperative agreements).

Each of the 10 case studies included several modes of investigation. All relevant reports (and available drafts) were reviewed. Interviews were conducted with the project officer and often with other persons involved with the project (for example, the extramural staff or the project officer's supervisor). Twenty-five persons were interviewed for the 10 case studies. The technical adequacy of each final report was rated on the basis of reviews by GAO analysts who were not involved in the field work for this study and by outside consultants (see appendix II). The 5-point rating scale ranged from very high to very low quality.

The retrospective case studies provided data about agency performance with respect to relevance, timeliness, and technical adequacy at each stage of the research management process. (Appendix III presents further description of the 10 projects.) The case studies also provided some information on trends over time.

Interviews on General Practices

In addition to the focused interviews conducted for the case studies, we conducted general interviews with 40 persons in ORD, other HCFA and HHS agencies, and OMB about current (as of fiscal year 1987) agency practices.[8] Within ORD, 26 persons were interviewed about general ORD practices. These included the ORD director, the special assistant to the director, the three office directors (see figure 1.1 on p. 12), the six division directors and ten project officers and branch chiefs in the Office of Research and the Office of Demonstrations and Evaluations, as well as five key staff in the Office of Operations Support (for example, the chief of dissemination).

In addition, we interviewed 14 persons outside ORD. They included HCFA's associate administrator for program development, the director and staff of the Office of Legislation and Policy, and staff from HCFA's Office of Management and Budget and Executive Secretariat. External to HCFA, we interviewed management and staff of HHS's Assistant Secretary for Planning and Evaluation and OMB staff.

[8]Of the 40 persons interviewed about general practices at ORD and related agencies, only four had also been interviewed as part of the case study effort. Each of the interviews on general agency practices pertained to the universe of ORD's mandated and nonmandated studies; by contrast, each case study interview was focused on one of the mandated projects chosen for our 10 case studies.

These interviews, together with analyses of relevant documents, provided data on current practices at each stage of the research management process as these affected relevance, timeliness, and technical adequacy.

How These Methods Answered Study Questions

The logic of our design is one of convergent analysis. As table 1.2 shows, multiple data sources were used to assess each quality dimension—relevance, timeliness, and technical adequacy.

Comparison of the content of selected mandated reports and the original mandate was one source of information on the relevance of mandated ORD products. Additional information on agency performance and relevance was derived from the process-oriented data in our 10 case study projects and from descriptions of agency practices in our agency staff interviews.

Table 1.2: Our Assessment Methods

Dimension	Methods
Relevance of mandated studies	Case studies
	Interviews
Timeliness of mandated studies	Archival analyses
	Interviews
Technical adequacy of mandated studies	Case studies
	Quality reviews
	Archival analysis
	Interviews
Dissemination	Archival analysis
	Interviews

A primary source of descriptive data on timeliness of mandated work was our comparison of the study request, award, completion, and reporting dates taken from documents describing the universe of mandated studies. Additional archival information on the duration of all ORD extramural studies, especially anticipated and actual completion dates, and interviews with agency staff served as secondary information sources.

For technical adequacy, we called on four sources of information, including the 10 case studies and the technical reviews of final reports

stemming from nine of these mandated projects.[9] Other sources of data included agency staff interviews describing general practices associated with various forms of quality control, and archival analysis of grant proposal ratings.

For dissemination, we drew primarily on archival data and agency staff interviews, with some additional information being provided by our case studies.

To identify the factors plausibly affecting the relevance, timeliness, and technical adequacy of ORD's work, and changes in quality, we examined prior studies of HCFA/ORD and analyzed documents, data from our case studies, and data from the separately conducted agency interviews. We examined factors under HCFA/ORD's control as well as policies and practices of HHS and OMB that might enhance or impede ORD's research and evaluation process.

Limitations and Strengths of the Study

Despite the complementarity of the elements of our study, an important limitation must be kept in mind. Specifically, the research and evaluation process within the executive branch is quite complex. It is difficult to be sure we have assessed all the factors that may impede or facilitate ORD's work. Further, the complexity of the research and evaluation process prohibits identification of a single activity (or even cluster of activities) as the "cause" of problems with timeliness, relevance, or technical adequacy. Therefore, we present our analysis as identifying factors that are plausibly linked to the quality of ORD products.

Our study design does, however, have an important strength. The use of multiple methods strengthens many of our conclusions. When the data supporting an inference are drawn from a single source (for example, case studies), the weaknesses of that data source (for example, low generalizability) apply. We therefore used multiple data sources (see table 1.3), which build upon findings from each study component and limit the weaknesses inherent in any single source. Thus, the quality of HCFA/ORD congressionally mandated studies was examined from several different vantage points.

[9]One of our case studies did not produce a final report.

Table 1.3: Strengths and Weaknesses of Our Study Design

	Criterion		
Design component	**Generalization**	**Depth**	**Explanation**
Synthesis of prior studies	Moderate	Low	Moderate
Archival analysis	High	Low	Low
Case studies	Low	High	High
Interviews on general practices	Moderate	High	High

The work under study was either initiated or completed by ORD between 1980 and July 1987. Our data were collected during fiscal year 1987. At the request of the Subcommittee, we did not obtain comments on this report from HHS, the grantees, or contractors whose work we reviewed. Because such comments were not obtained, nonfederal organizations are not named in the report, and our technical adequacy ratings are not identified with specific ORD projects.

The Structure of This Report

Chapters 2–4 of this report discuss the relevance, timeliness, and technical adequacy, respectively, of congressionally mandated studies conducted by ORD. In each of these chapters, we first report on the current status of ORD work and assess how it has changed since 1980. In subsequent sections of each chapter, the quality dimension of interest—relevance, timeliness, or technical adequacy—is explored in greater depth across the three phases of the research and evaluation process; namely, planning, execution, and review. Chapter 5 provides a review of efforts to disseminate ORD products. In chapter 6, we identify factors affecting the relevance, timeliness, and technical adequacy of ORD mandated studies and provide our conclusions and recommendations.

Relevance of Mandated Studies

Throughout the 1980s, various Members of Congress have expressed concerns about HCFA/ORD's responsiveness to their information needs. In a number of instances, the Congress mandated particular studies to ensure that information would be available. When mandated studies were undertaken by ORD, all relevant information was not always contained in resulting reports to the Congress. Problems affecting relevance occurred during all three phases of the research and evaluation process; that is, during planning, execution, and report review. Specifically, we found that HCFA had problems in determining congressional intent. The specificity of congressional language mandating ORD studies has varied, and many mandates required considerable interpretation. ORD efforts to obtain further information on congressional intent also varied, and there was no clear pattern to show that such efforts were targeted to those instances where more guidance was deemed necessary.

Studies whose initial plans seemed likely to meet the congressional requester's needs were not always conducted in accordance with those plans. Some projects have undergone substantial changes in scope and methods during the execution of the research; for example, when a survey was cancelled. These changes affected relevance in some cases. Other projects' reports were substantially altered during report review. In one of our five case studies for which reports to the Congress had been finalized, reviews by individuals outside ORD resulted in the removal of information bearing on issues raised in the mandate. In other cases, reviews outside ORD correctly noted that aspects of the mandate had not been addressed; however, it was too late to do anything about the omissions. Of the four mandated projects for which ratings were possible across the three phases of the research process, only two maintained an acceptable level of relevance from beginning to end.

Relevance of Mandated Studies and Changes Since 1980

Congressional concerns about the relevance of HCFA/ORD studies focused on the availability of information to meet its policymaking needs. For two of three reports to the Congress that we examined in depth, information was not presented on key aspects of the mandates. Examining the results of our prior review of HCFA/ORD's performance suggests that these problems have been longstanding.

Congressional Concerns About Relevance

The lack of relevance of ORD work to at least some congressional information needs has been a recent source of concern. For example, at hearings held by the House Appropriations Committee in March 1985, one committee member asked then Administrator Carolyn Davis: "Is it not

true that virtually no studies will be funded by HCFA unless they focus on cost containment or are mandated by Congress?" In her response, Ms. Davis pointed to the administration's interest in studying quality of care.

Various other members of the House Appropriations Committee expressed a special interest in working toward increased services for victims of Alzheimer's disease. In particular, one member indicated that a "pressing issue [in the Alzheimer's area] is the enormous financial and emotional toll that the disease takes on the victims and their families" and went on to ask "What can we do to provide the special services and care that Alzheimer's victims require without having to force whole families below the income levels required to receive Medicaid?" The secretary of HHS responded that some Alzheimer's care was now covered by Medicare. She and the HCFA administrator also stated that future health services studies that focused on Alzheimer's or other specific categories of needy beneficiaries were not anticipated. In an apparent reaction to the administration position, the Congress subsequently mandated a demonstration project to examine Alzheimer's services. Similar actions were directed toward studies of two other needy beneficiary groups: the frail elderly and the chronically mentally ill.

Other recent mandates reflect concern about the effects of Medicare's inpatient hospital prospective payment system (PPS) and, in particular, about its diagnosis-related groups (DRGs), which are used to group patients for payment purposes. For example, in introducing a bill for mandated PPS studies that were later included in the Omnibus Budget Reconciliation Act of 1986, Senator John Heinz stated that HCFA had chosen to "deny any deep flaws in the DRG system." Similarly, in justifying the need for a mandated study, Senator David Durenberger stated: "Unless we see to it that adequate funding is available and the survey is begun on time, we run the risk of having to make major decisions on issues such as catastrophic coverage, long-term care financing, and Medicare vouchers, without having reliable data with which to analyze specific proposals and to determine their likely effects on Medicare beneficiaries."

Three Case Examples

To assess the relevance of information forwarded to the Congress in response to mandates, we examined three recent reports to the Congress, prepared in intramural ORD projects that were included in our case study sample. These were: Medicaid Home and Community Services,

Medigap State Regulations, and the 1984 PPS Impact Annual Report.[1] In each case, either the original mandate was reasonably specific or ORD had followed up to ascertain congressional intent. Thus, we were able to contrast the content of each report to the Congress with the corresponding mandate.

Using this approach, we identified specifically expressed congressional interests or requirements that were not responded to in two of the three reports. The Medigap State Regulations report provided no information on cancer insurance to cover gaps in Medicare coverage or insurance companies' loss ratios—two points that, taken together, represented a significant portion of the congressional interest in this area. The PPS Annual Report to the Congress contained no recommendations, although these had been requested specifically, and it also failed to examine the effect of computing DRG rates by census division. Thus, while all three reports were at least partly responsive to the mandates, two of the three neglected substantial portions of the congressional request.

Changes Since 1980

In 1980, the relevance of reports to the Congress prepared by HCFA/ORD was systematically reviewed by GAO. Judging from the content of this earlier review, the relevance of ORD's current work, as described above, has not changed very much. In particular, in our 1980 testimony and report, we noted that demonstration and evaluation activities had "fallen short of the expectations and requirements of the cognizant legislative committees of Congress as expressed in their reports on bills and/or the legislation itself." Additional problems that were cited, beyond those identified in our current review, include (1) mandated demonstrations that were not initiated due to shortages of staff and money, and (2) the completion of demonstrations and experiments after the Congress or its committees had already deliberated and acted on the issue involved.

[1] The case study sample (as shown in table 1.1 on p. 18) is composed of three intramural projects and seven extramural projects. These were selected from a pool of seven recently completed ORD intramural projects and 18 recently completed extramural projects. Each of the three intramural projects was devoted to preparing a report to the Congress based on reports from one or more extramural projects.

Relevance of Mandated Projects During Planning, Execution, and Report Review

We examined indicators of relevance for each of the three phases of the research process. Table 2.1 shows these indicators for project planning, execution, and report review.

Table 2.1: Relevance—Indicators of Agency Performance by Stage of the Research Management Process

Stage	Indicator	Data sources
Planning	Specificity of mandates and ORD efforts to learn congressional intent	Agency interviews, case studies
	Level of funding and use of special solicitations	Archival data, agency interviews
Execution	Changes during execution that increased or decreased relevance to initial request	Case studies, agency interviews
	Discussing changes with congressional requesters	Case studies
Report review	Changes in draft reports that increased or decreased relevance to the initial request	Case studies, agency interviews
	Discussing changes with requesters	Case studies, agency interviews

Planning

To assess ORD's planning of mandated studies, we examined (1) the specificity of congressional mandates and corresponding ORD efforts to clarify congressional intent, and (2) the awards process for mandated studies, including levels of funding for mandated projects and the use by ORD of various solicitation mechanisms to ensure that studies matched congressional intent.

The Specificity of Mandates and ORD's Efforts to Learn Congressional Intent

Many mandates could not serve as guides to research planning without considerable interpretation. Yet, the extent to which staff gathered additional information on congressional intent varied considerably.

Congressional Language

Turning first to the 10 case studies, the textual length of mandates for these projects ranged from one line to several paragraphs. (See appendix IV for the full texts or table 2.2 for a summary listing.) Guidelines for amounts of research funding or level of effort were not given in mandates for any of the new initiatives in our case study sample (8 of

the 10 projects). Two of the mandates provided moderately specific instructions for HHS to continue ongoing ORD work; these two required little or no new planning on the part of ORD. The eight others did involve new extramural work, and in all eight cases we rated these mandates as requiring clarification. In six of these eight studies, project officers indicated that considerable issue definition and conceptualization work by ORD staff was necessary to plan the study.

Table 2.2: Mandate Specificity and ORD Efforts to Learn Congressional Intent in 10 Case Studies

	Mandate			
Case Study	**Public Law**	**Lines[a]**	**Specificity**	**ORD effort**
Urban Clinics—Evaluation of Demonstration	95-210	46	Nonspecific	Little or none
Hospice—Evaluation of Demonstration[b]	97-248	14	Moderately specific	Not applicable
Social HMOs—Planning of Demonstration[b]	98-369	46	Moderately specific	Not applicable
Fixed-Price Contracting—Evaluation	92-603	7	Nonspecific	Little or none[c]
Medicaid Home and Community Services—Evaluation	97-414	4	Nonspecific	Considerable
Medigap State Regulations—Synthesis	96-265	27	Nonspecific	Considerable
PPS Impact—1984 Report	98-21	10	Nonspecific	Some
Physician DRGs—Data Development	98-21	17	Nonspecific	Some
DRGs and Nursing—Pilot Study	98-21	1	Nonspecific	Little or none
Cost of Care Information—Literature Review	98-21	3	Nonspecific	Considerable

[a]Number of lines as printed in U.S. Statutes at Large.

[b]Continued initiative originated by HCFA/ORD.

[c]ORD planning was limited due to imposition of a plan developed by a program division.

Agency planners often view mandates as imprecise. ORD leadership feels that in some respects this is as it should be: the specifics of research and evaluation projects are best developed in the agency, and greater specificity in mandates reduces flexibility of study design. We believe, however, that when mandates are not specific, consistent agency efforts are needed to determine congressional intent. Without communication, it is difficult to plan mandated projects that are relevant to the needs of the congressional requester.

Clarifying Congressional Intent

In three of the eight extramural projects with less-than-specific mandates, ORD staff expended a considerable degree of effort to obtain additional information on congressional intent (see table 2.2). In all three cases, ORD staff directly communicated with congressional staff about the specific projects being planned and reviewed relevant legislative documents. In one of the three cases, the project officer talked with congressional staff, read a related letter from Members of Congress,

reviewed hearings, and studied reports prepared by congressional agencies. In a second case, the project officer met with congressional staff, exchanged phone calls regarding scope and feasibility as well as timelines, and examined hearings and relevant work by congressional agencies. In the third case, the project officer and congressional staff "informally" communicated via telephone calls or through in-person meetings. The project officer also pursued a legislative history and documents analysis on his own.

In two other cases, in which new extramural work was needed to fulfill broadly worded mandates, we rated ORD as having made "some" efforts. In one case, the project officer's superior had met with congressional representatives on the general issue area (if not the specific study). In the second instance, the project officer had reviewed background materials related to legislative intent.

In the three remaining cases, the project officer obtained little or no guidance on congressional interests during the planning phase; that is, there was not only a lack of verbal communication (over the phone or in person), but there was also a failure to obtain or to study written congressional background material. In at least one case, it was questionable whether the project officer had read the mandate itself or was able to identify or describe it.

Communications with congressional staff are supposed to be directed through HCFA's Office of Legislation and Policy. That office maintained that they have only rarely received such requests from ORD. (In none of the mandated projects we studied did we discover that HCFA's Office of Legislation and Policy had arranged meetings between staff and congressional sponsors to facilitate project planning.) Where ORD-congressional communication to plan studies occurred in the past, it was generally initiated either by the congressional side calling HCFA or by ORD staff informally approaching congressional staff. In other words, while a formal ORD procedure for clarifying imprecise mandates with congressional requesters exists, it was not being utilized effectively.

Management-level communication has, however, increased recently. Specifically, in response to mandates issued under the Omnibus Budget Reconciliation Act of 1986, ORD has held at least four official meetings with congressional staff. The intent of these meetings, however, has not been to discuss detailed study plans, although brief (one page or less) plans were submitted. Rather, in two meetings, the director of ORD presented information showing the increase in mandates, explained the time

required to solicit proposals and award funds, and provided two-line descriptions of work that would proceed from the 1986 mandates. In two other meetings, ORD representatives sought to have a mandate deleted or to explain difficulties.

Award Process: Levels of Funding and Mechanisms

Our 1980 review of ORD stated that some mandates were underfunded. Our work in fiscal year 1987 did not directly address this issue by assessing the adequacy of funding for individual projects; however, we did examine the funds awarded to more recent extramural studies and found that the mandated studies had been funded at or above the level assigned to nonmandated studies. We also found that where extramural work was needed, there were instances in which ORD did not use special procurements for mandated studies and in some cases, there may have been problems in obtaining extramural work designed to address congressional concerns.

Level of Funding. A comparison between funding for mandated and nonmandated ORD studies, reported for all extramural studies listed in ORD's Status Report volumes, shows that mandated studies have generally been funded at dollar levels equal to or higher than nonmandated studies. Our interviews with ORD staff revealed that in ORD budget planning, they gave a high priority to all mandated studies. In line with this, our case studies revealed no apparent instance of inappropriately low levels of funding assigned during planning.

Procurement Mechanism. Some ORD staff noted that contracts were the best procurement mechanism for mandated studies because contracts are specific and binding. In 5 of the 10 cases, awards were made through contracts or grants that resulted from special solicitations. Four of these five studies were initiated prior to 1983. Since 1983, contracts and other specially designed solicitations have only rarely been used to make extramural awards for mandated studies. Among the alternative mechanisms used were task orders to two policy centers—one at a major university and the other, a well-known research organization—and proposals submitted in response to ORD's annual solicitation for grants and cooperative agreements. A primary motivation in the choice of these mechanisms was to ensure a "speedy" response to the mandate. This tactic has met with mixed success (see chapter 3).

In fiscal year 1987, ORD facilitated use of the current annual submissions to garner proposals relevant to congressional mandates, by holding a technical conference in November—one month prior to the due date for

proposal submission. The November 1986 conference was intended to update prospective proposers about new priorities based on mandates in the Omnibus Budget Reconciliation Act of 1986. Some ORD staff complained, however, about not having had sufficient time to study the mandates and prepare the presentation of priorities for this conference.

Turning to the case studies, we found two problems in soliciting mandated studies. In one case, a task order to a policy center was used, and the center's approach was not in line with ORD's interpretation of what the mandate called for. In the other case, a vague phrase in a legislative mandate (which had not been clarified with congressional staff) was used to justify funding an existing grant proposal as a mandated project. This project, completed more than a year ago, has not contributed substantially to any report to the Congress.

Execution

To assess whether relevance is eroded or enhanced during execution we examined (1) whether the changes, deliberate or unintended, affected projects' relevance to the request, and (2) the degree of ORD communication with congressional requesters about these changes.

Changes During Execution

We looked at deliberate changes in scope and methods (for example, changes in funding, additions or deletions of major strategies such as cancellation of a survey) and unintended changes (such as problems in achieving desired response rates or decisions by project staff to focus on selected areas). Unintended changes can sometimes be minimized by careful monitoring (for example, the project officer holds an orientation meeting, performs site visits, demands regular reports); thus, we also examined project monitoring.

Changes in study design frequently, perhaps inevitably, occurred during execution. Some were caused by the hard-to-predict problems that can arise in the execution of any study. Some were improvements to increase relevance. Some, however, had adverse effects on the study. For example, a current study was planned to include a national survey, a literature review, and a set of case studies, but the survey portion was cancelled during the execution phase because of OMB's disapproval. According to ORD staff, OMB maintained the survey was duplicative of existing work, but ORD staff strongly disagreed. The staff now will rely on case studies as well as related literature, but the study will suffer a loss of generalizability.

Our 10 case studies provided more explicit information on changes during project execution that affected relevance—changes that could be examined in the context of earlier planning efforts. In the two cases in which relatively specific mandates had merely continued ongoing projects, no major changes in focus, direction, or methods followed the issuance of the mandate. Funding, however, in both cases was substantially increased.

In five cases, planning had been guided by some knowledge of congressional intent (based on moderate to considerable ORD efforts to learn it, as described in the previous section). Changes during execution threatened relevance in three instances. Alternate plans were developed to try to compensate for the changes, and in two of the three, relevance was not seriously eroded. However, in the third case (Medigap State Regulations), substantial changes, both deliberate and unintended, clearly affected relevance. In a deliberate change, the number of sites was reduced, although "comprehensive" data had been of interest to the requester. An unintended change occurred because a major survey had problems with its response rates. To compensate, alternative data were sought, but this effort was not fully successful.[2] For this project, monitoring efforts were considerable.

Thus, of seven cases (two continuations plus five new extramurals) in which planning had not been marred by serious relevance problems, only one (Medigap State Regulations) involved substantial revisions to the scope of the study that decreased relevance during project execution. In this case, both deliberate changes and unintended problems and changes occurred.

For the three remaining case studies—in each of which new extramural work had been planned and implemented by ORD without benefit of additional information to clarify generally worded mandates—two of the three underwent substantial changes after the funding award. In one of the two (Urban Clinics), ORD had solicited a project that appeared consistent with the general type of study called for in the mandate and had selected a responsive contract proposal. Once in the field, however, the contractor found that this type of study would not be feasible and that considerable changes in study plans would be necessary. In the other case in which substantial changes proved necessary, the work was of doubtful relevance to the (nonspecific) mandate from the outset. In the absence of communication with congressional requesters, the changes

[2]The alternative data were deleted during the review of the report, as explained below.

neither could be said to have improved nor to have worsened the situation.

Communication With Congressional Requesters About Changes

In both the cases in which relevance was eroded during execution of the project (that is, Medigap State Regulations and Urban Clinics), persons responsible for the study made an effort to inform congressional requesters and to seek direction about the continuation of the project.

In one of those cases, the ORD project officer attempted to go through formal channels at HCFA to inform congressional requesters about the changes. Apparently, however, HCFA did not forward the information provided by the project officer. In the other case, the contractor told us that his firm pressed HCFA/ORD to inform congressional staff of the problems and obtain their opinion as to whether the study should be continued; however, such advice was not sought from congressional staff.

Report Review

To assess whether relevance established during planning and maintained through execution might be eroded during review of draft reports to the Congress, we examined changes made in draft reports and communication with congressional requesters about the report.

Changes in Draft Reports to the Congress and Communication With Requesters

The number and types of changes made between the time a draft report to the Congress left ORD and the time the final version of that report was issued by the secretary of HHS varied considerably. We defined changes affecting relevance as those regarding scope, methodology, and issues addressed. According to one ORD staffer, the real scope of a mandated report in effect is not officially approved until the review of the report to Congress.[3]

Our 10 case studies included 5 reports to the Congress that had been cleared and released as of May 1987.[4] In two of these five cases, we found that revisions affecting relevance occurred as a result of report

[3]Although HCFA, HHS, and OMB routinely review and approve ORD's budget proposal, which includes brief descriptions of proposed studies, these plans historically have not provided sufficient detail on each project to allow indepth consideration of the appropriateness of the methodology to the questions to be addressed.

[4]This includes three intramural projects devoted to preparation of reports to the Congress and two extramural projects that had been used in reports to the Congress. Although three additional reports to Congress related to other extramural projects in our case study sample, we could not include these because they were not released until September 1987, by which time our field work was completed.

review outside ORD. In one instance, a variety of substantial changes resulted when the report was reduced from 240 pages to 29 pages. At least two of the many revisions clearly affected relevance. Specifically, revisions eliminated background material on insurance company loss ratios and cut original data on the study's closest approximation to loss ratio data—economic benefits per premium dollar paid. As had been made clear in related hearings, loss ratios were of special concern to the congressional committee. Other material that was cut from the report had provided key background that was essential to preserve the logic of the analysis.

In another lengthy review of a report to the Congress, two chapters were deleted. These chapters, dealing with health care community response to PPS and providing a report of planned research, were certainly relevant to congressional interest.

In three other cases where reports to the Congress had been issued, changes made in review were not (in our judgment or that of the project officer) substantial enough to affect relevance.

Despite the changes affecting relevance that can occur during report review, HCFA rarely informed congressional staff of changes in the report that affected its relevance to the request or mandate. ORD staff told us they were not allowed to transmit advance drafts of reports to congressional requesters, although there have been leaks. The transmittal letter to the Congress indicated what portions of the mandate were addressed in the report and which were not.

Belated Assessment

For some reports, analysis of the mandate was more prominent in the final stages of report review than in the earlier planning for the study. At the time that HHS reviewed the report and the transmittal letter, there was a final attempt to study mandate language and to identify which requirements the report met and which it did not. In one case, during the fifth month of review outside ORD, the HHS Office of General Counsel noted that "we did not see anything in the transmittal letters or even in the summary material within the report itself, which clearly addresses the items specifically required by (section) 603(a)(2)(A)." The HHS General Counsel's memorandum shows evidence of having studied the congressional conference report. Similar comments were made by reviewers in HHS' Office of the Assistant Secretary for Management and Budget.

The problem here is that the most effective way to ensure relevance is through designing the study—at the planning stage—to produce the information that is needed. At the report review stage, the best that can be done is to determine whether the report is or is not relevant. If it is not, it may be too late to do anything about it.

Future Plans to Improve Relevance

A new policy is being developed by ORD, HCFA, and HHS, which will involve increased communication between congressional requests and ORD. The proposed new policy, described to us by ORD leadership and staff, is to more aggressively prioritize mandated studies instead of assuming that all mandates are equally important. According to the director of HCFA's Office of Legislation and Policy, the need for HCFA to prioritize mandated studies was initially expressed at the top levels of HHS, and for some mandates, small-scale studies might now be planned in the hope that modestly scoped projects might fulfill the requester needs in a timely fashion. Resource allocation appears to be an increasingly important issue at ORD.

ORD leadership told us that, in the future, they intend to have more detailed discussions and negotiations with requesters, not only to establish the relative priorities of various mandated ORD studies but also to clarify congressional intent. In addition, ORD leadership would like to be able to meet with congressional staff in advance of legislation, so they will have an opportunity to comment on legislative proposals for studies. Each meeting would involve the ORD leadership and representatives of HCFA's Office of Legislation and Policy and would involve coordination with HHS leadership as well as OMB and HCFA leadership. The new director of ORD emphasized that these discussions should include "the top" of these agencies.

Staff in HHS' Office of the Assistant Secretary for Planning and Evaluation also said that increased communication with congressional staff was planned. However, in our interview with the director of HCFA's Office of Legislation and Policy, it became clear that in some quarters within HHS and HCFA, the focus of increased communication was essentially to obtain congressional agreement for conducting reduced efforts or smaller studies in response to mandates ("scoping back").

In our opinion, a change such as that proposed by ORD leaders might help make mandated studies more relevant by increasing ORD knowledge of congressional intent and by helping ORD draw up plans for individual studies that are relevant to congressional information needs. In some

cases, this might include discussions of resources (staff, time, funding) and of "scaled down" research and evaluation alternatives. We recognize that small-scale projects may be sufficient for answering some congressional requests, but HCFA's contribution to such discussions should go beyond a goal of consistently negotiating the least ambitious projects regardless of other considerations. Second, continuing communication with congressional staffers and other safeguards of relevance would be needed to ensure that, after relevance is established in study plans, changes that erode relevance during execution or report review will be prevented or compensated for, or at a minimum, known in advance.

Relevance Across Three Stages of the Research and Evaluation Process

Table 2.3 summarizes data on problems in relevance from our 10 case studies. In two of eight projects, serious problems in achieving relevance occurred during the planning stage.[5] For these two projects, practices during execution were not able to overcome problems during the planning stage. For another project (PPS Impact), some problems in achieving relevance also dated from the planning stage. Further, the relevance of a fourth project (Medigap State Regulations) was compromised by unexpected problems that occurred during execution. Finally, actions taken during report review further degraded relevance of this project and negatively affected another. In those instances where ratings were possible across all three stages of the research process, only two of four projects initiated by congressional mandates maintained their relevance throughout planning, execution, and report review.

[5]Two other studies (Hospice Evaluation and Social HMOs) were not included in this summary discussion because they were initiated prior to the congressional mandate; that is, the mandate ensured their continuation.

Table 2.3: Problems in Establishing and Maintaining Relevance in 10 Case Studies[a]

Case study	Planning	Execution	Review of report to the Congress
Urban Clinics—Evaluation of Demonstration	–	–	b
Hospice—Evaluation of Demonstration	NA	NA	+
Social HMOs—Planning of Demonstration	NA	NA	c
Fixed-Price Contracting—Evaluation	d	+	c
Medicaid Home and Community Services—Evaluation	+	+	+
Medigap State Regulations—Synthesis	+	–	–
PPS Impact—1984 Report	+/–	+	+/–
Physician DRGs—Data Development	+	+	e
DRGs and Nursing—Pilot Study	–	–	b
Cost of Care Information—Literature Review	+	+	+

[a]A "+" designates that few problems were noted or that practices overcame problems in earlier phases. A "–" designates major problems in achieving or maintaining relevance. NA designates those studies mandated after the planning or execution phase. We assume that plans were judged to be acceptable when the mandate was issued, but these projects could not be included in our assessment of relevance for planning and execution.

[b]Report was "in review" at the time our field work was completed.

[c]No report to the Congress issued during our study period.

[d]ORD planning was limited due to imposition of a plan developed by a program division.

[e]Report was "in review" at the time of our field work; partial drafts and other materials available for review indicated major revisions by OMB, but the entire report was not available for an assessment of relevance.

Timeliness

Timeliness of congressionally mandated studies has been a persistent problem for the Office of Research and Demonstrations. The majority of mandates allowed 2 years or less for ORD to respond, whereas the majority of ORD projects required 3 years or more to complete. Closer inspection of timeliness revealed improvements since the early 1980s in the amount of time it took to plan and begin a study. However, delays in the execution phase continued. The greatest source of delay was during review of reports to the Congress.

Timeliness and Changes Since 1980

Timeliness of HCFA research and evaluations, especially mandated studies, has been of concern to congressional committees throughout the 1980s. In 1980, we testified and reported that HCFA did not implement mandated studies in a timely manner and did not meet congressional due dates for reports. In a review of PPS research conducted during 1984-1985, the Office of Technology Assessment pointed to ORD's lack of timeliness with respect to mandated studies regarding the prospective payment system. Echoing these concerns, our 1986 report on HCFA evaluations of PPS effects on post-hospital care notes that: "Although due to the Congress on December 31, 1984, the first PPS annual report was not released by HHS until November 12, 1985, and then only in response to a subpoena from the Senate Special Committee on Aging."[1]

The Congress has expressed considerable concern about the lack of timeliness with which mandated reports are issued. At the request of the Congress, ORD prepared a list of those initiatives mandated since 1980 for which reports to the Congress were due as of the autumn of 1986, indicating which reports had been issued and which were still overdue. Using a version of this list updated to spring 1987, we found only 2 of 28 mandated reports had been delivered on or before the congressional due date. Twenty reports were overdue—in many cases by more than 2 years—and six had been delivered late (9 months to more than 5 years late).

Of course, certain types of research may be more time-consuming than congressional timeframes anticipate. Examination of timeframes appearing in legislation issued between 1980 and 1986 for 55 mandated reports showed that in 49 instances, the Congress or its committees specified a due date for reports. In four cases, the Congress requested a report within 6 months of the enactment of the legislation; in 5 cases, 3

[1]U.S. General Accounting Office, Post-Hospital Care: Efforts to Evaluate Medicare Prospective Payment Effects Are Insufficient, GAO/PEMD-86-10 (Washington, D.C., June 2, 1986), p. 54.

or more years were allowed before a report was due. In 22 of 49 instances (45 percent), ORD was given more than 6 months to respond, but less than 2 years. The average elapsed time across all mandates was slightly less than 2 years.

In some cases, shorter timeframes were realistic; ORD was able to respond by combining a mandated study into an existing or scheduled report to the Congress. In other instances, a reporting period of 2 years was designated, but demonstrations had to be initiated or clinical trials had to be conducted to answer the questions posed in the mandate and these were not completed in time to meet the deadline. Further, as noted in chapter 1, the technical requirements of issuing a special solicitation consume about 9 months, nearly 40 percent of the time allocated in the average mandate. The question of whether congressional due dates are realistic is a complex one, given that many mandates do not detail the specific type of study that should be conducted to answer the questions posed.

Changes in ORD Timeliness

Recently, ORD increased the percentage of projects it completed within 3 years. ORD's project status reports show that in 1983, 50 percent of ORD projects nearing completion had taken more than 3 years; by 1985, 64 percent had been conducted in 3 years or less. Lengthier projects (that is, those taking more than 5 years) constituted 10 percent of the studies being completed.

Timeliness During Planning, Execution, and Report Review

Of the three stages of the research management process, timeliness in one—planning—seems to have improved since the early 1980s. Little or no improvement has occurred, however, in execution and report review. The specific indicators of timeliness are listed in table 3.1.

Table 3.1: Timeliness—Indicators of Agency Performance by Stage of the Research Management Process

Stage	Indicators	Data sources
Planning	Time elapsed between the mandate issue date and project start date	Archival data, case studies
Project execution	Extensions of projected end dates for extramural projects	Archival data
	Extramural projects not completed by end date	Archival data
Report review	Time elapsed between the start of draft report review and date the secretary signs the report to the Congress	Archival data

Planning

During the 1980s, the elapsed time between the date a mandate was issued and the date the project was funded — the planning phase—has shown improvements. Using HCFA's tracking system as well as the ORD project status reports to track mandates issued between 1980 and 1983, we found that in 1983 there was a shift toward quicker initiation of mandated projects. Specifically, for the 24 mandates issued from 1980 through 1982, the ORD planning interval was between 1 and 3 years (the median was 2.6 years). For one initiative mandated in 1982, no design had been selected by May 1987. In contrast, for the 19 initiatives mandated during 1983, the median interval was 1.3 years.

Our case study sample showed similar patterns for the seven case study projects that involved new starts and therefore allowed a comparison of the date the mandate was issued and the date an extramural project was funded. Specifically, for two studies mandated before 1980, there were extreme delays in planning and awarding extramural projects: 4 years elapsed in one case and 10 years in the other.[2] A third study, mandated in 1980, was begun 15 months after the mandate issue date. All four of the case study projects mandated in 1983 were funded between 4 and 14 months after the mandate issue date.

When extramural sources are used, delay in addressing congressional mandates is inherent because of the required start-up time to procure information from nongovernmental organizations. While intramural projects can be immediately started if agency staff are available, lack of data and staff workload have led HCFA/ORD to use extramural sources. Decisions on the use of funding mechanisms are made by HCFA/ORD management and staff. Generally, as noted earlier, a competitively bid contract takes 9 months or longer to plan, solicit, and award, and delays beyond 9 months are not uncommon. Because 9 months represents 40 percent of the average timeframe specified for mandated studies, shortcuts in soliciting extramural work represent one possible way for the agency to try to improve timeliness.

In recent years, HCFA/ORD management has adopted several strategies to shorten the length of time involved in procurement of research that addresses congressional mandates. These strategies include using sole-source contracts where appropriate—which usually takes about 3 months—or using task orders issued to the two policy centers (one

[2]A 1972 law authorized a fixed-price contracting "experiment" for claims processing, but industry legal action opposed implementation of such experiments for part A of Medicare. This accounted for at least part of the delay.

based at a major university and the other at a major research organization). Three of our case study projects used one of these strategies; in one case, a sole-source contract was used, and in two others, tasks were given to policy centers.

Proposals resulting from the general solicitation for grants and cooperative agreements were also used to answer congressional mandates. Specifically, in 1986, ORD modified its use of the solicitation cycle in order to obtain proposals related to the Omnibus Budget Reconciliation Act of 1986 mandates, issued in October 1986. HCFA/ORD's annual, general solicitation for grants and cooperative agreements had been issued the previous January, and proposals were expected in November 1986. However, to enhance the probability that some submissions could be used to fulfill mandates, ORD leadership delayed the due date by 1 month and held a "technical conference" to explain the new congressional priorities to prospective grantees. This allowed prospective grantees a chance to modify proposals in advance of submission, to fit the 1986 mandates. In reviewing proposals, ORD staff told us that priority was given to projects fulfilling mandates. The review panels met in February 1987, internal briefings and recommendations were made in the spring, and notification letters to awardees were to be mailed in the summer. In this way, a number of projects mandated by the 1986 act would begin within a year of the date of enactment.

Execution

Timeliness in the planning stage has been improving, but data on ORD projects in the execution stage showed persistent lags behind schedules. Typically, extramural projects either were extended beyond or were not completed by their originally scheduled end-date. Setting aside "new" projects, we found that as of the fall of 1985, two-thirds of ORD's 180 continuing extramural projects had their end-dates extended or were overdue or both.[3] The large majority of the extensions were for less than 2 years (even when multiple extensions were counted cumulatively), but lengthier delays occasionally occurred. Only one of our case study projects was delayed more than 2 years during execution.

Report Review

In recent years, delays have become most pronounced during the report review stage.[4] We used HCFA's tracking mechanisms to trace the histories

[3]New projects are defined as those that first appeared in the ORD Status Report for September 1985.

[4]Delays occurring in the report review stage may derive not only from lack of promptness of the part of reviewers or the extent of revisions required, but also from delays in preparation of revised drafts.

of two groups of ORD reports to the Congress: those that were in the process of review and revision during 1984 and those that were in the same process during 1986. During 1984, three ORD reports were in the process of review and revision; these three reports had entered the review system at the end of 1983 or during the spring of 1984 and were not signed until 1986. In 1986, there were a total of 11 ORD reports in the review system; these had been mandated between 1980 and 1984, with due dates ranging from January 1982 to December 1985. Seven of these reports had been mandated by the Social Security Amendments of 1983, with due dates during 1985. Although these seven projects had been started quickly, and six had entered the review process between February 1985 and January 1986 (with the seventh having entered later in 1986), by July 1987 only three of these seven reports had been signed by the secretary of HHS. As of July 1987, the four unsigned reports in this group had been in the review and revision process for 1-1/2 to 2-1/2 years. As for the remaining four reports in review during 1986, these were signed in 1986 or in 1987 after periods of review and revision lasting from 10 months to almost 2-1/2 years.

The data from our case study projects are consistent with this picture. Specifically, for the six case study projects where the timeliness of the process of review and revision can be assessed, only one report to the Congress (Cost of Care Information to Consumers) proceeded through review quickly. Four other reports to the Congress were issued after review and revision periods lasting 9 months, 11 months, 1-1/2 years, and more than 2 years. The sixth report, regarding physician payment, had not been issued as of June 1987 and had at that time been in the process of review and revision for more than 2 years.

Efforts to Improve Timeliness of Reports

Some sources of delay were unavoidable, because of changes in regulations. For example, a study mandated in 1980 on "swing beds" changed its research design because of the national implementation of the prospective payment system.[5] According to explanatory notes in the HCFA tracking mechanism, this study was also delayed because data required from new cost-reporting systems under PPS were not readily available.

Other delays were avoidable, and in the past 5 years, HHS has periodically been concerned about the timeliness of congressionally mandated reports. A recent manifestation of such concerns suggests that, while timeliness has been a particularly difficult problem for ORD reports, it is

[5]Swing beds refers to a practice of using hospital beds for skilled nursing care.

a departmentwide concern rather than one limited to ORD alone. On March 17, 1986, the Executive Secretariat of HHS issued a memorandum calling for the timely submission of statutorily mandated reports to the Congress. According to this memorandum, "over the past several years, performance in meeting statutory deadlines has been uneven. As of February 28, more than 70 HHS reports were 'overdue.'" Half of these were HCFA reports.

Other HHS memorandums indicate that during 1986-1987 the secretary took action either to sign reports or to notify the Congress of the status of the overdue reports. He signed 11 ORD reports between March 19, 1986 and July 17, 1987. However, many ORD reports were still overdue.

More recently, in August 1987, the HHS chief of staff informed HHS reviewers that their comments would not be considered if they did not meet preset due dates. He allowed 2 weeks for reviewers to make comments and directed those responsible for preparing reports (within HCFA and other HHS agencies) that revisions must be made within 2 weeks; an additional 2 weeks were allowed for issue resolution. The chief of staff also noted that OMB would be approached about developing a similar process to ensure timely review within that agency.

This action by the HHS chief of staff was based on HCFA proposals for developing a system for meeting future due dates. HCFA's proposed system emphasizes early agreement on review timeframes within HHS (and to the extent possible, within OMB) and setting levels of priorities and research designs that will be consistent with these timeframes. Some staff suggested, however, that because of the turnover of political appointees, agreements on the design of future reports might not hold with new political appointees.

Prior to this action by the chief of staff, two related changes were in process at HCFA: (1) the computerization of the current management system for congressional reports, and (2) the monitoring of reports so as to meet the congressionally mandated due dates. The new reports management system, operational as of June 1987, is intended to pinpoint the places in the review and revision process where delays occur.

As discussed in the previous chapter on relevance, ORD is also suggesting that communication to obtain guidance on congressional intent be a part of this system. However, some staff have questioned whether the technical quality of reports will be compromised by the emphasis on timeliness and prioritization.

Time Elapsed Across the Three Stages of the Research and Evaluation Process

As seen in table 3.2, the archival data showed a shift to quicker start-ups of mandated projects beginning in 1983, a continuation of about 2 years as the time to execute a project, and slightly increased time in report review. Viewing the case studies across the three stages of the research process, two projects were completed without major delays (Cost of Care Information and Medicaid Home and Community Services), three early projects were delayed in planning or excessively delayed in project execution (Urban Clinics, Social HMOs, Fixed-Price Contracting), and four other studies were recently delayed primarily by report review and revision. A major problem in timeliness at present seems to be in the report review and revision stage of the research and evaluation process.

Table 3.2: Median Elapsed Time, in Years, for Mandated Studies During Each Phase of the Research Process

Mandates issued	Number of studies	Number of years		
		Planning[a]	Execution[a]	Review[b]
Prior to 1983	24	2.6	2.1	1.3[c]
1983 or later	19	1.3	2.0	1.7[d]

[a]Data derived from the Status Report archive.

[b]Data derived from ORD's tracking system.

[c]Based on five studies that had entered the review process.

[d]Based on nine studies that were in the review process. Because some had not completed the review process, this value underestimates the median elapsed time.

Technical Adequacy

Of the nine reports for mandated ORD studies that we reviewed, we rated only four moderate or high on technical adequacy.[1] Our examination of agency practices to ensure technical adequacy revealed problems during planning, project execution, and report review. Similar problems had been identified in other reviews dating back to 1980.

With respect to planning, we found that ORD's overall research agendas had not been developed in accordance with explicit strategies for addressing key issue areas and that planning for interrelated individual projects had not been sufficiently coordinated. As a consequence, the data ORD has relied upon for policy analyses have, in some instances, been of poor quality. And in other instances, the data necessary for certain analyses were lacking. Without explicit strategic plans, there is little opportunity for prospective review—either within the agency or outside—of the set of research and evaluation approaches ORD had planned to address key policy areas.

We also found that efforts to plan individual ORD projects varied considerably. Notably, selection of extramural research projects was not always guided by procedures designed to identify—in terms of technical features—the best project proposals. That is, for a substantial number of awards, the HCFA administrator selected proposals for funding that received low technical ratings or even disapprovals from the ORD review panels. At least in part, these proposals were selected to ensure coverage of topics that the administrator deemed to be of high priority.

During the execution of studies, monitoring by ORD officials or advisory panels was not systematically conducted. In some cases, deviations from initial plans that had important consequences for later phases of the study were not detected early on.

Finally, report review both improved and limited the content and scope of reports, thereby altering their technical adequacy.

[1]For 1 of the 10 projects we selected for our case study sample, Social HMOs, the grantee did not submit a final report to ORD, but instead published a book. The congressional mandate associated with this study was issued while the grant was in process to ensure the continuation of the work.

Technical Adequacy and Changes Since 1980

Criticisms of the technical adequacy of HCFA's research and evaluation studies have plagued the agency throughout the 1980s, although these earlier reviews differ in focus and in the strength of their negative assessments. Our 1980 testimony and report pointed to weaknesses in HCFA project design. For example, rigorous evaluation methodologies had not been built into experiments. Moreover, we noted that the breadth of HCFA studies was often inadequate—a single experiment in one city did not allow for generalization. In its more favorable review, conducted in 1983, the Rand Corporation praised steps that had been taken to remedy design problems, but pointed to deficiencies in the HCFA/ORD solicitation and award process. More recently, we and the Office of Technology Assessment have raised questions about the technical adequacy of ORD's data and measurement procedures. Our current review not only shows that these problems remain but also identifies new ones.

To assess the technical adequacy of mandated studies, we examined nine recently completed reports in our case study sample. Four of these were reports to the Congress, and five were the final reports of mandated extramural projects sponsored by HCFA/ORD. Because the nine studies differed in their purpose and scope, we applied standards appropriate to each study. We rated overall technical adequacy and its component parts (that is, site selection, research design, measurement, analysis, and the full reporting of methods and procedures) for each final report.

Six of the studies estimated the effect of either a demonstration (for example, the Hospice Evaluation) or a policy change (for example, Prospective Payment System Impact). Two were exploratory studies. One entailed a literature review to examine the advisability of providing information on costs of care to beneficiaries.

With respect to overall technical adequacy, we rated four reports as moderate to high in providing answers to the questions that had originally been posed.[2] The reasons for low ratings differed across studies, but some general problems were evident. In particular, of the six studies of program or demonstration effects, all but one (on effects of the prospective payment system) employed purposive or unrepresentative site selection or sampling procedures that constrained the options regarding the research design, which in turn limited the interpretability of the

[2]See the discussion of case studies in the chapter 1 section on our Study Methods.

results.[3] For example, in one case, ORD deliberately selected the demonstration sites prior to the development of an evaluation plan, leaving selection of comparison groups to the evaluation contractor. This resulted in technical problems that hampered the evaluator's ability to determine the true effects of the demonstration.[4]

Similar selection problems occurred in three other studies. In two of these cases, the research design was so adversely affected by the site selection process that it was impossible to confidently answer the original questions about program impact. However, in two instances, the use of sophisticated data analysis procedures improved the overall technical adequacy of the study, despite the initial problems engendered by site selection procedures and resulting research design constraints. But in another instance, even strong analytical procedures could not overcome site selection and research design problems.

As to the adequacy with which results and methods were reported, five of the nine cases were rated high to very high. That is, despite technical flaws in other components, these five reports provided extensive discussion of the procedures used in the attempt to complete the study. This level of candor is admirable, not only because it helps the reader in understanding the validity of results (by giving additional details on how the study was conducted), but also because it helps direct attention to the places where improvements need to be made in future practices and procedures for designing and executing studies.

Technical Adequacy During Planning, Execution, and Report Review

Examining technical adequacy at each stage of the research management process, we found that problems have persisted in the first two stages (planning and execution) and have increased in the third (report review). The specific indicators of technical adequacy examined in this chapter are listed in table 4.1.

[3]In none of the 10 case study projects had the sites been specified in advance by the congressional mandate; however, some mandates called for continuation of work in which site selection was underway or was completed.

[4]We recognize that the use of high-quality designs (for example, randomized experiments) would be difficult in some instances. We distinguished those design problems that were difficult to avoid and those that were avoidable, giving low ratings of quality only for avoidable problems. If avoidable site selection problems constrained the research design, the design quality was rated low—unless compensatory actions were taken.

Table 4.1: Technical Adequacy—Indicators of Agency Performance by Stage of the Research Management Process

Stage	Indicator	Data sources
Planning	Development of strategic plans for issue areas	Interviews
	Presolicitation planning of individual projects	Case studies
	Conformity with review-panel recommendations in the awards process for cooperative agreements	Archives
Execution	Conformity with the original plan versus changes that improve or decrease technical adequacy	Case studies
	Systematic and consistent levels of monitoring	Interviews, case studies
	Review and assistance by consultants and technical advisory panels	Case studies
Report review	Systematic and consistent levels of effort to review extramural research reports	Interviews, case studies
	Impact of executive branch reviews on reports to the Congress	Case studies

Planning

To assess the technical adequacy of ORD's performance in planning research and evaluation, we examined three indicators: (1) the prospective development of explicit strategic plans for key issue areas, (2) the extent of problems in the presolicitation planning and design of individual projects, and (3) the extent to which the solicitation and awards process for grants and cooperative agreements resulted in the most technically adequate projects being selected.

Strategic Plans for Key Issue Areas

Planning a research agenda means specifying concrete research and evaluation activities for major issue areas based on policymakers' concerns and priorities. These early planning efforts require decisions on types of project designs and on sequencing and coordination of related projects. Planning of this type would ideally make explicit the intended linkages between different components of HCFA's research and evaluation program and the rationale for selecting specific strategies.

We found that historically and currently there has been an absence of prospectively developed formal strategies to address key issue areas. Also, ORD does not develop explicit plans that specify, in advance, the intended linkages between different projects and different components of HCFA's research program. Finally, we found no effective "substitute mechanisms," such as meetings of division management to discuss issue-area plans.

A 1984 HHS management review recommended that ORD develop explicit strategies for addressing major research goals. Specifically, HHS recommended that strategies should be developed for each key issue area to

identify the information needed and the hypotheses to be tested, specify the appropriate methodologies, explain why the selected method was preferred to the alternatives, and define a time schedule for accomplishing key tasks. By using such an approach, ORD could establish frameworks that contain explicit rationales for the mixture of existing and planned demonstrations, evaluations, and research activities. However, ORD had not implemented these recommendations during the period of our review. In the past, HCFA has designed explicit research strategies either belatedly (for example, PPS effects[5]) or not at all (for example, capitation[6]).

In the early 1980s, short-, medium-, and long-range goals were specified for substantive areas of research, providing a general umbrella or overview of related efforts. But shortly after this planning approach was initiated, it was dispensed with. Currently, ORD lacks formal or official plans for two policy research areas that receive special emphasis in the current ORD budget: quality of care and capitation.

There are a variety of possible substitutes for explicit strategic plans approved by management. For example, organizational structure could mirror issue areas so that all quality of care or all capitation demonstrations, evaluations, and research projects would be conducted by a specified group. At ORD, however, organizational structure is based primarily on methodological approach rather than topics or issue areas (ORD's Office of Demonstrations and Evaluations and its Office of Research sometimes conduct different types of studies in the same issue areas). In contrast, some other research agencies are organized by substantive topics to be examined. Another possible substitute for written plans would be formal meetings and verbal agreements about strategies, or even consistent informal networking across organizational units. However, there are few formal opportunities for communication across ORD units; and according to our interviews with ORD division directors, individual networking among staff with similar research interests or assignments has varied depending on the individual.

[5]We recognize, of course, that the rapid enactment of PPS put the agency in a catch-up situation. It became responsible for numerous mandated studies that had not been anticipated or budgeted for.

[6]Capitation refers to a method of prepaying health care providers monthly on a per-person basis, similar to the way HMOs are paid; the fixed per-person fee covers a specified set of services. Capitation is one type of payment system related to a competitive environment in which different health care providers compete with each other by offering different sets of services for various fixed fees.

Problems in Presolicitation Planning and the Design of Individual Projects

Our case studies of mandated projects showed variation in the extent of effort devoted to early planning. In 5 of the 10 case studies, ORD's planning was marked by senior staff involvement, communication across ORD units, extensive exchanges of internal memorandums, and/or consultation with outside experts. In some of our case studies (notably the mandated ORD studies of PPS), we found evidence of consultation with the Office of Technology Assessment and the Congressional Research Service. And in at least one case, ORD staff efforts were supplemented by the substantial involvement of staff from HHS' Office of the Assistant Secretary for Planning and Evaluation. But in at least four of our remaining five case studies, we found little, if any, evidence of such planning efforts.

Different types of projects in ORD were associated with unique sets of planning problems. Demonstrations and evaluations, for example, have presented intractable design problems. Our 1980 report and testimony criticized such projects for inadequate research design. Our more recent case studies reiterate this problem. Demonstrations planned or initiated in the early 1980s were not designed to facilitate subsequent evaluation activities or the production of scientifically rigorous results, but continuing efforts have been and are being made to improve the design of such projects.

According to our ratings of the final reports and the judgments of the researchers and ORD project officers responsible for the four case studies that involved demonstrations, there were problems in planning these projects, in designing evaluations, and in coordination across projects. Both of the evaluations of demonstrations included in our case study sample (Urban Clinics and Hospice) were impaired by design problems associated with the demonstration projects.

Specifically, the technical adequacy of the Hospice Evaluation design had been limited in advance because HCFA/ORD had awarded demonstrations to the "best" hospice providers in the nation, leaving "less competent," and therefore noncomparable, providers as the pool from which a control or comparison group might be selected. In this case, the use of sophisticated analytical techniques partially offset this initial problem. The design of the Urban Clinics evaluation had been severely limited by the haphazard way in which the demonstrations had been implemented.

In a third major demonstration, where planning was undertaken by the grantee who had initially proposed the idea, participation rates were too low to accomplish the original objective. In our judgment, this project

might have benefited from technical assistance. A fourth project was of limited generalizability because of poor site selection practices. The design proposed by ORD's Office of Research had included assessment of a broader group of initiatives in similar areas by government as well as other large payers, but was altered after disagreements within HCFA.

Research activities at ORD included literature reviews, surveys, and data development and analysis. Such projects comprised six of our case studies, and we rated technical adequacy low for four of the six.

Three of four studies that rated low in technical adequacy had also been identified in our interviews with ORD project officers or in other field work as having problems during planning. In one case, planning of a survey was plagued by difficulties in obtaining advance cooperation from industry. In a second case, ORD was unsuccessful in negotiating an acceptable plan from the extramural researchers, despite considerable in-house efforts by the project officer and the ORD officials to devise a report outline. In a third case, the project officer confirmed that the design was limited by the use of the existing low-quality data on Medicaid. This had been recognized at the outset of the project, but no alternate approach was developed.

Two research studies, however, received higher ratings. In one, expert consultants recommended by ORD had substantially improved the quality of the study design. The other experienced no planning problems.

The Solicitation and Award Process for Cooperative Agreements

ORD's funding mechanisms for supporting extramural research are cooperative agreements, grants, and contracts. Nearly half of the mandated extramural projects have been funded as cooperative agreements or grants. HCFA's choice of projects from among proposals for cooperative agreements and grants, however, has not always been guided by review panel ratings, although there may have been some recent improvement.

Specifically, proposals for awards made through cooperative agreements are reviewed by panels. ORD's review panels consist of an equal balance of government representatives and private-sector researchers. Panels are chaired by ORD staff members, who summarize panel reviews and recommendations and discuss them with ORD management and HCFA officials. The recommendations of the review panel are not necessarily followed by the HCFA administrator, who is authorized to exercise broad judgment in selecting work he deems important to policy concerns.

In the award cycles for 1982-1985, we found considerable evidence of HCFA's funding of proposals that had been disapproved by panels. For example, 21 grants were funded in 1983. Eight, or 38 percent, had been disapproved by panels. But 11 other proposals that had been approved by the panels were not approved by the HCFA administrator.[7] To some extent, these "reversals" reflect the importance of the relevance criterion to the HCFA administrator as opposed to the importance of technical adequacy to the review panels. In our case studies, one of the three projects that had been funded as cooperative agreements—a project of special interest to the HCFA administrator—was awarded in 1983 despite its being disapproved by the review panel. However, this project's design was revised and improved by careful ORD monitoring and the use of consultants throughout.

The practice of funding disapproved proposals seems to have subsided in recent years—1 of 29 in 1985. This change may be partly owing to the increased weight assigned to project relevance in the 1985 technical standards by which panels were asked to judge proposals.

Execution

To assess technical adequacy in the execution of projects, we examined three indicators: (1) deviations from the original research design that affected technical adequacy, (2) variation in levels of project monitoring and supervision, and (3) outside technical review and assistance.

Deviations From Original Research Designs

Five of our ten case study projects experienced technical problems in execution, owing in four of the five instances either to difficulties in obtaining quality data or to deficiencies in extramural staff skills. Specifically, two of the five projects deviated from their original design when high-quality data on a major area of study could not be gathered. In the case of the Medigap study, the major insurance industry survey had different response rates among industry categories and could not be relied upon exclusively, forcing staff to use another survey, reviews of the literature, and analysis of extant data. In another case, state-gathered Medicaid data were found to have problems of validity and consistency that had not been anticipated in the original design. In both cases, these problems were foreseeable during planning, but perhaps because

[7]There may have been sufficient explanations for these choices. However, we are not able to assess whether or not this was the case because written justifications were not routinely required for the record.

there were no easy solutions, the designs were not changed and the problems became obvious during project execution.

In two other cases, problems were linked to insufficient skills in staff of the contractor or grantee. In the first of these cases, the extramural research organization assigned the project to a doctoral candidate whose unsatisfactory performance caused HCFA to take over the project 8 months into the 12-month study. In another project, staff with no marketing expertise were allowed, without intensive monitoring from HCFA, to plan and implement a major demonstration of a new health services product. Additionally, in a smaller project, ORD monitors found the extramural staff to have insufficient analytic skills. A statistician was subsequently added to the project, averting what might have been substantial technical problems.

Consistency of Monitoring and Supervision

The Rand study conducted in 1983 saw the ORD staff as a key ingredient in successful implementation and monitoring of projects; it said the expertise of senior staff enhanced the technical adequacy of project execution. Similarly, the 1984 HHS management review found that technical adequacy was associated with sufficient oversight by project officers. In our interviews, we found that the monitoring of current and recent projects by ORD project officers and supervision by ORD management varied considerably from one project to the next and even over time for a particular project. Some projects received frequent in-person monitoring in the form of site visits by project officers or meetings at ORD or both, whereas other projects were much less closely monitored. In many cases, this variation seemed to be determined as much by the workload of ORD staff as by the needs of the project.

Similarly, variable patterns were seen for supervision by management. Division directors and branch chiefs were responsible for supervising project officer monitoring, but branch chiefs also had project officer responsibilities and, in some cases, served as senior analysts with limited supervisory roles. Division directors, too, had varied levels of involvement in staff supervision. Again, the variation did not seem to correspond directly to project needs.

In 2 of the 10 case studies, the monitoring was rather intensive, characterized by frequent meetings, including site visits, and by targeted monitoring. In one of these, the project officer participated in the pretest of a survey in addition to other frequent monitoring. In the other one, the project officer targeted her monitoring efforts; for example, she held a

daylong work session at a critical stage early in the analysis so that a subset of data could be examined as a guide to further analysis. One of these studies was overseen by a project officer with a light workload. The project officer for the other study told us that such detailed oversight would not be possible under the greater project burden she now bears.

In most other case study projects, however, monitoring appeared either to be light throughout the course of the project or to be affected by staff turnover or changes in project officers—although most of these were not small, simple projects. The majority of these projects received a low technical adequacy rating by our analysts and consultants. For example, a low rating was assigned in one of two cases, where a busy division director whose staff had a high workload had himself assumed direct responsibility for "overflow" projects. In another project, after management-level staff had been heavily involved in early planning, a new project officer was left largely alone to monitor the research staff at a nationally recognized organization. This project officer reported to us that supervisory help and intervention materialized only after repeatedly trying to alert management to a potential problem. This project received a low rating on technical adequacy principally owing to the fact that the design was faulty from the start and corrective actions were too late.

Review and Assistance by Consultants and Technical Advisory Panels During Execution

Although review by outside consultants during execution is not a routine practice at ORD, 2 of our 10 case study projects were subjected to intensive technical review by outside consultants, who were recruited either by ORD or by a foundation that cosponsored the project. In both cases, the technical consultants consisted of small groups of noted methodological and substantive experts from nationally recognized universities who repeatedly reviewed specific project plans as well as interim reports of findings and even made site visits. Judging from our technical adequacy ratings, the outside reviews appear to have had a positive influence on the overall quality of the work. This impression was confirmed by ORD staff.

In other cases, outside reviews either were less formal and less intensive or were limited to a single aspect of the project (actuarial issues in an insurance study). For these cases, the outside reviewers did not appreciably affect technical adequacy.

A technical advisory panel (TAP) is another type of review that is used to monitor projects. Panels were established for 4 of our 10 case studies. The panels varied in size, focus, composition, and frequency of meetings. Generally, the experts were chosen solely because of their knowledge or were selected, at least in part, because they represented relevant industries or associations (insurance companies, hospitals, physicians). A large formal panel reviewed, to varying degrees, the PPS projects in our case study sample. We did not find any clear instances in which high-quality project ratings were directly related to input from these panels.

Report Review

Report review is usually done by a knowledgeable reader who has not been deeply involved in the conduct of the study. Such a review represents a primary form of quality control and is intended to ensure that the report does not contain major technical errors. To assess the technical adequacy of report review at ORD, we examined (1) the consistency with which extramural reports were subjected to in-house ORD review, review by outside consultants, or both, and (2) changes in technical adequacy stemming from the review of reports to the Congress by executive branch agencies.

In-House and Consultant Review of Extramural Research and Evaluation Reports

We found no consistent pattern of substantive or methodological review of final extramural reports to ensure technical adequacy. Our interviews on general ORD practices indicated that extramural research reports are subjected to varying amounts of review by ORD staff and that final reports are not sent in all cases to division directors (although this is now required in three of six ORD divisions). Division directors who have assumed project officer responsibilities (because of staff workload and turnover) did not subject these projects' final reports to review by other ORD managers. The need for consultant review was determined on a case-by-case basis.

Eight of our ten case study projects either produced an extramural report or were based on a preceding report from an extramural study.[8] In two of these eight cases, the extramural draft reports had been reviewed by consultants to the extramural research organizations who

[8]Specifically, these eight projects included six extramural studies that produced a final report and two intramural studies in which reports to Congress were prepared based largely on preceding extramural work. The two remaining projects in our case study sample did not involve an extramural final report. The 1984 PPS Report was essentially an intramural study, with only one chapter based on work prepared outside ORD. The extramural Social HMOs project did not involve the usual final report to the agency; the grantee submitted a published book later as a "report."

had been involved in the projects throughout. A third project received substantive review by technical experts within the executive branch who also had been active in planning the project. Three additional reports received some external or in-house ORD review by persons technically knowledgeable in the area. Less effort on the part of ORD staff to ensure a technically adequate report was evident in two remaining cases, however, and we received no assurance from the project officers that a thorough consultant review had been obtained by the contractors or grantees before submitting the draft to ORD.

Review of Reports to the Congress

Mandated reports to the Congress written by ORD staff are sometimes based largely on a single extramural research report, and at other times represent a synthesis of multiple studies. Currently, external peer review of reports to the Congress is the exception rather than the rule, apparently because of concern about potential "leaks" before the report is officially issued. Seven of our case studies involved reports to the Congress, but only two were reviewed by technical experts—and in only one of the two was the expert located outside the government.[9] In our interviews, however, we learned that some ORD staff believe there is a need for expert review and have unofficially obtained outside expert review of at least portions of drafts.

Our interviews with ORD authors revealed that internal review of reports to the Congress—within ORD—for technical and methodological soundness did not always occur. Reports to the Congress receive considerable executive branch review outside ORD, but according to ORD authors, these reviews have generally stressed conformity to administration policy rather than technical adequacy; substantial changes have sometimes been involved. Although some executive branch reviewers outside ORD are concerned with quality, they are not necessarily experts in the particular subject matter or methodological approach of a particular report.

An ORD office director cited an instance in which he believed that a policy-motivated request for reanalysis of data resulted in an improved, more refined analysis and more accurate conclusions. But ORD's staff thought there were other instances in which the review process lowered the technical quality of the report by excising descriptions of study

[9]In a third case, a draft report to the Congress was reviewed by sectors of the industry the report dealt with, but such exposure does not constitute the kind of independent, external review that is directed at achieving technical adequacy.

design or of analytical findings, or both. We found instances to support these complaints in two of the seven case studies that involved reports to the Congress. (See the description of OMB and HHS reviews in chapter 6.)

Staff in HHS' Office of the Assistant Secretary for Planning and Evaluation told us they attempt to review reports simultaneously for consistency with HHS policy and for methodological soundness. However, there are no explicit guidelines for methodological review (such as inclusion of a description of study methods), and there has been variation in terms of staff availability, expertise in subject matter, and prior involvement in the project. Further, staff must attempt to balance technical and policy concerns.

Technical Adequacy Across the Three Phases of the Research Process

Overall, our interviews indicated limited planning efforts, variable levels of monitoring during project execution, and insufficient review of at least some reports from a technical viewpoint. Seven of our 10 case study projects were marked by technical problems in the planning stage. In two of these seven, technical assistance raised the quality of the study considerably, but in other instances the problems were not solved, and additional problems arose in project execution or report review. An eighth project, for which planning and execution appeared to proceed smoothly, was marred by an inadequate report—a problem that may have been associated with the absence of a thorough review.

Dissemination

In assessing the dissemination of ORD research products, we found that official avenues for dissemination have become more limited in recent years. Not only were there fewer HCFA-based outlets in 1987 than there were in 1980, but access to reports was limited or delayed in a number of ways. With respect to congressionally mandated studies, a "6-month rule" prohibited contractors and those awarded cooperative agreements from disseminating a final report until 6 months after the report was officially accepted by ORD. In addition, reports issued through the National Technical Information Service (NTIS)—ORD's primary dissemination mechanism—were sometimes difficult to obtain, because of problems in identifying specific ORD project reports in the NTIS system. Because of the limitations of the formal mechanisms through which HCFA/ORD disseminates its work, informal or less formal modes of dissemination, such as presentations by ORD staff at professional meetings and distribution of reports by grantees and contractors, assumed greater importance. Communication with congressional users was limited.

Publications

Comprehensive coverage of ORD research projects was attempted by providing very brief updates of project status in the Status Reports and by including brief summaries of results of completed projects in the Health Care Financing Review. The much more indepth coverage of selected project results formerly provided by the HCFA Grants and Contracts Report series will be discontinued in fiscal year 1988, along with other dissemination outlets. ORD's extramural reports were maintained in the NTIS archive, while mandated reports to the Congress were distributed to a limited number of congressional users.

Official ORD Publications

Since the 1980 GAO report and testimony and the Rand study that was conducted in 1983, the repertoire of official publication mechanisms for dissemination of ORD research results, for both mandated and nonmandated work, has dwindled to the point that only a few such mechanisms remained. Chief among those remaining are the Health Care Financing Review and the ORD Status Report. Publication series, listed below, that had been established in 1979 were later modified to publicize rather than provide free copies and will be eliminated in 1988. These include the HCFA Grants and Contracts Report series (that is, selected final reports printed by the U.S. Government Printing Office), a

magazine entitled FORUM, Research Briefs, HCFA Trends, and HCFA Notes.[1]

In 1988, the remaining official mechanisms for publication of ORD research will be the annual Status Report and the quarterly Health Care Financing Review. The Status Report series, containing abstracts of ORD projects, was initiated in 1983. This publication, which briefly updates the status of each ORD project, resulted from a letter to the secretary of HHS from the Senate Committee on Finance, which pointed to inadequacies in dissemination of ORD project results to the Congress.[2] According to the director of ORD's Office of Operations Support, a new policy was implemented during our review; the quarterly Health Care Financing Review will now provide synopses of all final reports, in order to compensate for the elimination of the HCFA Grants and Contracts Report series.

The fiscal year 1987 publications budget covering ORD research and other HCFA publications (such as the Medicare and Medicaid Data Book) is $138,000.

Extramural Research and Evaluation Reports

Final reports from ORD's extramural studies (including mandated and nonmandated projects) were disseminated in two ways: the National Technical Information Service stored reports on microfiche, and occasionally, the Government Printing Office printed the product (1,000 or more copies). NTIS usually distributed paper copies from microfiche, which as a rule, were less legible than printed reports. The Government Printing Office selectively published ORD documents according to their marketing potential. In the past, relatively few extramural ORD reports were published by the Government Printing Office, typically through the now-defunct HCFA Grants and Contracts Report series. Thus, archiving at NTIS will become the predominant mechanism for disseminating the final reports of ORD's extramural research projects.

Project officers have been expected to routinely submit reports through the director of ORD for filing at NTIS, but there has been no check to ensure that reports were submitted. For several of our completed case

[1]In addition, a working paper series was intended primarily for internal distribution and required no review above the branch chief to make available 200-300 copies for interim reports. This series was changed in 1987, and the requirements now include periodic departmental and OMB review of the rationale for the series.

[2]The Medicare annual report to the Congress includes an overview of ORD work, but does not provide enough detail for the reader to assess individual study results, objectives, methods, or timelines.

studies, no NTIS report appears in its online listings.[3] New ORD procedures, instituted during our review, are intended to ensure that project officers will submit reports to NTIS in a timely manner, but there are no plans for periodic checks on whether all recently completed reports have actually been archived at NTIS.

Relying on NTIS as a major dissemination mechanism may not be completely satisfactory. Specifically, in assessing usage of the NTIS system, we examined a recent NTIS quarterly update of current demand for documents in the NTIS system. We found that of 21 ORD reports that had been sent to NTIS during the first half of 1986 and that were listed in the NTIS update, 13 received no requests in the fourth quarter. The other eight reports were requested by only one or two persons during that quarter.[4] Although this low level of demand could reflect lack of interest in some ORD reports, it could also indicate a lack of knowledge about the existence of the reports, a lack of awareness of NTIS as a resource, or a problem of access to the NTIS system—or all three. According to a long-term staffer at HCFA's Office of Legislation and Policy, few congressional staff are aware of the NTIS archive. Problems of access to reports stored at NTIS are discussed in a subsequent section of this chapter.

Reports to the Congress

Currently, after reports to the Congress are signed by the secretary of HHS, two copies are transmitted by the HHS Office of the Secretary to the Congress; one copy to the Speaker of the House and one to the President of the Senate. Additional distribution of reports prepared at ORD is achieved through selected distribution to congressional committees by the Office of Legislation and Policy as well as by the ORD project officer responsible for the report. However, in our interviews, many ORD staff often could not identify specific congressional users, and some expressed curiosity about congressional reaction to their work. Except for congressional hearings or specific requests by congressional committees or by Members of Congress, no channels were in place to provide

[3]In our case studies, we were told of an instance in which HCFA prohibited ORD from forwarding a sensitive extramural research report (on Medigap State Regulations) to NTIS, even though the corresponding report to the Congress had been signed by the secretary of HHS and sent to the Congress. ORD was, however, allowed to fund the contractor's distribution of its research report to state offices and to key congressional committees.

[4]This low demand does not appear to be unique to the December 31, 1986 quarter, based on checks of other quarterly updates. However, it should be noted that for a substantial number of reports, NTIS does perform a one-time "automatic" distribution of microfiche copies to advance subscribers in specific categories of reports. For the 21 ORD reports mentioned above, 15 were automatically distributed (45 to 55 microfiche copies of each were sent to subscribers); 6 apparently did not fall into subscriber categories and no automatic distribution was noted.

HCFA or ORD regular opportunities to brief committees and clarify or provide more information on the contents of its reports.

Professional Publications

Two dissemination avenues that have continued since the Rand study was conducted in 1983 are publication in professional journals and presentations at professional conferences. ORD project officers and others remain active in these more personal forms of disseminating the agency's research results.

Access

We found that access to the ORD publications and archived reports has been limited in a number of ways. These include (1) a "6-month rule" delaying access to extramural final reports, (2) failure to provide congressional staff with copies of extramural reports from mandated projects, (3) difficulties that can be experienced in accessing ORD reports archived at NTIS, (4) the lack of an ORD library, and (5) the lack of a format designed to enhance accessibility of reports to Congress.

"Six-Month Rule"

Extramural research and evaluation reports related to congressional mandates were subjected to greater dissemination constraints than were reports of nonmandated studies. Until recently, a "6-month rule" has been applied to contracts and cooperative agreements that involved mandated studies; this rule prohibited researchers from any dissemination of their final reports for 6 months following official receipt by ORD. During 1987, the requirement was decreased from 6 to 4 months. According to our interviews with ORD staff, the objective of this rule is to prevent research results from reaching the Congress in advance of the secretary's signed report. An ORD manager explained that while this may be true, the delay also allows for further technical assessment of the contractor's report and for HHS recommendations to be formulated in advance of releasing the contractor's report.

In some cases, agency acceptance of final reports of mandated extramural projects has been delayed beyond active review and revision of the extramural report, thus delaying the start of the prescribed waiting period. For example, the extramural report of one of our case study projects (Hospice Evaluation) was not officially received or accepted by the agency for a year after all revisions of the final draft had been completed by the grantee.

Providing Congressional Staff With Final Reports of Mandated Extramural Studies

Many reports to the Congress prepared at ORD are based on extramural studies initiated because of congressional mandates. Yet in most cases, there was little effort on the part of HCFA or ORD to provide committee staff with copies of the extramural research and evaluation reports that ORD had received from its grantees and contractors and had used in preparing the reports to the Congress. Apparently, the reports to the Congress prepared at ORD were viewed as sufficiently informative in most cases, or it have might been assumed that congressional staff themselves would obtain related research and evaluation reports from NTIS if they were interested.

Difficulties Accessing the NTIS System

Although ORD currently submits the results of most extramural work to the National Technical Information Service, it was sometimes difficult to track reports of ORD projects when these became available at NTIS. This is because final reports often had different titles than the projects on which they were based, and NTIS does not maintain a readily available cross-reference list linking HCFA/ORD project numbers or titles to NTIS report numbers.

Access to reports archived at NTIS may improve, however, in the near future. The ORD Status Report has occasionally included an NTIS accession number for recently completed projects. During our review, ORD initiated a new policy, which should take full effect in the 1988 edition of the Status Report, requiring all listings for recently completed projects to include the accession number.

Lack of an ORD Library

No central ORD library and listing of reports provides agency staff, grantees, or contractors with easy access to the results of past ORD work. Such access could help staff improve the technical adequacy of new project initiatives. However, according to ORD managers, final reports of extramural work as well as reports to the Congress are not centrally located because space limitations preclude the development of such a library. Reports are currently kept "on people's bookshelves." There is no computerized list of ORD reports, and we could only find one example of an effort to centralize past research findings for the benefit of ORD staff and sponsored researchers; that is, one ORD branch chief has designed a system which reports work done related to physician payment issues.

Format of Reports to the Congress

The current format of some reports to the Congress may make it difficult for congressional readers to use them. Some reports were hundreds of pages in length. We were told by the head of ORD's publications unit that, in the past, no customary ORD formats or reporting standards guided preparation of reports to the Congress. Some general guidelines were put forward near the end of our review, but these had not been implemented for a sufficient time to allow an assessment. Some ORD division directors felt that ORD reports would be improved and made more accessible to the reader if they more closely resembled those issued by other organizations conducting research in the health care policy area.

Delays in Official Dissemination and Alternative Routes

Although the major difficulty with dissemination was the length of time it took for congressionally mandated reports to be issued by HHS (discussed in chapter 3), we also found delays in releasing or disseminating reports from related extramural projects. In one of our case study projects, a grantee's report (Hospice Evaluation) was not sent to NTIS for 15 months after it was completed because the review process for the related report to the Congress was so lengthy.

Because ORD had so few remaining dissemination mechanisms and because reports to the Congress were frequently tardy owing to delays in preparation, review, and revision, it was not surprising that grantees and contractors would assume a role in dissemination. Primarily, contractors and grantees have done this informally, but on occasion, it has been by formal agreement with ORD. Specifically, in 5 of our 10 case studies, grantees and contractors were the major sources for information provided to Members of Congress and committee staff during the years between the mandated due date and the date on which the secretary delivered the official report. In two of these cases (the Hospice Evaluation and DRGs and Nursing studies), grantees published in professional journals. A third grantee published a book, describing the Social HMOs demonstration, which was not part of a planned report to the Congress.

In the fourth case, when HCFA prevented the Medigap State Regulations extramural report from being sent to NTIS, ORD supplied the contractor with address lists and funds to distribute the report to state regulatory offices and some congressional committees, and thus provided information independently of the delayed report to the Congress. In the fifth case, the Physician DRGs study was part of a larger ORD report to Congress on physician payment, which was in its third year of review in

May 1987.[5] The contractor, however, as part of another project had independently provided a congressional commission with knowledge and experience gained under the ORD contract.

Communication With Congressional Users

Communication with the user as part of the dissemination process can be used to check on the relevance and technical adequacy of reports. Congressional users' reactions to the appropriateness of a project in relation to the original question posed and to its design, cost, and timeliness could be an important guide to those who set ORD policy. We did not find any formal agency mechanisms to check customer satisfaction, although there were examples of informal communication. ORD managers and staff described their approach as a more passive one of waiting for reactions.

[5]This report to the Congress was issued in August 1987.

Factors Associated With Quality and Agency Capacity, Conclusions and Recommendations

Problems of quality in ORD research and evaluation have been the product of agency practice, external factors, and contextual constraints. Many of the specific quality problems at ORD that we identified in the foregoing chapters were clearly problems of agency practice in planning, execution, and report review. Logically, direct attempts to improve agency practices through more effective research management at ORD should have an effect on the quality of ORD work. However, various external and contextual factors that emerged during the course of our review appear to have limited—directly or indirectly—ORD's capacity to conduct high-quality research and evaluation studies. For example, some of ORD's quality problems derived, at least in part, from reviews and clearances required by HCFA, HHS, and OMB. Some agency practices and quality problems were also plausibly linked to larger, contextual factors, including changes in the numbers of congressionally mandated studies, changes in funding appropriated for extramural projects, increased workloads for some ORD staff, and turnover in HCFA and ORD leadership.

In examining the factors that affect the relevance, timeliness, and technical adequacy of ORD responses to congressional mandates, we drew on our findings from the preceding chapters as well as additional analyses of the 10 case studies, interviews with officials outside ORD, archival sources, and prior assessments of HCFA/ORD products and practices.

Internal Factors

Numerous problems of agency practice were identified earlier in this report with respect to relevance, timeliness, and technical adequacy.

In achieving ORD work that is relevant to congressional mandates, a major deficiency (described in chapter 2) was variation in ORD efforts to understand congressional intent, together with limited continuing communication with requesters through project execution and report review. ORD communication with congressional requesters was informal and was not determined by how generally the mandates were worded, so that nonspecific mandates were not always clarified. Further, during the execution of mandated studies and the review of reports to the Congress, the scope and methods of the projects sometimes changed, but communication with requesters was limited at best. In our judgment, continuing communication with congressional requesters is needed, first, to ensure that relevance is established during the planning stage, and second, that changes that erode relevance during execution or report review will be avoided, compensated for, or at a minimum, made known to requesters in advance.

Additional problems in ensuring relevance included lack of special procurements for congressionally mandated studies and possible concomitant difficulties in obtaining relevant extramural work. To some extent, these difficulties were associated with procurement "shortcuts" that ORD staff used in order to improve timeliness of mandated studies.

With respect to timeliness, we found that some improvements have been made at ORD, but that some delays, such as the 9-month start-up time needed to contract out extramural work, are inherently difficult to avoid without using shortcuts that may risk compromising relevance or technical adequacy (see chapter 3).

Despite some improvement in the time taken to initiate extramural projects, there were persistent lags behind the completion dates scheduled by ORD. Other delays that can be avoided or shortened were associated with the ORD report revisions made as part of the review and revision process involving reviewers in agencies outside ORD.

With respect to the technical adequacy of ORD research and evaluation, we found that there were no formally approved strategic plans for key issue areas (thus discouraging technical reviews of such plans) and that there was no consistent planning process for coordinating studies. Notably, in the mandated studies we reviewed in detail, site selection oftentimes had not been designed to allow effective evaluation. In addition, the proposals that were technically the best were not always selected by the HCFA administrator for cooperative agreement awards.

Monitoring of ORD's extramural projects during execution was uneven, as was supervision and review of report drafts for technical adequacy. In some cases, intensive monitoring, consultant help, or both appeared to have a definite beneficial effect on the technical quality of poorly planned or troubled studies. Conversely, some of the projects that we rated low on technical adequacy had experienced a low level of monitoring, supervision, or technical review at ORD. In our judgment, some of these projects might also have benefited from more intensive attention by ORD staff or expert consultants.

Many of these specific problems seem to point directly to the importance of more effective research management at ORD. Certainly, the lack of consistency we observed in ORD's communication with congressional requesters, in its project monitoring, and in its technical review of reports would all appear to be problems that could be ameliorated, to

some extent, by more effective management procedures within HCFA/ORD.

External Factors

External factors—those that are at least partly outside the control of ORD managers—have affected the agency's capacity to perform high-quality work at specific stages of the research and evaluation process. Two specific external factors we identified as directly or indirectly affecting the quality of mandated studies were (1) an ORD agenda-setting and solicitation process that is directed toward administration priorities and OMB approval, and (2) a process of review by HCFA, HHS, and OMB, and consequent revisions of studies and reports by ORD.

ORD's agenda-setting and solicitation process was not designed to incorporate congressional interests, and as a result, the overall plan and solicitation notice have been "retrofitted" to accommodate mandated studies. This process makes it more difficult for the agency to obtain relevant and technically adequate work in congressional interest areas. In addition, agencies outside ORD have had effects on the execution and report review stages of the research and evaluation process. The lengthy review and revision process for reports to the Congress created serious delays in many cases and also lessened relevance and technical adequacy in some cases.

Limited Planning for Mandates

Mandated studies have often focused on different issues than those emphasized by OMB or the administration. In recent years, the ORD planning process became more narrowly focused on administration issues and was increasingly responsive to OMB's policy research priorities. When mandates are in areas not emphasized in the administration's annual solicitation of proposals for grants and cooperative agreements, it is difficult to fulfill mandates via study proposals generated by this solicitation. This may, in some cases, contribute to problems of achieving timely, relevant, and technically adequate studies.

Since the early 1980s, the planning of the ORD research agenda appears to have become more focused on priorities established by the administration and OMB. Although these priorities were consistent with congressional interests in some areas such as quality of care, in others they were not. A plausible consequence of this disparity is that ORD has had to retrofit its agenda to be responsive, in terms of relevance and timeliness, to congressional mandates. As noted earlier, this was apparent in ORD's efforts to accommodate mandates stemming from the Omnibus

Budget Reconciliation Act of 1986. Specifically, the due date for proposals responding to the general solicitation that was initiated nearly one year earlier was postponed by 1 month, and a technical conference was held to provide potential applicants an opportunity to revise their proposals in accordance with the issues raised in the mandates.

Similarly, retrofitting occurred when proposals—relevant to mandates—were funded by cooperative agreements. This strategy increased timeliness in initiating studies, but as discussed in previous chapters, the selection of proposals that had been disapproved by the review panels, the technical difficulties occurring during execution of such a study, as well as other problems—all suggest that retrofitting is a risky strategy.

Disparities between calendar timeframes for legislative cycles and for ORD planning cycles suggest that unless a proactive planning process is instituted, the retrofitting will continue. Specifically, ORD's general solicitation for any given fiscal year begins early in the prior fiscal year. However, historically, the majority (66 percent) of mandates have been issued between July and December, after the grants and cooperative agreements announcement has been published and during the period when proposals are due to be submitted to ORD.

Increased congressional communication might avoid the problems associated with this disparity in cycles. But ORD's ability to effectively plan a research agenda incorporating congressional interests appears to be limited by the combination of a narrow agenda-setting process, the influence of OMB, and differences in policy research priorities of the administration and congressional committees.

Narrowing of Agenda-Setting Process

Various attempts have been made to establish agenda-setting processes that would enhance the relevance of HCFA research to policymakers in general. None were designed to formally take congressional interests into account. As part of our 1980 testimony, we suggested that the process of ORD agenda development include more participants, including congressional staff. At that time, we also described the ORD retreat, instituted in December 1979 that involved ORD managers and top-level HCFA program and policy officials. A study conducted by the Rand Corporation in 1983 gave high marks to this agenda-setting process. According to this study, the process was characterized by staff trying to anticipate HCFA and congressional policy needs, with subsequent decisions made on the final form of the agenda during a retreat by high-level ORD and HCFA

officials. This broad-based process was short-lived, ending before our review.

An HHS management review conducted in 1984 also called for additional mechanisms to ensure the policy relevance of individual projects and for a long-term plan. Initially, a long-range plan was drawn up in accordance with HHS recommendations, but this approach was abandoned in favor of a detailed 3-year budget planning document, which included brief project-by-project descriptions and was subject to review and approval by OMB as well as HHS. ORD officials told us that this change resulted from OMB requests for more detail on specific projects proposed for initiation or continuation by ORD. As noted earlier, this budget document was intended for executive branch use only. The Congress was provided summary and partial information in advance of OMB approval, and later, during the budget process, formally received information on HCFA's research plans in an aggregated form rather than the project-by-project descriptions that were submitted to HHS and OMB.

While Office of Demonstrations and Evaluations and Office of Research staff still annually submit proposals for new initiatives, the majority of the long-term staffers we interviewed (8 of 13 project officers, division directors, and office directors who had been at ORD for at least 4 years) either mentioned to us that planning is currently a predominantly "top down" process or pointed out that it has become increasingly so.

Influence of the Office of Management and Budget

In recent years, OMB has become increasingly active in influencing HCFA/ORD's research plan and ensuring that it meets administration interests and information needs. During House Appropriations Committee hearings for fiscal year 1986, concerns were expressed about the role of OMB in setting national policy. The HCFA administrator explained that HHS/HCFA set health policy but that OMB was involved in its review.

To illustrate the involvement of OMB in the planning process, perhaps the most significant administration initiative in the fiscal year 1988 proposed plan was a set of capitation demonstrations. These were suggested by OMB. Indeed, to ensure that the work would be initiated, OMB added $5 million to HCFA's budget request for fiscal 1988. The stated purpose of these demonstrations is "to harness free-market incentives to promote preconditions for full capitation." Other initiatives included evaluation of expanded consumer choice models.

The influence is consistent with a 1984 HHS management review, which recommended that HCFA increase coordination with OMB and senior HHS/administration officials in planning its research agenda. HCFA was responsive. In a November 1986 letter from the director of OMB to HHS Secretary Otis Bowen, the director congratulated Dr. Bowen on "turning around HCFA's research and demonstration program" and went on record as being clearly pleased with the latest plans for ORD research initiatives, which he attributed to HCFA Administrator William Roper.

Topics of Mandated and Nonmandated Studies

Using ORD project Status Reports from 1982 through 1985, we compared the topics of mandated and nonmandated studies.[1] We found that more than 40 percent of the congressionally mandated studies initiated from 1982 through 1985 were concentrated in the area of hospital payment. Most of these mandated hospital payment studies were investigations of the new prospective payment system, and indeed, several mandated studies in other (nonhospital) categories also had a PPS focus.[2] Less than 20 percent of ORD's nonmandated studies involved issues in hospital payment. Instead, nearly 40 percent of the administration's initiatives were studies of alternative payment systems (that is, capitation and competition). By contrast from fiscal year 1982 to 1985, only one of ORD's congressionally mandated extramural projects was categorized as an alternative payment study.

Differences in emphasis were also apparent in recent legislation. Specifically, 12 of the 19 projects planned by ORD in response to the Omnibus Budget Reconciliation Act of 1986 relate to prospective payment; the administration's major budget initiatives for research and demonstrations in fiscal years 1987 and 1988 examine alternative payment systems (capitation and competition).

Rising numbers of congressional mandates in areas that sometimes diverge from administration initiatives point to the need for prospective planning in areas of interest to the Congress. Our analysis of the language in HCFA statements of research priorities and plans, which are included in budget documents and general solicitation notices, suggests that HCFA may now have allocated congressional information needs a lower priority than in earlier years. Specifically, the policy overview

[1]Our coding of a single topic area for each project was based on ORD's assignment of each of its mandated and nonmandated projects to one of its seven topic areas in the Status Report volumes.

[2]For example, a mandated study of the effects of PPS on quality of inpatient care is categorized under "quality and coverage."

statement accompanying ORD's budget plan for fiscal year 1988 lists congressional policymakers fourth as users of HCFA research.[3] This is in contrast to the fiscal year 1986 budget which is worded to give "equal billing" to the administration and the Congress. And while proposals responding to ORD's general solicitation notice were chosen to fulfill mandates, this notice was revised in 1986 to substantially emphasize administration research interests in the area of competition; by contrast, the 1985 solicitation prioritized congressional research interests in prospective payment. In sum, the current agenda-setting process for HCFA seems to represent an effective constraint on ORD's capacity to respond to congressional mandates—a constraint that does not appear to be wholly within ORD's and HCFA's control.

Clearances and Reviews of ORD Work by Other Agencies

During planning and execution, timeframes were lengthened by required OMB clearances; for mandated reports to Congress, the report review and revision process, involving HCFA, HHS, and OMB, produced further delays and, in some cases, was associated with problems in relevance or technical adequacy, or both.

OMB Clearances and Reviews During Planning and Execution

OMB reviews affected the timeliness of ORD research. These include forms clearance and review of solicitations. OMB review of data collection forms is required by the Paper Work Reduction Act of 1980 to avoid unnecessary burdens on the public; other OMB reviews have been established by longstanding practice. Such reviews represent a factor that is beyond the control of HCFA and that affects the timeliness with which ORD studies can be completed.

With respect to the project planning and execution phases, OMB has been involved in "preclearance" of some individual studies, in the review and approval of proposed questionnaires, and in the approval of waiver applications for demonstration projects.[4] Generally, these reviews apply equally to mandated and nonmandated ORD projects.[5] While the majority

[3]First, second, and third users listed are the secretary of HHS, the HCFA administrator, and the Office of Management and Budget.

[4]"Preclearance" refers to the preliminary review of early project plans by OMB in advance of the official OMB clearances (for example, OMB clearance of final forms for data collection or approval of a formal request for a waiver). The practice of obtaining preclearance reviews helps to avoid situations in which substantial amounts of time or funding might be invested in planning and starting projects that would later be "scrubbed" owing to OMB disapproval of forms or waivers.

[5]An exception would be waivers that must be granted according to legislation.

of project requests were approved, some were not. For example, a proposed survey of hospital decisionmakers was disapproved by OMB.

In our interviews and case studies, we learned of efforts to avoid OMB forms review, including the selection of methods that do not involve forms. OMB forms clearance has resulted in extending the timeframes for some studies. (For example, the Clinical Social Workers demonstration project was delayed by OMB disapproval of a survey.) Forms clearance is seen as a time-consuming step by ORD management and staff, although the time lags involved are not as long as those attributable to report review.

An ORD document concerning OMB reviews of demonstration projects (preclearance and waiver clearance) from 1983 through 1986 reports the dates of ORD submission of each review package and the date of OMB final action on the package.[6] These data show that the OMB review periods ranged from less than 1 month to nearly 5 months, with a median elapsed time of 2-1/2 months. This is roughly equal to the 10-week median period of OMB review of data collection instruments reported by federal program evaluation units in a 1987 GAO report.[7] OMB reviews of proposed data collections do, therefore, extend the preparation time required for some projects, but ORD's general experience appears typical for nondefense departments and agencies throughout the government.

OMB can also affect the timeliness of research activity through its reviews of ORD announcements for grants and cooperative agreements. According to ORD staff, publication in the Federal Register of ORD's 1985 grants announcement was slowed by OMB review. These delays are not common in ORD's experience, but to the extent that grant-supported research is intended to support mandated studies, these reviews could hinder the timeliness of mandated reports.

Review of ORD Reports by HCFA, HHS, and OMB

The report review and revision process had several effects on quality; not only timeliness but, in some cases, relevance and technical adequacy also were adversely influenced. Timeliness has been an ongoing concern for the Congress. While ORD has improved the timeliness with which it

[6]These tabulations were prepared by ORD's Office of Operations Support for submission to the Office of the Secretary, HHS, for use in the secretary's response to a congressional request for information on OMB reviews of HHS health-related research activities.

[7]U.S. General Accounting Office, Federal Evaluation: Fewer Units, Reduced Resources, Different Studies From 1980, GAO/PEMD-87-9 (Washington, D.C.: January 23, 1987).

initiates studies, delays due to report review increased between 1982 and 1985. We were not able to separate out delays in review from delays in revision, and in some cases, delays in review may have been exacerbated by delays in revisions on the part of ORD authors. However, in two of our case studies, there was reluctance to issue reports on the part of HCFA and HHS (see below). OMB has also exerted influences on studies at various phases of the research process, which were plausibly linked to aspects of study quality.

HCFA Clearance Process and Report Review. Although tracking mechanisms within HCFA and, more recently, within ORD have set milestones for the review process, these dates have not been met consistently. In at least one case, delays in report review were traceable to reluctance to release a particular report. According to several sources, one report (the Hospice Demonstration Evaluation) spent 17 months in the review process, partly because conclusions diverged from those contained in an interim report. Regulations had already been implemented on the basis of the earlier data. The report was not substantially changed, but during the delay, the Congress acted on the hospice program benefit—without being able to review the information in the report evaluating the hospice demonstration. Our point relates to timeliness of clearance reviews; as discussed earlier in this chapter, we found some evidence that ORD and expert review was positively related to technical adequacy.

Report Review by the HHS Office of the Assistant Secretary for Planning and Evaluation. The Office of the Assistant Secretary for Planning and Evaluation and other high-level HHS offices review drafts of reports to the Congress for consistency with policy, because these are to be reports from the secretary of HHS. In our case studies, we found that the Medigap State Regulations report was changed ("watered down" according to an internal HHS communication commenting on completed changes) in ways that affected its relevance to requester needs. Based on other HHS communications, one concern in making these changes was to help ensure smooth relations between the secretary and the insurance industry, in view of the secretary's support for the Medicare catastrophic care initiative. Further, according to an internal HHS memorandum, an official in the Office of the Assistant Secretary for Planning and Evaluation suggested intentionally delaying issuing this already overdue report because of its possible adverse impact.

OMB Report Review. While some changes in reports that were suggested by OMB were based on the quality of ORD work, other changes appeared to be a function of the political sensitivity of findings. The belief that

these reports reflect policy views (rather than merely presenting empirical data) and should therefore conform to official policy positions has been put forward as a justification for some OMB changes in mandated reports.

OMB reviews of mandated ORD reports to the Congress have sometimes been associated with long delays before final delivery to the Congress. As of July 1987, three ORD-prepared reports were in review at OMB and had been there for more than a month. While one had arrived less than two months before, our interviews indicated that this report had undergone previous OMB review. The other two reports had been there for close to six months and for nearly a year.

Three of the four reports to the Congress received low or very low technical adequacy ratings from us. All four reports to the Congress had been subjected to OMB and HHS review, and the one that had been subjected to the most extensive review by HHS and the most substantial revision received the lowest rating. Comparing an early ORD draft of this report to the final version, we found no evidence that reviews by OMB and HHS had improved technical quality. Some changes, in fact, reduced it. For example, one change made was to eliminate all description of study methods, so the reader could not judge the basis for the conclusions or the quality of the data.

For another case study project, which is one of several projects feeding into a report to the Congress that was in review during our study period, we examined draft revisions of a chapter of this report, which ORD had prepared in response to OMB comments. As a result of this review, interpretations and conclusions were changed so as to emphasize administration policies. These revisions did not enhance, but rather in some cases appeared to reduce, technical adequacy.

Contextual Factors

Four contextual factors were identified as possible constraints on the quality of HCFA/ORD's responses to congressional mandates. First, since 1982, congressionally mandated studies increased—both in absolute numbers and as a percentage of ORD's workload. Second, between 1981 and 1987, ORD funding declined by 43 percent (in 1980 constant dollars). Third, a variety of staffing problems—increases in workload for some ORD divisions and staff, as well as decreases and turnover in staff—combined to limit agency capacity to perform intensive monitoring and supervision as well as technical in-house report reviews. Fourth, rapid

changes in key leadership positions within HCFA and ORD resulted in policy changes that influenced agency practices, especially those associated with planning. These contextual factors may affect ORD's future capacity to respond to congressional mandates.

Increase in Mandates

A recent increase in mandates is plausibly linked to various problems of agency performance with respect to technical adequacy and perhaps other quality dimensions. As described earlier, less intensive levels of project monitoring or supervision for some projects were associated with high workloads for certain divisions and for some key staff members. This unequal distribution of workload derived, to some extent, from increases in the numbers of congressionally mandated studies conducted at ORD—especially mandated studies in particular areas that required specific staff skills or expertise.

As shown in table 6.1, the number of congressionally mandated studies assigned to ORD has increased markedly since 1982—both in terms of absolute numbers and in terms of percentage of new studies.[8] In 1982 and 1983, 9 percent of studies were the result of congressional mandates. In subsequent years, this percentage rose, to 22 percent in fiscal year 1985. In terms of newly initiated studies relative to 1982, congressional mandates commanded an even larger share, accounting for 36 percent of all new starts in 1985.

ORD's fiscal year 1987-1988 budget plan shows that the number of new ORD studies initiated in response to recent mandates continues to

Table 6.1: Number of Extramural Projects for Fiscal Years 1982-1985[a]

Type of study	1982		1983		1984		1985	
Mandated	**14**	**9%**	**16**	**9%**	**25**	**15%**	**36**	**22%**
New	4		6		14		19	
Continuation	10		10		11		17	
Nonmandated	**138**	**91%**	**159**	**91%**	**140**	**85%**	**130**	**78%**
New	40		55		31		34	
Continuation	98		104		109		96	
Total	**152**	**100%**	**175**	**100%**	**165**	**100%**	**166**	**100%**

[a]Classification of extramural projects as new or continuation for each fiscal year is based on the project start and end dates given in the ORD Status Report volumes. Excludes projects for which start and end dates were not included in the Status Report, as well as continuing overdue projects whose official end dates were not extended.

[8]The GAO analyses presented here counted studies identified by ORD as mandated projects in its annual Status Report volumes; other studies in the Status Report volumes were counted as nonmandated or administration-initiated.

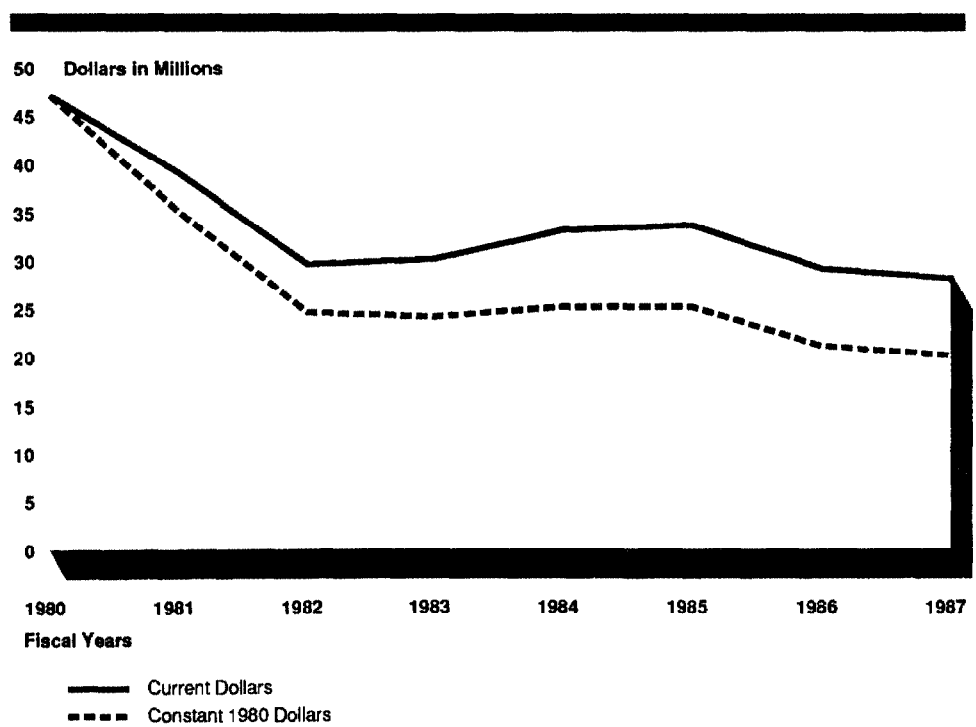
increase. The plan includes 19 studies resulting from mandates appearing in the Omnibus Budget Reconciliation Act of 1986. This represents 19 of 46 new starts, or 41 percent of ORD's research, evaluation, and demonstration agenda.

Further, mandates increased as a percentage of the annual ORD budget. In fiscal year 1980, 2.1 percent ($1 million in 1980 dollars) was spent on mandated studies; by fiscal year 1987, 43 percent ($12 million in 1987 dollars) was allocated for mandated activities.

Reduction in Fiscal Resources

Although the number of new and ongoing extramural studies remained roughly constant between fiscal years 1982 and 1985 (see table 6.1), increasing by 9 percent (from 152 to 166 projects), fiscal resources declined. As seen in figure 6.1, $38.9 million was appropriated in fiscal year 1981. For fiscal year 1987, ORD received $28 million, a 28-percent decline in current dollars. In terms of purchasing power, in 1980 constant dollars, this represents a 43-percent reduction.

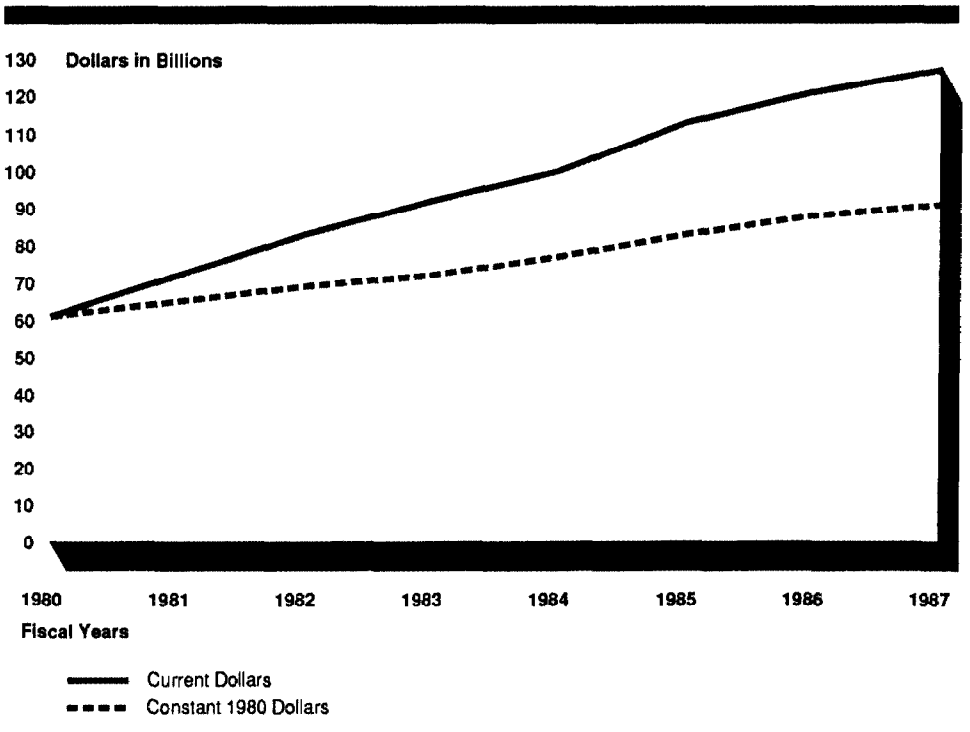
Figure 6.1: Total Obligations for HCFA Research, Demonstrations, and Evaluation Budget



1987 estimated total obligations

Relative to changes in program expenditures, this decline is even more dramatic. As figure 6.2 shows, total program costs (in current dollars) more than doubled between 1980 and 1987, rising from $60.8 billion to $127 billion (a 109-percent increase). In 1980 constant dollars, this represents a 50-percent increase. We would not expect resources for research, evaluation, and demonstrations automatically to rise or fall with changes in program expenditures. However, ORD resources declined during a period when program expenditures more than doubled, significant changes in the program occurred (such as the prospective payment system for hospital payment), and the administration emphasized studies in the area of capitation.

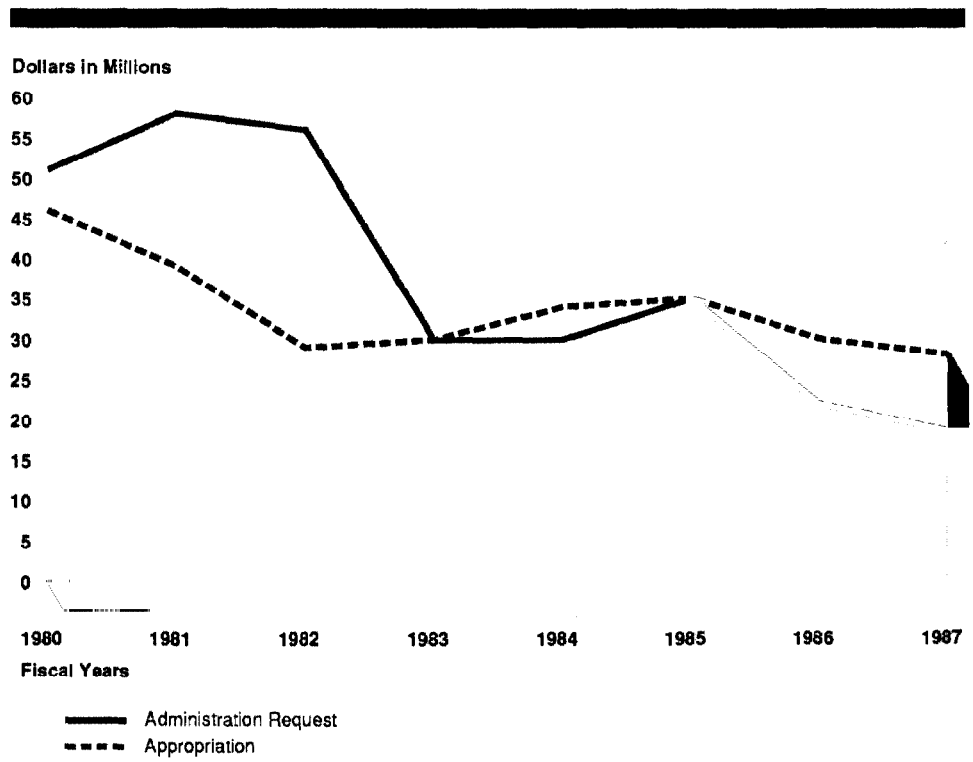
Figure 6.2: Program Costs for Medicare and Medicaid



1987 estimated program costs

Figure 6.3 (on p. 77) shows the pattern of appropriations and administration requests for ORD funding between fiscal years 1980 and 1987. This analysis shows two points of departure between the Congress and the administration on the appropriate level of funding for ORD. In the early 1980s, the administration request was consistently higher than what was ultimately appropriated. Between 1983 and 1985, request and

Figure 6.3: Administration Requests for Funding and Appropriations for HCFA Research, Demonstrations, and Evaluation



Current dollars

appropriation amounts were roughly equal, hovering around $30 million per year. However, while the Congress generally has not tied dollar amounts to specific studies, in 1986 and 1987 the Congress did not approve proposed administration cuts in funding for ORD's extramural work and continued to appropriate funds similar to the previous year's appropriation. Also, the House Appropriations Subcommittee for Labor, Health and Human Services, Education and Related Agencies, has indicated concern that HCFA/ORD be provided sufficient resources to carry out the mandated studies.

As described in chapter 2, there are current agency efforts or proposals to prioritize mandates, conduct small-scale studies, and in some cases, convince committees to withdraw the mandate. Interviews with ORD officials and staff suggested that reductions in funding may underlie this current trend. Since these proposals were relatively new (or in planning stages), we were not able to assess, empirically, whether reductions in funding influenced the three dimensions of quality—relevance, timeliness, and technical adequacy.

Staffing Issues

High workloads and turnover of project officers on case study projects were associated with lower scores in our ratings of reports. For the four rated projects where workloads were heavy (6-14 projects), three received low to very low technical adequacy ratings from us. By contrast, a low rating was assigned to only one of the three projects in which officers had a light workload.

General reductions in ORD staff influenced workloads and project leadership. Although some attrition may be healthy for an organization, in recent years, outside hires to replace ORD staff have been limited by HHS, and the expertise levels of those who have left may not be matched by their replacements. Thus, increased workloads for some ORD project officers and managers, as well as project officer turnover, may be associated with the low levels of scrutiny that were given to some projects and reports that could have benefited from a greater degree of assistance.

Individual Staff Workload

The issue of workload has been a persistent problem, identified in our 1980 testimony and report, in the Rand study, and in the HHS management review. As seen in table 6.2, the average number of projects monitored by a project officer increased from 2.8 in 1982 to 3.3 in 1985. The increase was entirely due to changes in workloads within the Office of Research. In 1982, the average number of projects assigned to each project officer in the Office of Research was 2.6; by 1985, the average had risen to 3.6 projects per project officer.

Table 6.2: Changes in Project Officer Workload[a]

Organization	Year	Number of projects	Number of project officers	Ratio of projects to project officer
Office of Demonstrations and Evaluations	1982	102	34	3.0
	1985	111	37	3.0
Office of Research	1982	67	26	2.6
	1985	138	38	3.6
Total	**1982**	**169**	**60**	**2.8**
	1985	**249**	**75**	**3.3**

[a]Based on extramural and intramural projects listed in the Status Report volumes published in April 1983 and January 1986 (giving project status for fall/winter of the prior year). This count includes only projects for which the ORD division was identified in the Status Report; multisite studies were counted as a single project.

Individual staff workloads varied considerably across six ORD divisions. In three of the divisions in 1985, the average project officer workload was relatively low (2.0 to 2.4 projects); in the three other divisions, the workload was higher (4.1 to 4.5 projects). In the divisions with heavier workloads, between 40 and 50 percent of the project officers were each assigned responsibility for managing four or more projects, accounting for 69-77 percent of the projects assigned to these divisions. (In all divisions, including those with heavier workloads, extramural projects averaged over $500,000 in cumulative funding.) One division—Division of Reimbursement and Economic Studies—was assigned a large number of congressional mandates and the workload per staff was substantially higher than in most other divisions.

Division director workload also varied considerably and was correlated with the project officer workload within the division. During fiscal year 1986, the busiest division director had oversight responsibility for a total of 75 projects. This included 62 extramural projects (totaling nearly $38 million in cumulative funding) and 13 intramural projects. Owing to an increase in the number of projects and the limited staff, this division director had to assume some project officer duties. Additional projects were assigned to this division in 1987.

Division Workload

As the emphasis of ORD's work changed from demonstrations and evaluations to other kinds of research projects (many of which were congressionally mandated), the locus of the workload similarly shifted. In 1987, we found a heavy workload in the Office of Research, while some divisions in the Office of Demonstrations and Evaluations had a relatively light agenda, and in others, a large number of projects were ending. As noted earlier, the busiest division, with an above-average project officer workload was responsible for 62 extramural projects (totaling nearly $38 million in cumulative funding) plus 13 intramural projects.

In explaining ORD workload patterns to us, division directors and staff throughout ORD said that assignments were made on the basis of expertise rather than existing workload. When shifts in priority topics occur and new kinds of studies are emphasized in the ORD research agenda, the workloads of staff members with relevant expertise increases. Others may have decreased workloads. As a result, even though the average workload may not be excessive, some key staff working in priority areas may be heavily burdened.

Cited difficulties in shifting staff assignments include lack of appropriate background or expertise necessary to perform the types of work required. Generally, more staff in the Office of Research had received advanced degrees in economics or other social sciences.

Turnover and Decreases in Professional Staff

Within the Office of Research and the Office of Demonstrations and Evaluation, staff size has been reduced. Between 1980 and 1987, professional staff in the Office of Research declined by 22 percent (from 67 to 52). In the Office of Demonstrations and Evaluations, professional staff declined by 21 percent (from 52 to 41).

We analyzed project officer turnover on projects that were active in December 1982 and still continuing in September 1985. In 42 percent of these projects, the original project officer was replaced, and in some cases re-replacement had occurred. An analysis of staff turnover at ORD in 1984 showed a similar level of turnover. Most of ORD's management were concerned over the lack of backup staff to fill the slots of key staff if they decide to leave. According to one division director:

> "There is little or no backup on projects. As ORD has taken on more and more assignments, we have increased our performance efficiency, but the organization has become more dependent upon the existing staff. . .The organization is increasingly vulnerable to the loss of personnel."

Although outside hires are an alternative for filling the slots of key people if they leave, HHS and HCFA constraints on hiring have made it difficult for ORD management to hire individuals with the specialized skills needed. To fill some of these technical voids, however, ORD has successfully used expert consultants. In the two highest rated studies, experts in health services research advised the project staff throughout and, as noted in chapter 4, substantially and positively affected the study design and analysis.

Changes in Leadership

Leadership turnover and especially a lack of management continuity are plausibly linked to ORD's lack of plans laying out coherent approaches to given areas, which we described in chapter 4. For example, a plan on

quality of care was drafted within ORD, but when the current HCFA administrator was appointed in 1986, the plan became essentially defunct, although we were told that elements of it related to the administrator's research interests in this area. Leadership turnover also affected an overall long-range plan, which laid out short-, middle-, and long-term goals in each of ORD's major research areas. Division directors saw it as valuable; however, when the ORD director who initiated it left, the plan was dispensed with.

During the period of our review, turnover in six leadership positions in HCFA and ORD was substantial. Between 1982 and 1987, most of these positions were filled by four or five different individuals. Project officer turnover was also substantial. Redistribution of staff across divisions was hampered by the absence of specialized skills in existing staff.

Recent evaluations of government practices have documented the effect of changes in leadership and staff within agencies.[9] Table 6.3 shows the number of individuals occupying six leadership positions within HCFA and ORD for the 6-year period between 1982 and 1987. For this period, at least 23 individuals occupied these 6 positions; in 7 cases, individuals served in an acting capacity. During the 6-year period, four or five persons served in most of these positions.

Table 6.3: Changes in HCFA/ORD Leadership, Fiscal Years 1982-1987

Organization	Year	Number in position	Number acting	Total
Health Care Financing Administration	Administrator	3	1	4
	Associate Administrator for Program Development	2	2	4
Office of Research and Demonstrations	Director	3	1	4
	Deputy	2	0	2
Office of Demonstrations and Evaluations	Director	3	2	5
Office of Research	Director	3	1	4
Total		**16**	**7**	**23**

Source: ORD Status Report, Health Care Financing Review, and agency organization charts.

[9]See, for example, U.S. General Accounting Office, Education Information: Changes in Funds and Priorities Have Affected Production and Quality, GAO/PEMD-88-4 (Washington, D.C.: November 4, 1987).

Conclusions

Based on our analysis of internal, external, and contextual factors associated with study quality and agency capacity at HCFA's Office of Research and Demonstrations, we conclude that:

1. To promote relevant, timely, and technically adequate research and evaluation in areas of concern to congressional policymakers, more effective ORD management is needed with respect to developing research plans, ensuring adequate monitoring of all studies, and requiring appropriate technical review of reports, including technical review of mandated reports to the Congress. To promote research plans and project designs that include studies relevant to congressional interests, communication between researchers and representatives of the Congress is essential. Continuing communication from HCFA/ORD to congressional requesters is needed during project execution to ensure that changes affecting relevance are prevented, compensated for, or at a minimum, known in advance. Such communication should highlight changes in ongoing projects that substantially affect relevance to the original mandate or information need.

2. To promote technical adequacy of extramural projects and reports through agency assistance to researchers and evaluators, additional staff may be needed to plan, monitor, and review reports of ORD extramural projects, especially congressionally mandated projects.

3. To improve the timeliness of executive branch review for reports to the Congress, thereby speeding dissemination of results from congressionally mandated studies, there is a need for HHS to develop mechanisms that formalize the review process and prevent avoidable delays.

4. To facilitate the quality of mandated studies, it may be necessary to increase the specificity of congressional requests and establish procedures for clarifying the nature and scope of studies and timelines for reporting. ORD's resource and staffing levels and the timeframes needed to plan and execute studies represent effective limits on ORD's responsiveness to congressional requests.

In light of these conclusions, we offer the following recommendations and matter for consideration.

Recommendations to the Secretary of HHS

GAO recommends that the secretary of HHS direct the HCFA administrator to develop internal management procedures that will address the issues raised in this report. This would include, for example, procedures to ensure that agency communication with appropriate congressional committees is adequate during all stages of mandated studies and that ORD consider areas of congressional concern in developing its research and evaluation plans.

GAO recommends that the secretary of HHS implement formal report review procedures designed to ensure that HHS reviews of reports to the Congress will be timely and that the secretary work with other executive branch agencies to develop similar procedures for reviewing HCFA's reports.

GAO recommends that the secretary of HHS direct the HCFA administrator to assess whether ORD has sufficient staff and resources to plan, monitor, and review studies mandated by the Congress, as well as those supported by discretionary funds.

Matter for Consideration

To facilitate the quality of mandated studies when it is impossible to be ideally specific about requests, congressional committees may wish to consider establishing either procedures for clarifying the nature and scope of studies or timelines for reporting, or both. In mandating new HCFA studies, it may be useful to specify scope and time by considering the resources available to HCFA in light of ongoing ORD studies, prior requests, and planned work.

Agency Comments

At the request of the House Subcommittee on Human Resources and Intergovernmental Relations, we did not seek comments from the Department of Health and Human Services on this report.

ORD Mandated and Nonmandated Studies: Status Reported for Fall 1985

Studies[a]	Final report in preparation, completed, or overdue	Project in planning or execution
Mandated		
Extramural	18	28
Intramural	7	7
Total	**25[b]**	**35**
Nonmandated		
Extramural	79	100
Intramural	5	18
Total	**84**	**118**

[a]Counts all projects included in the Status Report published in January 1986; multisite studies were counted as a single project.

[b]Case study pool.

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Ten Case Studies

This appendix presents synopses and tables describing the 10 case study projects.

Synopses

Urban Clinics—Evaluation of Demonstration

The purpose of this extramural project was to evaluate a demonstration of physician-directed clinics in urban medically underserved areas. The demonstration was intended to "test the relative advantages and disadvantages of cost-based and fee-for-service reimbursement for...clinics that employ physician assistants or nurse practitioners." The evaluation was intended to determine and analyze the impact of the Medicare reimbursement changes on clinic operations and performance and on Medicare utilization and costs. The mandate for the study was issued in 1977, the demonstration project began in 1981, and the evaluation of the demonstration began in 1982. The report to the Congress, prepared at ORD on the basis of this study, was in review in summer of 1987.

Hospice—Evaluation of Demonstration

This extramural project evaluated a national demonstration of hospice care in which 26 sites provided care to terminally ill Medicare beneficiaries. Among the questions this study sought to answer were: What are the differential costs of caring for comparable terminally ill patients in hospices and conventional care settings? And, what are the costs of different patterns of service? The mandate for the study was issued in 1982, while the project was ongoing, to ensure continuation of the project and to request a report of findings. The evaluation project had been begun in 1980. The report to the Congress, based directly on this study, was issued in 1986.

Social HMOs—Planning of Demonstration

This extramural project developed and implemented the concept of a health maintenance organization that would integrate health and social services for long-term care. All services are provided at a fixed annual prepaid capitation sum. Four sites initiated service delivery by March 1985. The research organization conducting the study did not submit a final report to ORD, but published a book of study findings. The project was started in 1980, and the mandate was issued in 1984 to ensure continuation of the project.

Fixed-Price Contracting—Evaluation

The purpose of this extramural project was to examine the impact of experimental fixed-price contracting for Medicare Part A intermediary services in New York and Missouri. The evaluation focused on the performance of the contractors and the economic impacts of the experiment on the Medicare program. Congress authorized these experiments in 1972; however, the project was not begun until 1983, in part because of industry legal suits aimed at preventing the study. The extramural research report for this project was issued in 1985.

Medicaid Home and Community Services—Evaluation

This intramural study was devoted to preparing a report to the Congress based on preliminary findings from extramural studies of home and community-based health services. The study attempts to evaluate the cost-effectiveness of home and community-based services in terms of reducing aggregate Medicaid costs by diverting clients who would otherwise have gone into a nursing home and caring for them in the community. A 1983 congressional mandate called for a report of these ongoing studies. The report to the Congress was issued in September 1985.

Medigap State Regulations—Synthesis

This intramural study was devoted to preparing a report to the Congress on the effect of various state approaches to regulating Medicare supplemental insurance policies. The report to the Congress, which is largely based on an extramural study performed under contract, covers the extent of such problems as agent abuse, informed choice, and duplicative coverage; the types of regulations that affect these problems; the prevalence of effective regulations; and ways to enhance effective regulation. The congressional mandate for the study was issued in 1980. The report to the Congress was delivered in spring 1987.

PPS Impact—1984 Report

The purpose of the study, which was the first in a series of annual reports to the Congress, was to "describe and analyze the impact of the Medicare Hospital Prospective Payment System (PPS) on hospitals, Medicare beneficiaries, other providers of health care, and other payers for inpatient hospital services." The mandate for this study was issued in spring of 1983, and called for a report by December 1984. The 1984 annual report was issued in November 1985.

Physician DRGs—Data Development

The purpose of this extramural study was to obtain "statistical algorithms...to improve estimates of the values of physician services for inpatient care by diagnosis-related groups." The study also examined

questions related to policy issues regarding physician reimbursement reform (for example, variation in billing practices). This study was one of a set of studies on DRG-based physician reimbursement conducted in response to a 1983 congressional mandate. The extramural study was completed in 1985. The report to the Congress on physician payment was issued in September 1987.

DRGs and Nursing—Pilot Study

This extramural pilot study examined the relationship between reimbursement based on diagnosis-related groups and nursing resource utilization and nursing costs. The study was begun in 1983 on the basis of a 1983 mandate. The extramural research report was issued in summer of 1985, and the report to the Congress that cited this work was issued in summer of 1987.

Cost of Care Information—Literature Review

In accordance with a 1983 mandate, this study reviewed the literature pertaining to hospital price information and consumer choice. A policy center performed the literature review extramurally, under a task order; the report to Congress based closely on this extramural work was issued in 1985.

Tables

Table III.1 provides a guide to the various titles and project numbers that have been associated with each of the 10 case study projects. Tables III.2-III.4 provide descriptors of agency performance with respect to relevance, timeliness, and technical adequacy for each of the case studies. The tabular format allows cross-case comparisons of agency performance during planning, execution, and report review.

As noted in chapter 1, at the request of the Subcommittee we did not obtain comments on this report from HHS, the grantees, or contractors whose work we reviewed. Because such comments were not obtained, nonfederal organizations are not named in these tables.

Table III.1: GAO Short Titles and HCFA/ORD Titles

Short Title	Full Project Title	Extramural Project Number	Report Title
Urban Clinics—Evaluation of Demonstration	Evaluation of the Urban Health Clinics Demonstration	500-82-0025	Evaluation of the Urban Health Clinics Demonstration
Hospice—Evaluation of Demonstration	National Hospice Study	99-P-97793/1	Final Report of the National Hospice Study
Social HMOs—Planning of Demonstration	Social Health Maintenance Organization Project for Long-term Care	18-C-97604/1	No report
Fixed-Price Contracting—Evaluation	Study of the Quality and Effectiveness of Experimental Fixed-Price Medicare Part A Intermediary Contracting	500-83-0030	A Study of the Quality and Effectiveness of Experimental Fixed-price Medicare Part A Intermediary Contracting
Medicaid Home and Community Services—Evaluation	Studies Evaluating Medicaid Home and Community-Based Services: A Report to Congress	[a]	Report to Congress: Studies Evaluating Medicaid Home and Community Based Care Waivers
Medigap State Regulations—Synthesis	Medigap Study of Comparative Effectiveness of State Regulations	[a], [b]	Report to Congress: Study of Health Insurance Designed to Supplement Medicare
PPS Impact—1984 Report	Annual Report to Congress on the Impact of the Medicare Hospital Prospective Payment System	[a]	Report to Congress: Impact of the Medicare Hospital Prospective Payment System
Physician DRGs—Data Development	Medical Doctor Diagnosis-Related Groups Algorithms	500-84-0024	Developing MD-DRG Algorithms
DRGs and Nursing—Pilot Study	Diagnosis-Related Groups Refinement for Nursing Care	15-C-98421/7	DRGs and Nursing Care
Cost of Care Information—Literature Review	Cost of Care Information to Consumers	[c]	Informing Consumers About Health Care Costs

[a]Intramural study; no project number.

[b]Intramural study was based largely on contract number 500-81-0050.

[c]Study conducted as part of a cooperative agreement with a policy center.

Table III.2: Relevance Project Descriptors

	Planning		Execution		Review of Report to the Congress	
Short title	**ORD efforts to learn congressional intent**	**Special HCFA solicitation**	**Major change affecting relevance**	**Change discussed with congressional staff**	**Status as of 5/87**	**Draft report changes affecting relevance**
Urban Clinics—Evaluation of Demonstration	Little or none	Yes[a]	Yes, demonstration deteriorated	No	In review[b]	N/A
Hospice—Evaluation of Demonstration	N/A	Yes[c]	No	N/A	Issued	No changes
Social HMOs—Planning of Demonstration	N/A	No[d]	No	N/A	No report	N/A
Fixed-Price Contracting—Evaluation	Little or none[e]	Yes[a]	No	N/A	No report	N/A
Medicaid Home and Community Services—Evaluation	Considerable	Yes[a,f]	No	N/A	Issued	No changes
Medigap State Regulations—Synthesis	Considerable	Yes[a,f]	Yes, relevance eroded as scope cut and survey response rate problems developed	No	Issued	Major changes
PPS Impact—1984 Report	Some	No[f,g]	Some changes, but compensated	No	Issued	Some changes
Physician DRGs—Data Development	Some	No[h]	No	N/A	In review[b]	N/A[i]
DRGs and Nursing—Pilot Study	Little or none	No[d]	No[j]	No	In review[b,k]	N/A[k]
Cost of Care Information—Literature Review	Considerable	No[g]	Some changes, funding cut, but compensated	No	Issued	No changes

[a]Contract RFP.

[b]Reports to the Congress issued after study period (between June and Sept. 1987).

[c]Special grant announcement.

[d]General grant announcement.

[e]ORD planning was limited owing to imposition of a plan developed by a program division.

[f]Categorization based on the extramural project that was used in intramurally preparing the report to the Congress.

[g]Awarded to policy center.

[h]Sole-source, unsolicited proposal.

[i]In our study period, the report was not available for an assessment of relevance; some draft sections were subjected to major revisions by OMB.

[j]Changes improved technical adequacy; effect on relevance is unknown.

[k]Project cited only; did not contribute substantively to report.

Table III.3: Timeliness Project Descriptors

	Planning					Execution	Review of Report to the Congress		
Short title	Date of mandate	Mandated due date	Project start-up	Time elapsed	Details	Delays	Status as of 5/87	Elapsed time	Delays
Urban Clinics—Evaluation of Demonstration	12/77	1/81	9/82	4 years 9 months	Slow demonstration start	1-1/2 years	In review	Unknown	Unknown
Hospice—Evaluation of Demonstration	9/82	9/83	9/80	N/A[a]	N/A	1/2 year	Issued	17 months	15 months to avoid releasing data inconsistent with interim report
Social HMOs—Planning of Demonstration	6/84	1/88	3/80	N/A[a]	N/A	Extended 3 years	No report	N/A	N/A
Fixed-Price Contracting—Evaluation	10/72	N/A	6/83	10 years 8 months[b]	Industry legal suits	None	No report	N/A	N/A
Medicaid Home and Community Services—Evaluation	1/83	12/84	Unclear	N/A[a]	N/A	Minor	Issued	9 months	N/A
Medigap State Regulations—Synthesis	6/80	1/82	9/81	15 months	Industry lobbying delayed operations	1 year	Issued	26 months	OMB and administration policy review
PPS Impact—1984 Report	4/83	12/84	1/84	9 months	Awarded task order to policy center	None	Issued	11 months[c]	Received extensive HHS policy review
Physician DRGs—Data Development	4/83	12/85	2/84	10 months	Funded unsolicited proposal	None	In review	Unknown (25 months as of 6/87)	OMB and administration policy review
DRGs and Nursing—Pilot Study	4/83	12/85	8/83	4 months	Funded low-rated proposal from grant cycle	None	In review[d]	Unknown	Unknown
Cost of Care Information—Literature Review	4/83	4/85	6/84	14 months	Awarded task order to policy center	None	Issued	6 months	N/A

[a]The congressional mandate was passed after project planning, as Congress ensured the continuation of a project or requested a report on an ongoing project.

[b]The experiments were delayed by industry resistance, including lawsuits.

[c]Report released in response to subpoena from the Senate Special Committee on Aging.

[d]Project cited only; did not contribute substantively to report.

Table III.4: Technical Adequacy Project Descriptors

	Planning[a]		
Short title	**ORD efforts**	**Planning problems**	**Award type**
Urban Clinics—Evaluation of Demonstration	Moderate[d]	Sites not selected for evaluation	Contract
Hospice—Evaluation of Demonstration	Limited[e]	Sites not selected to allow comparison	Grant
Social HMOs—Planning of Demonstration	Unclear	Various; responsibility left to lightly monitored grantee	Cooperative agreement
Fixed-Price Contracting—Evaluation	Limited	Operation unit dictated RFP, limiting technical adequacy	Contract
Medicaid Home and Community Services—Evaluation	Considerable[h]	Deficiencies in existing data base	Intramural[i]
Medigap State Regulations—Synthesis	Considerable[h]	Failed to compensate for uncooperative industry	Intramural[i]
PPS Impact—1984 Report	Considerable[h]	Failed to negotiate project expected with policy center	Intramural[k]
Physician DRGs—Data Development	N/A[l]	N/A	Sole-source contract
DRGs and Nursing—Pilot Study	N/A[l]	Selected low-rated proposal[n]	Cooperative agreement
Cost of Care Information—Literature Review	Moderate[d]	No problems	Policy center task order

Execution		Review of Report to the Congress		Factors	
Design changes that limited technical adequacy	Outside HHS technical review	Outside HHS technical review	Policy expert review[b]	Project officer workloads[c]	Project officer turnover
Yes	Limited	No	Unknown	Moderate	Yes
No	Outside consultants throughout	No[f]	None reported	Moderate	No
Yes	Limited	N/A	N/A	Heavy	No
No	Limited	N/A	N/A	Heavy[g]	No
Yes; data deficiencies	Moderate	Yes[j]	None reported	Heavy	No
Yes; major survey problems	Formal TAP and actuarial consultants	No	Yes—HHS and OMB	Heavy	No
Yes; introduced data analysis late in study	Moderate; formal TAP saw partial first draft	No	Yes—HHS	Light	No
No	Limited TAP[m]	Components reviewed informally	Yes—HHS and OMB	Heavy[g]	No
No (improved by ORD)	Outside consultants throughout; limited TAP[m]	N/A	N/A	Light	No
No	Moderate	Yes	Limited	Light	No

[a]Planning, here, refers to work done prior to the solicitation.

[b]Refers only to federal government policy experts.

[c]A light workload was defined as 1-3 projects; moderate, 4-5; and heavy, either 6-14 projects or as noted.

[d]Senior staff involvement and communication across ORD units.

[e]Some consultation with outside experts.

[f]Earlier research report reviewed by contractor or grantee consultants.

[g]Division director with oversight of 60+ projects also took on project officer role on "overflow" projects when short of staff.

[h]Senior staff involvement and communication across ORD units. Consultation with outside experts.

[i]The intramural project to prepare a report to the Congress was based on work done under an extramural contract.

[j]Expert from HCFA Office of the Assistant Secretary for Planning and Evaluation.

[k]The intramural project was based in part on work done under a policy center task order.

[l]Planning for these projects occurred primarily after selection.

[m]Formal TAP did hear results but functioned as information receivers not as critics.

[n]The project was selected for funding in spite of a low technical rating of the proposal and a recommendation by the review panel not to fund.

Mandates for 10 Case Study Projects

In this appendix, we present the legislative language from the public laws mandating the 10 ORD projects we selected for our case studies.

Urban Clinics—Evaluation of Demonstration

Mandate from Public Law 95-210 dated December 13, 1977, for demonstration projects for physician-directed clinics in urban medically underserved areas:

"Sec. 3. (a) The Secretary shall provide, through demonstration projects, reimbursement on a cost basis for services provided by physician-directed clinics in urban medically underserved areas for which payment may be made under title XVIII of the Social Security Act and, not withstanding any other provision of such title, for services provided by a physician assistant or nurse practitioner employed by such clinics which would otherwise be covered under such title if provided by a physician.

"(b) The demonstration projects developed under subsection (a) shall be of sufficient scope and carried out on a broad enough scale to allow the Secretary to evaluate fully—

"(1) the relative advantages and disadvantages of reimbursement on the basis of costs and fee-for-service for physician-directed clinics employing a physician assistant or nurse practitioner;

"(2) the appropriate method of determining the compensation for physician services on a cost basis for the purposes of reimbursement of services provided in such clinics;

"(3) the appropriate definition for such clinics;

"(4) the appropriate criteria to use for the purposes of designating urban medically underserved areas; and

"(5) such other possible changes in the provisions of title XVIII of the Social Security Act as might be appropriate for the efficient and cost-effective reimbursement of services provided in such clinics.

"(c) Grants, payments under contracts, and other expenditures made for demonstration projects under this section shall be made in appropriate part from the Federal Hospital Insurance Trust Fund (established by section 1817 of the Social Security Act) and the Federal Supplementary Medical Insurance Trust Fund (established by section 1841 of the Social

Security Act). Grants and payments under contracts may be made either in advance or by way of reimbursement, as may be determined by the Secretary, and shall be made in such installments and on such conditions as the Secretary finds necessary to carry out the purpose of this section. With respect to any such grant, payment, or other expenditure, the amount to be paid from each trust fund shall be determined by the Secretary giving due regard to the purpose of the demonstration projects.

"(d) The Secretary shall submit to the Congress, no later than January 1, 1981, a complete, detailed report on the demonstration projects conducted under subsection (b). Such report shall include any recommendations for legislative changes which the Secretary finds necessary or desirable as a result of carrying out such demonstration projects.

"(e) As used in this section, the terms 'physician assistant' and 'nurse practitioner' have the meanings given such terms in section 1861 (aa) (3) of the Social Security Act."

Hospice—Evaluation of Demonstration

Mandate from Public Law 97-248 dated September 3, 1982, for hospice demonstration evaluation:

"[Sec.122] (h)(1) Notwithstanding any provision of law which has the effect of restricting the time period of a hospice demonstration project in effect on July 15, 1982, pursuant to section 402(a) of the Social Security Amendments of 1967, the Secretary of Health and Human Services, upon request of the hospice involved, shall permit continuation of the project until November 1, 1983, or, if later, the date on which payments can first be made to any hospice program under the amendments made by this section.

"(2) Prior to September 30, 1983, the Secretary shall submit to Congress a report on the effectiveness of demonstration projects referred to in paragraph (1), including an evaluation of the cost-effectiveness of hospice care, the reasonableness of the 40-percent cap amount for hospice care as provided in section 1814(i) of the Social Security Act (as added by this section), proposed methodology for determining such cap amount, proposed standards for requiring and measuring the maintenance of effort for utilizing volunteers as required under section 1861 (dd) of such Act, an evaluation of physician reimbursement for services furnished as a part of hospice care, and for services furnished to individuals receiving hospice care but which are not reimbursed as a part of

the hospice care and any proposed legislative changes in the hospice care provisions of title XVIII of such Act."

Social Health Maintenance Organizations—Planning of Demonstration

Mandate from Public Law 98-369 dated July 18, 1984, to continue social health maintenance organization demonstration projects—waivers for social health maintenance organizations:

"Sec. 2355. (a) In the case of a project described in subsection (b), the Secretary of Health and Human Services shall approve, with appropriate terms and conditions as defined by the Secretary, applications or protocols submitted for waivers described in subsection (c), and the evaluation of such protocols, in order to carry out such project. Such approval shall be effected not later than 30 days after the date on which the application or protocol for a waiver is submitted or not later than 30 days after the date of the enactment of this Act in the case of an application or protocol submitted before the date of the enactment of this Act.

"(b) A project referred to in subsection (a) is a project—

"(1) to demonstrate the concept of a social health maintenance organization with the organizations as described in Project No. 18-P-9 7604/1-04 of the . . .;

"(2) which provides for the integration of health and social services under the direct financial management of a provider of services;

"(3) under which all medicare services will be provided by or under arrangements made by the organization at a fixed annual prepaid capitation rate for medicare of 100 percent of the adjusted average per capita cost;

"(4) under which medicaid services will be provided at a rate approved by the Secretary;

"(5) under which all payors will share risk for no more than two years, with the organization being at full risk in the third year;

"(6) which is being provided funds under a grant provided by the Secretary of Health and Human Services; and

"(7) with respect to which substantial private funds are being provided other than under the grant referred to in paragraph (5).

"(c) The waivers referred to in subsection (a) are appropriate waivers of—

" (1) certain requirements of title XVIII of the Social Security Act, pursuant to section 402(a) of the Social Security Amendments of 1967 (as amended by section 222 of the Social Security Amendments of 1972); and

"(2) certain requirements of title XIX of the Social Security Act, pursuant to section 1115 of such Act.

"(d)(1) The Secretary of Health and Human Services shall submit a preliminary report to the Congress on the status of the projects and waivers referred to in subsection (a) 45 days after the date of the enactment of this Act.

"(2) The Secretary shall submit a final report to the Congress on the projects referred to in subsection (a) not later than 42 months after the date of the enactment of this Act."

Fixed-Price Contracting—Evaluation

Mandate from Public Law 92-603 dated October 30, 1972, for fixed-price contracting experiments:

"[Sec.222.] (F) to determine whether, and if so which type of, fixed price or performance incentive contract would have the effect of inducing to the greatest degree effective, efficient, and economical performance of agencies and organizations making payment under agreements or contracts with the Secretary for health care and services under health programs established by the Social Security Act."

Medicaid Home and Community Services—Evaluation

Mandate from Public Law 97-414 dated January 4, 1983, for Medicaid home and community services evaluation:

"Sec. 6. (b) The Secretary shall report the results of studies currently evaluating home and community based health services, and any recommendations for legislative action which might improve the provision of such services, to the Congress prior to January 1, 1985."

Medigap State Regulations—Synthesis

Mandate from Public Law 96-265 dated June 9, 1980, for Medigap state regulations:

"[Sec.507] (f)(1)(A) The Secretary shall, in consultation with Federal and State regulatory agencies, the National Association of Insurance Commissioners, private insurers, and organizations representing consumers and the aged, conduct a comprehensive study and evaluation of the comparative effectiveness of various State approaches to the regulation of medicare supplemental policies in (i) limiting marketing and agent abuse, (ii) assuring the dissemination of such information to individuals entitled to benefits under this title (and to other consumers) as is necessary to permit informed choice, (iii) promoting policies which provide reasonable economic benefits for such individuals, (iv) reducing the purchase of unnecessary duplicative coverage, (v) improving price competition, and (vi) establishing effective approved State regulatory programs described in subsection (b).

"(B) Such study shall also address the need for standards or certification of health insurance policies, other than medicare supplemental policies, sold to individuals eligible for benefits under this title.

"(C) The Secretary shall, no later than January 1, 1982, submit a report to the Congress on the results of such study and evaluation, accompanied by such recommendations as the Secretary finds warranted by such results with respect to the need for legislative or administrative changes to accomplish the objectives set forth in subparagraphs (A) and (B), including the need for a mandatory Federal regulatory program to assure the marketing of appropriate types of medicare supplemental policies, and such other means as he finds may be appropriate to enhance effective State regulation of such policies."

Prospective Payment

Mandates from Public Law 98-21 dated April 23, 1983, related to prospective payment

PPS Impact—1984 Report

"[Sec. 603] (2)(A) The Secretary shall study and report annually to the Congress at the end of each year (beginning with 1984 and ending with 1987) on the impact, of the payment methodology under section 1986(d) of the Social Security Act during the previous year, on classes of hospitals, beneficiaries, and other payors for inpatient hospital services, and other providers, and, in particular, on the impact of computing DRG prospective payment rates by census division, rather than exclusively on a

	national basis. Each such report shall include such recommendations for such changes in legislation as the Secretary deems appropriate."
Physician Diagnosis-Related Groups	"[Sec. 603] (2)(B) During fiscal year 1984, the Secretary shall begin the collection of data necessary to compute the amount of physician charges attributable, by diagnosis-related groups, to physicians' services furnished to inpatients of hospitals whose discharges are classified within those groups. The Secretary shall include, in a report to Congress in 1985, recommendations on the advisability and feasibility of providing for determining the amount of the payments for physicians' services furnished to hospital inpatients based on the DRG type classification of the discharges of those inpatients, and legislative recommendations thereon."
Diagnosis-Related Groups and Nursing	"[Sec. 603] (2)(C) In the annual report to Congress under subparagraph (A) for 1985, the Secretary shall include the results of studies on . . . "(iii) . . . other modifications to the diagnosis-related groups. . . ."
Cost of Care Information to Consumers	"[Sec. 603] (3)(D) The Secretary shall also report on the advisability of having hospitals make available information on the cost of care to patients financed by both public programs and private payors."

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